Child Assent to Clinical Research Participation: How to Determine a Child's Ability to Assent

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A thesis submitted to the University of Oxford

for the degree of D.Phil

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Abstract

Assent, currently defined as "a child's affirmative agreement", is a way in which some children are included in the decision-making process regarding their participation in clinical research. Current guidelines for paediatric research do not provide clear directions for how assent should be handled, resulting in confusion among researchers. The goal of this research project was two-fold: to examine the ethical arguments for assent with a view to developing concrete moral justification for its being required, and to develop a framework of significant issues for an investigator to consider when deciding whether to gain assent from an individual child.

After an in-depth analysis, it was determined that the ethical justification for assent arises from the researcher's dual obligations to the child and his parents. A child's parents are responsible for determining when and how he will develop his decision-making ability. The researcher has an obligation to engage with the child in a manner that complements their pedagogical style, while also treating the child as a being of moral worth. As a child's family context has an influence on his participation in medical decision-making, further research on children's daily decision-making within their families is needed.

To this end, a three-phase research agenda was designed: a qualitative focus group study, a quantitative questionnaire study, and a discussion panel with paediatric experts. The children in these studies clearly desired to make decisions but did not express an interest in having complete control. They expected their parents to provide them with decision-making guidance in most aspects of their lives. Data collected from parents illustrated that they often tried to involve their children in decisions by providing them with limited options from which to choose and encouraging family discussion. Participants in the discussion panel stated that they did not expect children to make an independent decision regarding medical care, but they might attempt to give children smaller decisions, such as the arm used to provide a blood sample.

These results indicate that the definition of assent should be revised, emphasising the child's involvement in the overall decision-making process, without an expectation of an "affirmative agreement", likely mimicking a familiar decision-making setting from his family context. This could then be documented in the child's clinical notes through a brief description of all relevant interactions and/or discussions with the child, resulting in an accurate portrayal of the entire assent process.

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Author’s declaration

This thesis represents original research. No portion of this thesis has been submitted to another university in support of an application for another degree or qualification.

Statement of Work

Thesis

- The author was solely responsible for all research and writing involved in this thesis.

Focus Group Study

- The author was solely responsible for the following activities in relation to the Focus Group Study: applying for ethical approval, moderation of all adult focus groups, assistant moderation of all child focus groups, and all data entry and analysis.
- Recruitment for the study was conducted by the author, with assistance from Elizabeth Davis, an experienced Paediatric Research Nurse with the Oxford Vaccine Group.
- Questioning Routes were written by the author, with assistance from Elizabeth Davis.
- Moderation of all child focus groups and assistant moderation of all adult focus groups was conducted by Elizabeth Davis.
- Maintenance of the Investigator Site File and all paper study documents was led by the author, with assistance from Elizabeth Davis.
- Monitoring of the study documents was conducted by Simon Kerridge, the Quality Assurance Manager at the Oxford Vaccine Group.

Questionnaire Study

- The author was solely responsible for the following activities in relation to the Questionnaire Study: applying for ethical approval, and all data entry and analysis.
- Recruitment for the study was conducted by the author, with assistance from Elizabeth Davis (as above) and Christina Palma, an experienced play specialist with the Oxford Vaccine Group.
- Child and parent questionnaires were written by the author, with assistance from Elizabeth Davis.
- Moderation of child questionnaire sessions was conducted by the author, Elizabeth Davis, and Christina Palma.
- All statistical analysis was conducted by the author, however the statistical methods and analyses were reviewed by Maureen Reiner, a highly experienced external biostatistician.
- Maintenance of the Investigator Site File and all paper study documents was led by the author, with assistance from Elizabeth Davis.
- Monitoring of the study documents was conducted by Simon Kerridge.

Multi-Disciplinary Panel

- The author was solely responsible for the following activities in relation to the Multi-Disciplinary Panel: recruitment, moderation of the panel discussion, and all data entry and analysis.

Publications

- The author is responsible for the preparation of all joint-authored publications that emerge based on the conduct of this research, with assistance and writing support from Professor Pollard, Professor Fitzpatrick, and Dr Sheehan.

Chapter 1. INTRODUCTION

1.1 Statement of the Problem

The act of gaining a child's assent as a component of the enrolment process presents ethical dilemmas that must be addressed in paediatric research[1,2]. Children are not considered to have the necessary emotional and developmental capacities to provide fully informed consent[3,4]. Therefore, in order to enrol a child into research, permission (or proxy informed consent) is required from the parents with additional assent from the child when appropriate[4-7]. In most western societies, an individual is considered a child or a minor until the age of 18 years old. Assent is defined in the literature as "a child's affirmative agreement to participate in research"[8]. While there has been a general assumption within the medical community that some form of assent should play a role[6,9-20], there is little consensus regarding how to determine when or in what manner an individual child should be asked to provide assent for research participation[20-44]. Current guidelines do not clearly outline how a researcher can determine when assent should and should not be obtained, nor do they detail the necessary elements of the assent process[9,20,42,45]. The resulting confusion has led numerous researchers to recommend various age-related cut-offs for assent[9,46], while others have come to question the very validity or usefulness of assent[47-49].

The establishment of an age limit for assent would easily provide an artificial answer to the question of when a researcher should seek assent from a paediatric research participant. Some researchers have referenced the work of Jean Piaget in support of a suggested age limit for the assent process[50-52]. Piaget was a philosopher and developmental psychologist who devised a theory of cognitive development involving the

child's progression through a sequence of stages usually associated with specific ages[53-55]. However, this has created ethical debates since the age at which a child achieves various developmental landmarks is highly variable[19,32,44,56-58]. The problem with applying these strict developmental theories to the assent process through the application of a set age limit is that some children who have the developmental capacity to assent for research participation will be excluded from the decision-making process, while other children who lack the necessary developmental capacity will be asked for their assent even though their understanding of the information will render that assent less meaningful[1,16,31,59-61]. If we depend solely on an age cut-off to determine who should be asked for assent, this removes the necessary accountability from the investigator to assess the competence of each individual child participant[62]. As the maturation process from childhood to adulthood is extremely variable from child to child, the use of age limits often has much less bearing on an assessment of the child's developmental capacities than a competence-based approach would[63,64]. Current guidelines for paediatric research[10-13,17] suggest that researchers should obtain assent based on the child's age and maturity or his capacity to understand the proposed research. However these guidelines assume that researchers all have the ability to determine the individual competence and maturity of their paediatric research participants, and therefore do not provide guidance on where the line between competence and incompetence exists nor the components necessary to ensure a child's meaningful assent[14-16,18,58,65-67]. Therefore, it is left to paediatric researchers and local Research Ethics Committees to determine both when a child's assent is required and how that assent should be taken and recorded[19,26,42,68,69]. This lack of clear standards is striking in a field dominated in every other respect by robust regulatory requirements[70,71].

The lack of explicit guidance from medical and ethical authorities on assent as a component of the research enrolment process and the resulting confusion among the paediatric research community illustrate a clear need for an improved method to determine when a child is capable of granting valid and meaningful assent for research participation. With an increase in paediatric clinical trials, the need to properly address the paediatric enrolment process has become even more critical[72-74]. The goal of this research project was two-fold: first to examine the moral theoretical arguments for assent with a view to developing concrete moral justification for its being required. Then, based on this theoretical foundation for assent, to develop a framework of significant issues for an investigator to consider when deciding whether to gain assent from an individual child. Only once a clear ethical justification for assent has been established can we then move forward to start improving the assent process, creating a standardised assent procedure that can be implemented throughout paediatric research. There will be some discussion throughout this thesis of the assent process within both clinical research and clinical care settings; however it is important to note that, while the notion of assent does exist within the arena of medical treatment, the arguments in this thesis concentrate on its application to clinical research.

1.2 Children's Rights

The issue of children's rights is one of considerable debate worldwide and has grown in scope over the last century. A comprehensive discussion of assent must include a brief description of the fundamentals of children's rights, as the concept of assent and the challenges it represents are an embodiment of the attempt to balance two main categories of children's rights: welfare rights and participation rights. Welfare rights, also known as

protection rights or provision rights, are those which guarantee a child those goods and services required to maintain a child's overall health and development. It is important to note that welfare rights do not change a child's diminished legal status with reference to adults; in fact, the provision of welfare rights to a child may actually decrease his autonomy [75]. In general these rights are claims for the child to be provided something such as education or health care[76] and are based on the best interests of the child. All children are considered to have interests and therefore they deserve to have rights guaranteeing these interests as well as their well-being. These rights, while held by children, do not necessarily need to be exercised, or claimed, by the children themselves. Instead, these rights may also be exercised for them by parents, caretakers, teachers, or the legal system[77]. A principal argument for the justification of welfare or protection rights is "the argument from incompetency"[76]: children are not fully able to protect themselves and due to their only partially developed cognitive abilities they are likely to make unwise decisions which may lead to further injury. This argument is based on the fact that children have limited life experience and therefore warrant a period of protection from the burden of autonomous decision-making during which they will have time to gain life experience and develop their own individual autonomy as part of the maturation process. A second argument for the justification of welfare rights is one based on the rights of the parents[76]. If parents, as caretakers for their child, are granted by law the authority to make decisions on behalf of their child and in the child's best interests, then providing the child self-determination rights would be in direct conflict with the parents' rights as principal caregivers and decision makers for the child. While these two justifications of welfare rights are reasonable, they fail to consider that the term "child" covers a fairly wide age range. There are surely differences between infants, school children, and teenagers that

should be taken into account when discussing a child's life experience and ability to take on some responsibility for their own welfare.

Participation rights, also referred to as liberty rights or self-determination rights, are rights to an individual's autonomy and for that autonomy to be respected and not interfered with by others[76]. In opposition to welfare rights, participation rights should only be granted to those individuals who are considered capable of self-determination. Children are usually thought of as non-autonomous due to their under-developed decision-making abilities and consequently are not automatically granted participation rights[76]. The debate over participation rights as they pertain to children centres around the core questions of whether children are capable of holding these rights and if so, to what degree those rights should be granted to them. Upon crossing the theoretical threshold from childhood to adulthood, an individual does not automatically inherit the capability of self-determination; rather it is a gradual skill that is cultivated as part of a child's development into a fully autonomous adult, and thus it is reasonable that a child be granted gradually increasing participation rights throughout childhood. Participation rights for children are justified by acknowledging children's developing or evolving capacities. Consideration of a child's evolving capacities is similar to the competence approach to granting rights. This concept recognises that children develop cognitive abilities at different rates and times, and that their development of these skills depends on their ability to actively participate in activities that will promote their development[76].

There are some inherent conflicts between welfare rights and participation rights. If a child is granted participation rights and therefore is allowed to make his own decisions, he may

forfeit his welfare rights as his parents or guardians will no longer be able to protect him from potential harm. Conversely, if his parents and guardians act to fulfil his welfare rights by the provision of care and protection, their actions will automatically decrease his autonomy and freedom and therefore his participation rights. To partially solve this conflict, we can view both welfare rights and participation rights on a sliding scale, with welfare rights gradually decreasing and participation rights gradually increasing in direct correspondence with that child's development and maturation. This technique however does not solve the problem for children in the middle years of childhood where these two sliding scales converge. For these children, both welfare and participation rights would have equal weight. On the other hand, if we accept that children as human beings possess all human rights, but that their exercise of those rights will depend on their individual circumstances, including both their ability to exercise the rights as well as their need for those rights, we can approach the apparent contradiction between welfare and participation rights on a case by case basis, i.e. for each individual child[77].

1.3 Problems with Assent

Assent can represent a way in which, in the medical setting, there is an attempt to balance a child's welfare and participation rights. By allowing a child the opportunity to participate in the decision-making process, his participation rights can, to some extent, be respected. In addition, his welfare rights are also being respected in that the child's decision is not the only or ultimate authority: his parents must still grant the proxy informed consent on his behalf. However, this process is not easily navigated. It is unclear what the best course of action is in the determination of when a child should be asked for his assent. Unlike the process for informed consent which is heavily regulated and standardised, the existing guidelines do not provide details on the necessary elements of

the assent process, leading to the potential for wide variation between the interpretation of assent across ethics committees, research studies, and individual researchers[20,22-44,78].

To further complicate matters, in the debate over child assent some researchers seem to have confused the concept of assent with that of consent[70,79-83]. In the assent literature, there are arguments to support different extremes of childhood decision-making. Some assent advocates are actually in favour of assuming that all children are competent to make decisions, giving the clinician and parents the responsibility for proving incompetence[84,85]. In other words, this could mean granting children the right to self-determination, thus asking children for their informed consent and bypassing assent altogether. Other researchers call for a very strict set of criteria to establish a child's "competence" to assent, making assent very similar to consent[66,86], the only major difference being that assent is meant for those under the legal age of majority while consent is asked of those over the legal age of majority. This however is removing the very reason behind the assent; that is to involve a child in the decision-making process to the extent that his current developmental stage will allow[22,87-91]. In paediatric research, parental permission acts as the "informed consent" portion of the enrolment process, and therefore the parent or guardian is required to meet the strict standards for understanding detailed aspects of the research, including the risks and benefits, in order to make an informed decision in the child's best interests[71,92]. In contrast, when asked for his assent, a child participant is being asked merely to communicate his preference for research participation, and is not in the normal course of events required to exhibit a detailed level of understanding of the research subject matter[52,93-96]. If a child is meant to have the same level, if not a higher level, of decision-making capacity to provide assent as an adult would be required to have

to provide consent, then surely the debate should be over lowering the age of consent, not the establishment of a special assent process designed for children. If, on the other hand, assent is considered less than consent, then it is reasonable to assume that the standards for assent should be less substantial than those for consent[23,65,81,97-102].

Another aspect of the assent process that seems to have become confused with informed consent is its documentation. Some guidelines recommend that investigators use assent forms that mirror a typical informed consent form, both in the amount of information that is included and in the requirement that the child signs his name at the bottom of the form to illustrate his assent[13]. Asking a competent adult to sign a document has a legal significance because it is assumed that the adult understands the meaning of his written signature. A child, on the other hand, is unlikely to understand the significance of his signature, if he even has one. Asking him for his signature therefore is merely proof of meeting a regulatory requirement but without having any bearing on whether the child in question actually understands the fact that he is giving "assent" for his research participation[71,97]. The focus in this case is on an assent form and a signature on that form, rather than on the actual assent process and the act of involving the child in decision-making about matters that affect him[22].

Beyond the problematic convergence with consent, another complication in the discussion of assent is the concept of dissent. While assent represents a child's agreement to participate, dissent is defined as a child's "objection to participation"[96]. It is important to note that the lack of dissent does not necessarily indicate a child's assent[8]. Guidelines for clinical research suggest that we should respect any occurrence of dissent from a child,

unless the research procedures will provide a substantial health benefit otherwise unavailable outside of the research environment[94,103]. This is problematic as the policy directly contrasts with how dissent is dealt with in the realm of paediatric treatment. In a treatment situation, a child's dissent can be overridden by his doctors or parents, even if that same child was already deemed "competent" to be asked for his assent[84,104-108]. In this circumstance, a child is "competent" if he agrees with his doctors or parents, but he immediately becomes "incompetent" and his dissent is disregarded if he disagrees with their decision. In clinical research on the other hand, investigators are encouraged to respect all instances of a child's dissent, even if his parents have already granted consent and irrespective of whether his assent had been sought[84]. Guidelines have explained this seeming double-standard by stating that in instances of treatment, where a child will receive a health benefit from the contested procedure, his dissent can be overridden out of concern for his best interests; whereas in non-beneficial research with no certain prospect of a health benefit, a child's best interests are no longer at stake and therefore his dissent should be respected[78,109]. In these instances, the guidelines are encouraging clinicians to respect the child when it suits them, which is not in fact demonstrating respect for the child at all. Moreover, it is unreasonable to assume that the child's capacities could transform from "competent" to "incompetent" purely based on the decision that he reaches.

A second concern with the concept of dissent is that if we are expected to respect any instance of dissent in non-beneficial research, this does not leave room to differentiate between a contrary child who always says no but who is not actually opposed to the procedure in question, and a child who understands the procedure and legitimately wants

to refuse[91]. An investigator is unlikely to know each child participant personally and consequently would not be able to make this distinction alone. In this scenario it would seem much more reasonable for the investigator to discuss the situation with the child's parents, who are better able to judge whether their child is actually dissenting[21,29]. However this too is problematic in situations where a child and his parents disagree[110]. In cases of disagreement between parent and child, it is left to the investigator to balance the arguments of both parties, the potential benefits of the procedure, and the best interests of the child[20]. Unfortunately this may represent a conflict of interest for the investigator who likely has a personal stake in the enrolment of all eligible children in the clinical trial.

Clearly, the current guidelines on dissent require modification and clarification. Treating assent and dissent differently in treatment versus research contexts will merely lead to further confusion of these issues within the medical community. In addition, there should not be different criteria for the establishment of a child's ability to dissent compared to assent. If a child is asked for his assent out of respect, then his dissent should be respected just as his assent would have been respected had he provided it. Conversely, if we would be happy to continue with a procedure without a child's assent if he is thought to be unable or unequipped to provide it, then we should not be deterred by his dissent. If we create a set of criteria by which to determine a child's ability to assent, then clearly this should be the same criteria used to determine his ability to dissent. The existence of numerous rules by which to determine a child's "competence" will only lead to further confusion of medical practitioners.

1.4 Re-defining Assent

While confusion about assent clearly exists[20,22-44], researchers have widely accepted one definition of assent: "a child's affirmative agreement to participate in research"[8]. Yet even with this definition in place, there are many different interpretations of the word "assent" currently in use within the medical community. Some people have described it as a way in which we can get the child to go along with the research agenda, while others refer to "informed assent" or "consent/assent" as if assent and informed consent are synonymous[88,111,112]. This confusion represents the key problem with assent, and illustrates why the medical community has wrestled with the logistical questions of who should give assent, when it should be taken, and how it should be recorded. Getting a child to go along with the proposed research agenda is not necessarily assent, it's merely a way to stop the child from dissenting. Instead, we need to step back and think about what the concept of assent involves: assent is about the participation of the child in the decision-making process. The word "assent" therefore should not be defined as the child's affirmative answer, but rather should describe the process by which we engage with the child. Informed consent has been described as an ongoing process and a dialogue between the researcher and potential participant[113]. Yet assent, which is supposed to represent another part of the enrolment process in paediatric research, is often discussed as a discrete event instead of a continuous process. In order to attempt to solve the problems associated with assent, the medical community as a whole must re-configure how assent is viewed and defined. Rather than asking a child to go along with the research agenda in question, instead a clinician should consider the overall enrolment process and where that individual child fits in with it. This would then eliminate any claims that assent is a pointless exercise due to the fact that the child's wishes can be overridden in many circumstances[47,48]. The emphasis would be placed on the child's appropriate level of involvement in the process,

rather than on his specific opinion. When the final decision is reached, it would be important to explain to the child how that decision had been made, and how his own wishes had affected that decision. In this way it would be clear to the child that his views had been heard, even if they had not been successful in determining the final outcome[63]. In other words, there is an established process by which people are enrolled in medical research. In this thesis, this will be referred to as the enrolment process. There are many elements that, when combined, comprise this enrolment process. The two elements that are most relevant to the research in this thesis are the informed consent process and the assent process. The informed consent process represents the way in which a presumptively autonomous adult is entered into a research study. Typically there are two outcomes to this process: informed consent and informed refusal. The assent process on the other hand is the way in which a minor is entered into a research study, and it represents how the clinical team engages with the child. Possible outcomes to the assent process include explicit assent and explicit dissent. In paediatric research it needs to be decided what this assent process should look like with children, namely when and to what extent should children be involved in the decision-making process.

1.5 Treatment vs. Research

As mentioned above in the discussion of dissent, many clinical researchers also have a clinical practice within the treatment setting. The difference in guidance between the treatment and research settings only serve to convolute the existing confusion and problems surrounding the concept of assent. If the definition and expectations of assent change in the treatment setting in contrast to the research setting it is no wonder that there is so much current confusion surrounding assent and how to approach it. If the medical

community were able to adopt a new definition of assent, namely the process by which a child is involved to some degree in the decision-making process, without the expectation that the child's decision must be followed, this could then be applied equally to both the treatment and research settings. This would eliminate any confusion regarding how assent should be applied to treatment versus research. In a treatment setting, the worry about assent is that if the child's decision is different from what the clinician and parents consider as medically in the child's best interests, his decision can be overridden. However, if assent is viewed not as the child's affirmative agreement to the proposed procedure, but instead involving the child to an appropriate degree in the decision-making process, then it avoids this seeming double standard. In this way, the child is still involved in the decision but the clinician and parents retain the authority to decide the best course of action with respect to the child's medical best interests. What matters here are the relative risks and benefits of the intervention, whether research or treatment. The level of importance of involving the child in the decision may increase or decrease depending on the potential risks or benefits of the intervention, but this judgement is independent of whether that intervention falls under research or treatment.

1.6 Family Context

Much research has been conducted in the attempt to establish the appropriate age at which a child should be asked to provide assent for research participation[28-35,114]. These research studies have concentrated on a child's understanding of the research material provided to him, and have correlated the results with the child's age, thereby determining the age at which the majority of children were able to understand the information. This narrow view of the situation neglects to examine myriad other influences on a child's

competence[60,68,110,114-118], one of the most important of which is the child's family context[61,65,90,119]. At birth, responsibility for decision-making lies with a child's parents[120]. As the child matures, he typically will be granted an increasing amount of decision-making responsibility until the point at which he attains adulthood with full, independent decision-making authority[9,15,61,105,121,122]. In the period between infancy and adulthood, when a child gradually assumes a greater amount of decision-making power within his family, there is generally a period of joint decision-making between the parents and their child[58,79]. However, this process can vary considerably from one child or one family to another[15,16,30,123]. The amount of decision-making authority that children have within their family can impact the development of their decision-making abilities and critical thinking skills and can shape their view of their individual rights[20,22,30,58,60,124-130]. Past research has suggested that both a child's ability and desire to play an active role in the decision-making process for research participation are directly affected by his role within his family unit[22,25,110,120,129,131,132]. Therefore it would be expected that a child with little or no autonomy within his family would be ill-equipped to provide a meaningful assent to research participation as he would be accustomed to the family, (i.e. his parents), making decisions related to his life and well-being. Asking that child to provide assent would most likely result in the child deferring to or agreeing with the decision already made by his parents[22,49,60,83,96,104], especially considering that past research has shown children to be very likely to obey adult authority[20,45,52,68,80,120,126,133,134]. Although it is important in research to recognise and respect a child's developing autonomy, a child should not be treated in a research study in a way different from that to which he is accustomed within the context of his family[15,22,30,58,123,129,135,136]. In fact, some research has shown that a shift in a child's family decision-making dynamic could have a negative impact on his competence[83]. It has been recommended by some researchers that as a child develops

greater decision-making power within his daily family context, there can be a corresponding increase in that child's decision-making capacity in the external environment outside of the family, including in the context of participation in medical research[79]. This would support the existence of an assent process by which children are involved to some degree in the decision-making process. However, that does not yet help to answer the question of which children should be involved or when they should be involved. In order to answer these questions, more must be learned about the family context of childhood decision-making.

Due to the influence of the family context on a child's ability to provide assent for research participation, there is a recognised need for further research into how children are involved in daily decision-making within their families[20,123,135]. Through comparing how decision-making responsibilities are divided between parents and their children across individual families and cultures, it may be possible to develop assent guidelines that incorporate specific family contexts and the evolving nature of a child's decision-making role within his family[45,58]. Therefore, in order to begin the process of improving the methods for gaining child assent to research participation, the way in which children make decisions in their daily lives must first be examined. It is only after addressing a child's decision-making within the context of his family unit that a practical and relevant method of gaining child assent can be developed. To this end, a three-phase empirical research agenda was designed to attempt to solve this problem: a qualitative study involving focus groups, a qualitative and quantitative study involving a series of questionnaires, and a multi-disciplinary discussion panel with experts in the field of paediatrics regarding their

current assent practice and potential improvements that can be made to the existing guidelines on assent.

1.7 Outline of Thesis

As discussed in this chapter, children are not considered to be sufficiently competent to make their own decisions regarding their participation in clinical research. It would then seem to follow that children should not be involved in the decision-making process. Yet the existence of the concept of assent illustrates that for some reason the medical community is still motivated to include some children even if they are not believed to be capable of making the entire decision alone. What matters here, then, is how to justify their involvement in the decision-making process. We clearly feel as though we should involve these children, but it's not immediately clear why we feel this way, and because it is not immediately clear why, it is also not clear how and when they should be involved. This explains the current circular debate about assent in the literature. Therefore, in order to answer the questions of when children should be asked for their assent, what assent should involve and how that assent should be documented, a better understanding of the motivation to gain assent should first be obtained. **Chapter 2** will examine various potential ethical justifications for why some children should be included in the medical decision-making process. This chapter will begin by exploring the explanations found in the current literature: that assent is grounded in a child's human rights or respect for the child's developing autonomy. Through this discussion these explanations will be shown to be incorrect or insufficient. The chapter will conclude with a description of a newly developed two-fold justification for assent: respect for the parent's pedagogical role in

teaching their child to become an autonomous being and respect for the child's moral worth.

This new ethical grounding for assent is based mainly in the child's family context and dynamic. As was discussed earlier in this chapter, the judgment of a child's ability to participate in the decision-making process cannot be attempted without taking into account his daily decision-making experience within the context of his family. Therefore, an empirical research agenda was designed to produce data on the family context of a child's daily decision-making, without concentrating solely on medical decisions. **Chapter 3** will discuss a series of focus groups held with children aged 5-12 years old, parents of children aged 5-12 years old, and primary school educators. These focus groups served as exploratory research through which to learn about the family context of childhood decision-making. These focus groups illustrated what areas of the family context needed further study in order to come to any conclusions about this segment of a child's daily life. Once analysis of the focus groups was complete, these data were used to design a series of complementary questionnaires for children aged 5-11 years and their parents, as will be described in **Chapter 4**. The analysis of the questionnaire data illustrated in quantitative terms some of the main themes that emerged from the focus groups and helped to shape a theory of how to attempt to involve children in the decision-making process within the medical setting. **Chapter 5** will describe a service development meeting of clinical experts within the field of paediatrics where the current practice of assent, both in treatment and research settings, was discussed. In that meeting there was also a discussion of the culmination of the research described in this thesis and how, based on the current usage of and drawbacks associated with assent, the concepts that have been

developed therein might be applied to clinical practice to improve the current understanding of assent. **Chapter 6** will synthesize all of this information and discuss the direction needed for future research on this topic.

Chapter 2. THE ETHICAL BASIS FOR ASSENT

2.1 Introduction

This chapter will explore some of the ethical arguments that have been used in favour of or against assent in the literature. Given the previous stipulation that assent should be understood as the process by which children are involved to some degree in medical decision-making, as discussed in **Chapter 1**, these arguments will be framed accordingly; although originally they may have been applied to the current definition of assent as getting the child's affirmative agreement. This discussion will illustrate why these arguments are mistaken or incomplete in the context of child assent. Once the current arguments about assent have been examined, a two-fold argument for the justification of assent will be presented: that assent is part of the broader process through which children learn to become better decision-makers and that it represents respect for the child's moral worth.

2.2 Children As Human Beings Have Rights

It has widely been suggested that children should be involved in medical decision-making for medical procedures which affect them due to the fact that children are human beings and therefore have rights. The mere fact of being human grants people a set of rights to "continued life and liberty"[137]. It is an accepted truth that an adult is in charge of his own being and therefore is seen to also have a set of rights that accompany this self-determination. However this becomes more debatable when it is applied to children rather than adults. Philosophers have theorised that one's possession of rights depends on the individual's interests or will. Do children forfeit their right to self-determination due to their initial dependence on adults, both in the requirement to be born as well as early

childhood caretaking? The premise of this argument is that all human beings have rights, regardless of their age or other demographic characteristics. However at present, based purely on their chronological age, children are deprived of the basic human rights of freedom and autonomy which are granted to adults[64,75]. Children have their own set of needs, wishes, and ideas and, like adults, they should be given the opportunity to communicate these desires in a forum that both listens to and respects them[105]. A medical treatment or research procedure directly affects a child's personal health and well-being and therefore a child should have the right to at least voice an opinion regarding that treatment, even if he is not allowed to make the entire decision himself. Involving the child in the decision-making process for that specific treatment or research procedure allows him to articulate his desires with the knowledge that the relevant adults must listen to him, even if the final decision made by his guardians is in opposition to his wishes.

Some would argue that children are wrongly denied their lawful human rights on the false premise that their chronological age automatically renders them incompetent[64]. This is not to say that all children are equally competent as adults; rather, it is incorrect to assume that all children are necessarily incompetent solely by nature of their age[77,114,115,137]. In this argument, it is important to recognise that children are inherently heterogeneous. Children represent a varied group of skills and abilities and therefore should not all be immediately classified as incompetent[75,76]. It is unsurprising that members of a group that includes everyone from infants to teenagers would have significant differences in their competencies and aptitudes. It is true that very young children such as infants or toddlers are unable to care for themselves, but as children mature they gradually develop more of the abilities and attributes that they will require to exist as autonomous adults[52,128]. As

child development does not occur along a pre-determined trajectory, it would be reasonable to assume that at least some children might develop key competencies earlier than others, regardless of their chronological age. The foundation of this argument is related to the democratic principle of non-arbitrary treatment, which states that two groups of people must have evident and verifiable differences to warrant the receipt of different treatment[138]. The age-based boundary between childhood and adulthood could be viewed as an arbitrary cut-off and therefore it violates the principle of non-arbitrary treatment. For example, it cannot reasonably be stated that there is a demonstrable difference in competence between an individual aged 17 and three quarters and an individual aged 18, yet there is a demonstrable difference in the rights that are accorded to these two individuals. In addition, some individuals younger than 18 years may possess the necessary competencies for the holding of a specific right while individuals older than 18 years may not[137,139]. Furthermore, many competencies are actually task-specific. A child might be sufficiently competent to participate in the decision-making process about one subject but not another[59,67,110,114,131,135,140]. In fact, research has indicated that children can enhance their competence through personal experience with a specific situation, regardless of their age or developmental stage[20,59,141]. To assume blanket incompetence across all children and all situations overlooks the key fact that the acquisition of competence does not occur on a perfectly linear progression across all children and situations[139]. By assuming that all children are incompetent, we do not allow them the appropriate degree of autonomy for them to accomplish a particular task, and therefore they are unable to demonstrate their ability to accomplish it. Moreover, without the opportunity to practice these newly learned skills, children are less likely to further expand and enhance those skills and competencies, thus hindering their overall developmental process[77,137,142].

Although many of these arguments raise important considerations, they are not sufficient to justify a child's involvement in medical decision-making. While children are indeed human beings, and human beings do have rights, this should not automatically grant children the same rights to self-determination as adults. Secondly, while it is true that children are not all equally incompetent, this does not justify the granting of additional self-determination rights to all children. In fact, when exploring these arguments in more detail in the coming pages, it is clear that they are much more complex than they would initially seem.

2.2.1 Paternalism and Paternal Rights

Some individuals, in arguing against the granting of any decision-making power to minors, will cite how this would be in violation of the rights of the parents. If parents have the authority to act on their child's behalf, then giving the child any decision-making power would actually detract from the parent's role as the caretaker[76]. In order to ensure that they are in fact protecting their child to the best of their ability and acting in that child's best interests, decision-making power must rest solely in the hands of the parents rather than shared between them and their child. Denying a child any degree of self-determination and allowing his parents to make decisions on his behalf is both honouring the parents' rights as parents as well as protecting the child's present and future interests[79].

In fact, some paternalists take this argument a step further by stating that it is precisely a concern for the child's best interests that motivates them to deny children any degree of self-determination. The best interests principle requires that in any decision that will affect

a child, that child's best interests must be the overriding factor in that decision[76]. The underlying idea behind this principle is that a child's most important interests are those related to his security and nurture, and that these must be protected over any other less important interests. Decisions made which invoke this principle must also consider each child's specific needs and vulnerabilities. In the medical context, the child's best interests should always be our primary concern when making decisions involving children[135]. Thus, in the child's best interests, both short-term and long-term, ultimate medical decision-making power currently rests solely with the child's caretakers, rather than shared with the child, until the child reaches the legal age of majority[3,6]. As parents or guardians are the people who are best acquainted with their children, they should be capable of making decisions that are truly in the best interests of their child and the child's future adult self[135]. In this system, parents for the most part determine what counts as the child's best interests. Therefore the parents have the right to determine the course of their child's life and consequently determine what the child's best interests are and will be. It is only when the child transforms into his future adult self who is capable of self-determination that he should be granted the right to act autonomously without the protection and guidance of a caretaker. At this point the person himself is best placed to know and to determine his own best interests.

If these paternalistic arguments represented the whole story, this would eliminate all need for involving a child in medical decision-making, with the power of informed consent shifting from adult caretaker to the child's future adult self once he reaches the age of majority. However, as is shown below, this is not the case and therefore, standing alone, these arguments are flawed.

First of all, while it is hoped that the decisions made by parents on behalf of their children are in fact in the best interests of those children, there are too many examples of situations when this is not the case. On an extreme level, cases of child neglect and abuse illustrate that not all parents and guardians truly have a child's best interests at heart. In addition, a parent or guardian could justify a decision that he knows is against the desires of a child by merely stating that the decision had been made according to the best interests principle[117]. However, beyond these more severe instances, even if a parent is truly attempting to act in his child's best interests, it is impossible to be certain what those best interests are[76]. A child's best interests may change over time, depending on that child's age, developmental stage, culture, and current environment. When making a decision in the child's best interests, it is often suggested that one should consider the future adult that the child will become, making the decision that this future adult would make[76,137]. This is sometimes described as "future-oriented consent", with the idea that as a child becomes a rational adult he will recognise the wisdom in those past decisions that were made on his behalf and lend his support to them[3,75]. The problem with this suggestion, however, is that it cannot be known what a child's future adult self might think about the situation. Instead, a decision can only be made that in the current view would seem to be the best possible decision for the child at that time[3]. Therefore a decision made in the child's "best interests" is often only based on the subjective opinion of the adult decision-maker. To this end, some have argued that when invoking the best interests principle the child in question must also be allowed a recognised means by which he may dispute the decision[105]. A further problem with reference to a decision made in the child's best interests stems from the origin of what those interests actually are. The decisions that parents make on behalf of their child shape the future person that child will become, thereby affecting what his best interests are going to be. If that is the case, those best

interests cannot then be used as criteria in the current decision. With the knowledge of this uncertainty surrounding the notion of a child's best interests, it would then be unfair to cite those best interests as a reason to deny children any involvement in the decision-making process in situations regarding their health and well-being.

Secondly, any argument based on the violation of a parent's rights is actually confusing a parent's provision of the child's welfare or protection rights with actual parental rights. Children have the right to receive care and protection from their caretakers but by itself this does not mean that the parents or caretakers gain any parental rights[117]. Conversely, while children possess welfare rights as human beings, this does not automatically mean that they should be free to determine what counts as their welfare. Rather, caretakers such as parents or legal guardians or the government can make those determinations on the child's behalf[137]. If the welfare of the child is paramount, this imposes responsibilities on the parent, not rights. Here, it is important to recognise the distinction between parental rights and parental responsibilities, or between legal rights and moral rights. The parent's obligation to look after the child is different from the right to be able to make decisions about what counts as best for the child. A child's welfare rights and self-determination rights should be considered as having an inverse relationship: as the child becomes more autonomous his rights of self-determination should increase, with a corresponding decrease in his parents' provision of welfare rights on his behalf[3,105,120,143,144]. As "parental rights" are actually the child's welfare rights exercised on his behalf by his parents, they are not a sufficient reason to stop a child from participating in the decision-making process for his clinical research participation. If parents have the right to make decisions for their children only until those children are capable of making decisions for themselves, then

clearly it is necessary to allow children to participate in the decision-making process as they become able. This relationship between a child's self-determination rights and a parent's provision of the child's welfare rights mimics my concept of the assent process: as a child matures, he should be increasingly involved in the medical decision-making process about matters that affect him, but only to the appropriate degree that his individual maturity and development will allow.

So in summary, the counter-argument that a child's involvement in decision-making would jeopardise his best interests and be in violation of parental rights is not an adequate justification for why children should be denied any degree of self-determination. Firstly, there remains too much uncertainty surrounding the origin and identification of a child's best interests, and secondly, this argument demonstrates confusion between parental rights and parental responsibilities.

2.2.2 The Alleged Incompetence of Children

This returns us to the argument that children are unfairly denied their fundamental rights to self-determination based purely on their chronological age and the unfair assumption that all children are incompetent. The consequences of this argument being right would be that the current assent process would be radically changed. Based on this view, it looks as though assent would be mistaken. Rather than being involved in an assent process, a child would be given the full opportunity to decide for himself. In fact, this is not a problem because this argument is incomplete, as will be demonstrated below.

In order to possess a right, in this case the right to self-determination, an individual must meet the criteria that are necessary for the possession of that right. If the criterion for the possession of the right to self-determination is a specific level of cognitive ability, any individual, regardless of age, must be shown to meet that criterion before being granted the right. If a child does not possess the necessary capacity to exercise the right to self-determination, granting him that right would be improper. This does not just apply to full self-determination but also to partial self-determination, or involvement in the decision-making process. Clearly if a child is not yet sufficiently competent to participate in the decision-making process, he should not be asked to participate as his involvement and any subsequent decision would be meaningless or perhaps even detrimental to his best interests. Along these same lines, it can be argued that the alleged incompetence of children actually is due to their lack of life experience rather than their chronological age. It is thought that children do not have enough life experience to be considered fully competent beings[27,57,76], and therefore they should not be asked to make decisions when there are others, such as parents or guardians, who can better make those decisions for them. Childhood represents a time in life where the individual needs to be protected and nurtured in order to mature and develop into an autonomous adult being[67]. Here, a child's inherent incompetence is not a problem to his well-being, as his adult caretakers prevent him from making decisions that may be harmful or ill-informed[75,76,137]. The caretaker's role is to make decisions on behalf of the child until such a time as the child has developed into an autonomous adult capable of making his own decisions[92,121]. Self-determination is thus seen not as a mere right but as the aim of one's human development. In order to attain that end goal upon reaching adulthood, a child's individual autonomy is limited during childhood, allowing him time to develop fully. It is only once he has attained all necessary competencies throughout childhood that he should be granted the right to self-

determination as an adult, when he is sufficiently competent to exercise that right properly.

If one accepts this argument, there would only remain an ethical problem regarding the alleged incompetence of children if they were denied rights solely on the basis of their chronological age, with no corresponding association to some other quality. In fact, these rights are only withheld from children based on the assumption of an association between chronological age and the competencies deemed necessary for the possession of the rights[3,99,137]. The concept of "childhood" is a social construct, its definition shaped by society[77]. While each society might define a stage of life between birth and adulthood as "childhood"[76], this does not mean that the boundary between childhood and adulthood, or immaturity and maturity, is the same, or that the duration of "childhood" is a pre-determined length[75,137,138]. The dividing line between these two life stages will depend on what specific qualities the individual society deems necessary for an individual to be considered an adult[64,76,145].

2.2.2.1 Establishing Appropriate Boundaries Between Categories

Legally, it is often necessary to identify a distinction between where childhood ends and adulthood begins as membership in one group may grant the individual a differing set of rights, privileges, and responsibilities[64]. Yet how can this boundary between childhood and adulthood be identified? In general there are two different methods for determining where this boundary lies: the status approach and the competence approach[64]. The status approach identifies the boundary between childhood and adulthood at a fixed time point, based on the individual's chronological age. This cut-off is often viewed as occurring at

age 18, however this varies depending on the geographical location as well as on the specific right in question. A well-known example of a right which is given following the status approach is the right to vote, as this right is earned once an individual reaches the required minimum voting age, without having to prove the development of specific abilities. However, while categorisation based on the status approach uses age as the cut-off, the specific age is usually chosen with the assumption that it represents a time when those individuals will have developed sufficient competencies to entitle them to the corresponding right. The competence approach, on the other hand, identifies the boundary between childhood and adulthood through an assessment of competence. This approach therefore would allow different individuals to cross this boundary at different times or ages according to their development or possession of specific competencies required for the right in question. An example of the competence approach would be the licensing procedure for clinicians: an individual can technically become licensed as a clinician at any age, provided that he passes a specific set of licensing exams to prove medical knowledge. In some cases, the status and competence approaches are used together to set a limit. For example, in order to earn a driving license, an individual must reach a specific minimum age limit at which point he then must prove his competence to operate a moving vehicle prior to earning the license. While these two approaches, status and competence, are fairly clear and straightforward, both can be applied differently for each individual right, thus creating numerous different boundaries for the same individual based on the belief that a child achieves adult competence for "different purposes at different ages"[64]. Currently in Britain, for example, an individual can buy a pet, choose his own doctor, leave school, and become employed full-time at age 16, be sent to prison and earn a driving licence at 17, attain legal majority, vote, and enter into marriage at age 18, and become a Member of Parliament at age 21. These variations in accepted cut-offs are not

necessarily representative of the requisite competencies and maturity required for the attainment of each individual right, but illustrations of cultural values and standards of the society at the time each regulation was developed[146].

The current guidelines for informed consent utilise the status approach to identify the cut-off between childhood and adulthood, stating that an individual can provide his own informed consent once he reaches the age of 18 years old. As stated above, some people see this age-based boundary as problematic, based on its alleged violation of the principle of non-arbitrary treatment, as age alone is not always a reliable marker for the possession of a particular competence. The problem with a strict application of this principle, however, is that it is not possible to identify a single chronological age when all individuals can be said to possess a specific competence for the first time, thus entitling them to the possession of the corresponding right[137,147]. Therefore it is perfectly reasonable that some individuals below the boundary of adulthood may possess sufficient competencies to be considered capable of self-determination while other individuals above the boundary may not. In general, children below the age of 18, the current boundary with adulthood, are assumed not to have the fully developed key competencies necessary to grant them the right of self-determination. So, on the basis of their age and its correlation with competence development, children are assumed to be sufficiently incompetent to warrant the denial of this right. Secondly, although in theory it would appear more just to grant a right based on a demonstration of one's competence rather than on one's chronological age, it would be extremely difficult if not impossible to implement this for every right[76]. Therefore, without a better alternative, age would seem to be a suitable boundary for the granting of most rights.

Furthermore, an ethical argument based on the principle of non-arbitrary treatment is clearly confusing the notion of policy with that of ethics. The world is full of seemingly arbitrary boundaries in other aspects of human life[59,132,137]; for example there are speed limits for operating motor vehicles on different types of roads, schools set cut-offs to determine which grades are passing or failing, and an individual's income is taxed based on income brackets decided by the government. When examining any of these examples, it is clear that the units at the border between two categories will always seem too similar to necessarily warrant a difference in classification, however in order to form categories, a boundary must be chosen[137]. The goal then is to ensure that the separation between the categories is logical for the majority of individuals or entities within those categories, thus eliminating the charge that the boundary is entirely arbitrary.

The discrepancies in the age at which rights are granted are understandable when it is considered that the time from childhood to adulthood covers a period of life with intense development, both physical and mental. With this much change occurring so quickly over a relatively short period of time, it is not surprising that current standards for the attainment of various rights may not make sense when viewed together. These standards are both the product of the societal norms when they were enacted as well as an attempt by that society to create boundaries that would be appropriate for the majority of people in that age group. Unless the requirements for the attainment of a right were based solely on the assessment of one's competencies, it would be relatively impossible to develop standards that would be relevant to everyone[75]. Nonetheless, the current system uses an age limit to determine the age of majority. The fact that a policy exists to define the age of majority means that an age cut-off must be used. With any policy there will inevitably be

exceptions but it does not logically follow that the entire policy is wrong. There would only be an ethical issue with the policy if it was not appropriate for the majority of individuals involved.

2.2.2.2 Gillick competence or mature minors

As discussed above, when setting an age-based boundary between childhood and adulthood, it is likely that a few individuals who fall below that threshold will actually be sufficiently competent to be considered capable of self-determination. There are already procedures in place that allow some children who have not yet reached the age of majority to make their own decisions regarding medical issues, without input from a parent or guardian. In the UK, clinicians refer to a "Gillick competent" child, or in the US a child can be deemed a "mature minor"[49,50,59,64,97,102,105,117,131,135,147-154]. With the concept of consent, it is accepted that an autonomous being can make his own decision and an age cut-off is used as proxy for an autonomous being. In general, at the age of 18 years an "adult" is considered to be a competent, autonomous being and can make his own decision, or can consent to medical treatment or research[117]. By this view then, nobody under the age of 18 should be involved in the decision because they would be incompetent. However this does not tell the whole story because it is recognized that there are some people under the age of 18 years who are actually competent and are perfectly able to make their own decisions. To deal with these exceptions to the rule, additional guidelines or legislation have been created.

The term "Gillick competent" comes from a judgment from the House of Lords in 1985[155]. The case in question began when a mother, Mrs Victoria Gillick, argued against a health

department policy that allowed a doctor to prescribe contraception to children under 16 years old without parental consent. In Lord Scarman's final judgment, he affirmed that a child has the right to make a decision regarding a proposed medical treatment, provided that he "achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed"[148,155]. A child who is deemed to meet these criteria would be referred to as "Gillick competent". One of the principal ideas upon which the Gillick ruling is based is that the transition from childhood to adulthood is gradual rather than sudden. Adolescence, then, is the transition period between childhood and adulthood, representing a time of change and increased autonomy that can be highly variable between specific children. The Gillick ruling recognises that as a child's autonomy increases, the parental control over that child must correspondingly decrease to acknowledge the child's developing autonomy[64]. This illustrated the court's view that parents do not have rights over their children beyond the obligation to protect their child's best interests. So, at the point when children are able to make autonomous decisions, those decisions should be respected and not overruled, just as an adult decision would be respected[156]. The concept of Gillick competence is widely recognised in clinical medicine in the UK, however it is important to note that there is no specific test or set of rules by which a child can be judged to be "Gillick competent". Rather, it is based on the clinician's professional opinion that the child is sufficiently able to understand the proposed treatment and make an informed decision. In the US, clinicians use the mature minor doctrine. Much the same as Gillick competence, the mature minor doctrine allows for a minor to provide his own informed consent for a proposed treatment or procedure, provided that he is deemed sufficiently able to understand it. Once again, this allows for the clinician to make a subjective judgment regarding the competence of the minor in question.

It is important that procedures for Gillick competence or mature minors exist, as it is true that children are a heterogeneous group made up of individuals with greatly varied cognitive and developmental abilities, and there are certainly some children to whom it is appropriate that the right to self-determination be granted in certain circumstances. However these conditions should not be confused with arguments as to whether children in general should be allowed to participate to some degree in the overall decision-making process, as participation in the discussion with one's adult caretakers is very different than leading the decision-making process oneself. While the concepts of Gillick competence and assent both involve some process by which to judge a minor's cognitive capacities, they embody very different roles. Gillick competence allows for the possibility that a few select minors will be legally permitted to grant their own informed consent for medical-related matters. Yet, it is important to remember that this is an exception to the rule. The majority of individuals under the legal age of majority will likely not be deemed Gillick competent. Assent, on the other hand, is a way in which a minor can be involved in the decision-making process regarding medical-related matters, but the overall decision-making authority will continue to remain with his parents or guardians. This is a practice that can be applied to many individuals under the legal age of majority, although a consistent method by which to identify and involve those individuals has not yet been agreed upon in the medical community. The research in this thesis was designed with the aim of improving the current process for assent, including how to determine whether to gain assent from a particular child. Therefore, the remaining research and discussion will not focus on children who might be Gillick competent.

So in summary, the argument for an assent process grounded in the child's fundamental human rights is not sufficient justification for such a process. Children do possess rights as

human beings, but that does not imply that all children should be allowed to determine what constitutes their welfare. There are specific criteria to be met for the possession of a right and there remains an association between chronological age and the attainment of certain competencies. Furthermore, the arguments surrounding the alleged competence or incompetence of children below the age of majority are actually better suited for discussions surrounding a change in the age at which children are considered adults and thus granted full self-determination rights, rather than as justification for the establishment or abolishment of the assent process. The ultimate goal of the assent process is to involve those children who are sufficiently able to participate in the decision-making process, while excluding those who are not. The problem lies in the disagreement over how to properly assess which children are considered to be "sufficiently able" to participate.

2.3 Respect for Developing Autonomy

Earlier in this chapter it has been established that while the arguments surrounding a child's human rights and varied levels of competence may have some legitimacy, they are not sufficient ethical justification for the idea that children should be involved in medical decision-making. A more widely accepted justification for assent in the literature is related to respect for the child's developing autonomy[20,87,99], and it is to this argument that we now turn. As children develop from infancy through to adulthood, their maturation is not purely physical but also mental. Individuals do not suddenly become mature, autonomous adults on their 18th birthday; rather, they develop increasing cognitive capacities and an ability for self-determination throughout childhood[52,91,128,143,156]. As children mature they develop capacities and competences related to decision-making, rational thought processes, and self-determination that allow them to gradually become increasingly autonomous as they approach adulthood. Adults are asked for their informed consent to

research participation out of respect for the fact that they are autonomous individuals[139]. The act of asking an adult for consent recognises that the individual is a fully autonomous being and therefore his decisions should be respected. If all instances of full autonomy must be respected, it could be argued that instances of partial autonomy should also be respected, such as are found in children who have developing capacities for autonomy but who are not yet fully autonomous[143]. As the child demonstrates greater capacity, he earns the right to be granted some degree of self-determination[105]. Involving the child in the decision-making process demonstrates respect for his developing autonomy[20,87,91,99]. During childhood it is important for children to be given an increasing amount of autonomy in correlation with their newly developed capacities in order to help them further their development[26,91,105,156]. This makes logical sense; surely when a child has developed sufficient cognitive abilities to make decisions about his own interests, he should be allowed some degree of control over these interests[76]. Asking a child to participate in the decision-making process allows him a voice in the discussion, to the extent that his current cognitive capacity will allow[20,28]. Therefore, it would be reasonable to assess the child's current capacities in order to have an idea as to what level of decision-making contribution he can be expected to make. This participation not only respects the child's increasing abilities and desire to become an autonomous individual, but also gives that child a safe forum in which to practice his expanding self-determination.

However, the argument that the justification for the child's involvement in the decision-making process lies in respect for his developing autonomy is problematic for several reasons. First of all, the attempt to describe children as "competent" or "incompetent" to assent is complicating what is already a very difficult issue. The use of the word

"competence" in this situation is misleading. The very concept of assent exists because children are not considered to be sufficiently competent to make their own decisions. Therefore, a person under the age of majority is considered to be incompetent and cannot provide his own informed consent. To then introduce a second level of competence, now applied to a child's ability to be involved in the decision-making process rather than making the entire decision himself, further complicates the issue and makes it even more likely that there will be confusion regarding which children should be involved in medical decision-making. Describing a child as competent to assent has generated much confusion in the medical community surrounding what constitutes "competence" and has led some researchers to recommend lowering the age of consent to include these "competent" minors, bypassing assent altogether[47-49]. As discussed earlier in this chapter, there are procedures in place to allow some select minors to be declared "mature minors" or "Gillick competent" and thus make their own informed decisions, however these children are competent to provide their own informed consent which is very different than what is actually meant by the phrase "competent to assent". The problem with the usage of the word "competent" in any discussion of assent is that if a set of criteria are proposed by which to judge an individual's competence to provide his own consent, anyone not meeting those criteria should be labelled as incompetent. There cannot then be a reclassification of some of these individuals as "quasi-competent" (which is essentially what "competent to assent" means) based on a different set of criteria.

A second problem with the developing autonomy argument lies in the concepts of "partial autonomy" and "partial respect". If instances of complete autonomy are fully respected, and instances of a complete lack of autonomy are not respected, then instances of partial

autonomy would seem to justify partial respect. Yet it is unclear how "partial autonomy" and "partial respect" can be defined. Autonomy and respect are traditionally binary concepts[23]: a choice is either autonomous or non-autonomous, and something can either be respected or not respected. The process of assent covers a broad range of capacities and this range would seem to be greater than any similar range among autonomous adults. Assent represents an attempt to engage with children who exist along a sliding scale of competence found between a non-autonomous infant and a fully autonomous adult[131].

The term "partial autonomy" poses a problem as it is not obvious how to determine whether an individual choice is autonomous and thus should be respected. When confronted with a choice by a normally functioning adult, it is assumed that he is autonomous unless proven otherwise, and therefore his choice is also assumed to be autonomous. But these assumptions do not apply for a child's "partial autonomy". In this case, a child is already considered as not fully autonomous, so the most plausible interpretation of "partial autonomy" would seem to be that some of the child's choices are autonomous while the rest are not. It is then necessary to distinguish between his choices that are autonomous and those that are non-autonomous. However, if this is the case, then the child's autonomous choices should be accorded full respect precisely because they are autonomous. This does occur in the instances where a child is declared Gillick competent. The problem as it relates to assent is that the developing autonomy argument has already indicated that partial autonomy warrants only "partial respect", a notion which is no easier to grasp.

As stated above, respect is usually a binary concept. Similar to the definition of partial autonomy in that only a subset of the child's decisions would be deemed autonomous, "partial respect" of a child's decisions would seem to indicate that some of his decisions would be respected while other decisions would not be respected. This is problematic however as, in the current assent process, none of the child's decisions are being respected. While assent represents the belief that some children ought to be involved in the decision-making process, the child's decision is ultimately not accorded respect as would be given to the fully informed consent of an adult research participant or the proxy informed consent of a child participant's caretaker. Even when a child's involvement in the decision-making process is actively sought, there are instances where a child's decision can be overridden[147,154]. This usually occurs when the child's decision is in conflict with the views of the clinician and parents as to what is medically in his best interests[157]. In the medical context, when a decision is truly respected, it is accepted as that individual's decision and the treatment plan is adjusted accordingly. When a decision is not respected, it is not taken into account in the final treatment plan. In the case of assent, a child's decision is not necessarily accepted as an authority when finalising the clinical plan, leaving open the possibility that the final decision reached might be contradictory to the child's stated preference. In this occurrence, "partial respect" would in effect have no meaning. If the child's decision is not taken into account when making the final decision, then it is not in fact being respected. This problem has led some researchers to question the point of involving children in the decision-making process at all[47-49]. Their argument is that if a child is asked for his decision, even though that decision can be overridden if it does not correspond with the decision of the clinician and the child's parents, there is little point in going through the pretence of involving the child in the first place. To do this

could actually damage the child's developing autonomy as he will learn that his wishes and opinions are not respected by his caretakers[84].

A further problem is that, because the child's decision can be overridden, the concept of "competence to assent" is essentially meaningless. If a child is declared as "competent to assent" and then the parents and clinicians do not agree with his decision, they are then forced to declare that the child was in fact not competent to assent after all and move forward with the proposed treatment or procedure. As discussed in **Chapter 1**, one way in which this problem can be addressed in the future is by thinking about assent as the involvement of the child in the decision-making process, but without the expectation that the child's wishes must necessarily be respected. A clinician could therefore decide to what degree an individual child should be involved in the decision-making process, irrespective of the decision that he will make, all the while with the understanding from all parties that his involvement in the decision would not necessarily mean that his decision would be accepted as the final decision by the clinician and parents.

However, regardless of any discussion of the child's "competence", the fundamental argument that assent illustrates respect for the child's developing autonomy is wrong. If a child's decision is not fully respected, instead being granted only a partial respect due to his partial autonomy, then clearly the existence of assent cannot be justified by the "respect" for his developing autonomy because it is not, in fact, being respected. Therefore, although a child does develop the capacity of autonomy throughout childhood, respect for this developing autonomy is not an appropriate justification for the existence of assent.

2.4 Pedagogical role

So far this chapter has examined how the ethical grounding for the involvement of children in medical decision-making does not stem from children's rights or respect for their developing autonomy. These are both fairly widely discussed justifications for childhood assent in the literature[9,15,83,84,156,158,159]. If they are not correct, perhaps the problem should be approached from a different direction. Rather than trying to find the justification for assent in the language of rights, there should be an examination of the fundamental reasons behind the original motivation to involve and engage with the child. Involving a child in the decision-making process about a medical procedure that affects him is about the researcher's obligations to that child: how the researcher ought to act towards the child. A medical researcher confronted with a potential child participant typically feels that he ought to engage with the child in some way about the decision-making process. This obligation is less about something possessed by the child, such as his fundamental human rights or developing autonomy, but about the obligation of the researcher towards that child.

So what is the obligation of the researcher to the child? In order to formulate an answer to this question, the problem should be examined from the opposite perspective. Rather than searching for something in the child that grounds the obligation on the researcher to involve him in the decision, we might instead begin by examining the benefits that the child might receive if he were to be involved in the decision-making process. One obvious benefit for the child would be that his involvement in the decision-making process would teach him how to become a better decision-maker. By allowing the child to participate in the decision, without placing the onus on the child to make the entire decision, he is given

the opportunity to practice decision-making while still under the protection of his caretakers and other adults such as doctors and nurses. Assent utilises his developing capacities and gives him a voice in matters which affect him, but most importantly it allows him to practice his decision-making skills in order to further enhance his development and become a better decision-maker as an adult[87,121,131,151]. The key difference between this argument and one grounded in developing autonomy is that there is an important distinction between respecting a decision and encouraging a decision. It is true that a child is developing increasing cognitive capacities throughout childhood, thereby forming improved decision-making abilities[52,91,128,143,156]. This decision-making should be encouraged in order to further the child's development[26,91,105,156], but that encouragement does not need to be associated with respect or partial respect. Instead, the act of encouraging the child in his newly developed decision-making capacities is based upon the aim of teaching him, and not, in fact, on a level of respect for him.

Yet on further analysis, while assent does teach children to become better decision-makers, this pedagogical role does not completely justify the act of involving a child in the decision-making process. If the sole concern were to teach children to make decisions, then the main focus of this justification for assent would be on the parent rather than the child. Parents are ultimately responsible for this pedagogical role, determining throughout a child's upbringing when and under what circumstances the child develops his capacity for autonomy and reasoning[20,119,132,144,151,160]. So it is up to the parents to determine where in the spectrum of decision-making development the child is at any given time.

A good parent, who is successful in rearing his child to become an autonomous adult, will teach the child to adopt a perspective towards himself that is very like an ideal parental perspective[160]. This in effect means that the child will learn how to make good decisions based on the example the parent has set when making decisions for and on behalf of the child while under parental care. By adopting this ideal parental perspective as his own, the child will learn how to recognise what really is in his best interests, learning the process of how to make a good decision, although not necessarily how to make the same decision that his parents would make. So, to be a "good parent", one has the obligation to teach one's children to be autonomous. In the context of medical decision-making, the researcher has the obligation to respect this parental obligation by allowing the parents to teach their child. Assent, then, could be viewed as another pedagogical tool that parents can adopt in the overall education and nurturing of their child. However, if the parents are responsible for constructing the context in which a child develops his autonomy, then this implies that the parents should be allowed to determine whether or not their child should be included in the decision-making process, putting the onus on the parents rather than the investigator. Logistically this means that the researcher should engage with the child only in such a way that fits in with the individual pedagogical techniques of the child's parents. The researcher should customize his interaction and involvement with the child depending on how the child's parents would like him to do so. So, on this view, the researcher's obligation is to the parents rather than to the child.

However, when seeking a child's involvement in the decision-making process for research participation, the researcher is concerned primarily with the child rather than with his parents. This illustrates that, in addition to his obligations to the parents, the researcher

also has an obligation to the child. This is seen most clearly in a situation where a researcher believes the child should be involved in the decision-making process but the parents do not agree (or vice versa). If assent were purely justified by its pedagogical role for decision-making, the researcher would be content to accept the parental view that the child is not yet capable of participating in the decision. However, the judgment that a particular child ought to be involved, even against the opinion of his parental caretaker, demonstrates that the researcher believes that he ought to get assent not because he feels that he owes something to the child's parents but because he feels that he owes something to the child: he has an obligation to the child.

This realisation is the key in completing the actual justification for assent. In paediatric settings, then, there are two obligations on the researcher: an obligation to the parents who lead the pedagogical role for their individual child, and an obligation to the child himself. In some situations these obligations are in harmony and thus there is little cause for dispute. However there are situations where these obligations on the researcher can come into conflict, such as when the researcher feels that the child should participate in the decision, while the child's parents disagree. This conflict between the two obligations illustrates that the pedagogical role is not sufficient as the only justification for assent. While the researcher does have an obligation to the parents to assist in the development of their child's autonomy, this does not speak to the researcher's obligation to the child. If the pedagogical role were the only justification for assent, then the researcher would be able to pass off to the parents any involvement with the child. In this scenario the researcher could give the parents all of the information and ask them to tell their child what they feel is appropriate, involving the child to the degree that they see fit. However

this would not absolve the researcher of his own obligation to the child. Therefore it is clear that there must be an additional element of the justification for assent: one that addresses this second obligation of the researcher.

2.4.1 Moral worth

Although the researcher has an obligation to the child, independent of his obligation to the parents, the grounds of this obligation are not clear. Some philosophers have argued that autonomous individuals have moral worth because they are autonomous[161]. Following this logic, a child is not autonomous and therefore cannot have moral worth. However by asking a child for assent he is being treated as if he already has moral worth[87]. While a child is technically non-autonomous, he is not equated with an inanimate object or a non-autonomous being with whom communication is impossible[93]. Instead the inherent value of the child is recognised, illustrating that he warrants treatment as a being of worth. This recognition of the child's inherent value and worth can play an important role in justifying a process of assent. The child ought to be involved in the decision-making process about his own life rather than let adults make all of those decisions for him. Furthermore, a child will come to understand he is of value by being treated as if he is of value. Past research in paediatrics has indicated that children feel appreciated and valued when they are involved in some capacity in the medical decision-making process[108,162,163]. Involving a child in the decision-making as part of the overall enrolment process is a sign of respect[120,164] and teaches the child his inherent value and worth as an individual, a notion that will affect not just his ability to make good decisions but also every other aspect of his life as an autonomous being[85]. In fact, the development of a sense of self-worth is a fundamental step in a child's overall maturation from a child to an adult. Without a sense of self-worth,

an individual will struggle to have a happy and normally functioning life[144]. In the medical context, this sense of worth has been documented as having an affect on the emotional status of the child patient. Children have reported feelings of distress and anger when they were excluded from the decision-making process regarding their medical treatment, while children who were included in that process have experienced decreased nervousness or anxiety[108,162,163,165-173]. The process of assent, or involving the child in the overall decision-making process, therefore, is an important way in which respect for the child as an individual can be demonstrated[63]. The value lies not in the response given by the child but the fact that his views were solicited in the first place. There is a good deal more to be said about these concepts and the role that they play in the treatment of a child. Here, these suggestions function as an initial placeholder for future work. As will be shown below, it is the pedagogical role that has a bigger part to play in what follows.

2.5 Conclusion

This chapter has outlined some of the justifications in the literature that have been used to explain the concept of child assent, such as arguments from children's rights or respect for a child's developing autonomy. While these arguments raise important issues, they are incomplete, and do not provide a full justification for an assent process as an element of the overall enrolment process in paediatric research. A child does indeed have rights, however that does not necessarily mean that he will be the individual to exercise those rights. His parent or guardian is expected to make decisions on his behalf until such a time as the child has developed sufficient cognitive abilities to be able to act autonomously without assistance. While a child also develops his autonomy throughout childhood, and therefore has an increased capacity for decision-making, respect for this developing

autonomy cannot be cited as a reason for assent. Involving a child in the decision-making process does not mean that his opinion will dictate the final decision that is reached. Due to the fact that a child's opinion on the subject can be solicited and then overridden if it is different from that of the clinician and/or parents, it is clear that the child's decision is not being respected. So, respect for his developing autonomy, and therefore his decision, cannot then be used as a justification for his initial involvement in the decision-making process.

Instead, the justification for involving a child in the decision-making process for medical decisions that affect him is found through examining the benefits to the child from his involvement. Assent should be understood as playing a pedagogical role for the child, helping to teach him how the specific decisions are made and therefore helping him to become a better decision-maker in the future. Here, the researcher is working with the parents to help teach their child to be autonomous, fulfilling an obligation to the parents who lead this pedagogical role in the context of their family. Of course, the researcher must also recognise a potentially competing obligation to the child, regardless of the parents' pedagogical techniques. If the parent is not present in the clinic room, the researcher still has an obligation to engage with the child. How the researcher engages with the child supports his obligation to the parents as that communication is still a way in which the child can learn about decision-making. However, why the researcher engages with the child stems from the child's self-worth. The key concept to remember with this obligation is that the child is a person and therefore has worth. By involving the child in the decision-making process, he is being treated as if he has moral worth and therefore learns that he is a being of moral worth.

The current debate about assent in the medical community centres on the questions of how and when a child should be involved in the decision-making process. Given that the main principles for how a researcher should engage with the child stem from his obligation to the child's parents, to respect their obligation to teach their child to be autonomous in the manner in which they see fit, it is evident that a greater understanding of the overall family dynamic is needed before the assent process can be improved in clinical practice. Clearly, if the justification for the child's involvement in the decision-making process is derived from the parents' pedagogical obligation to their child, then that child's family context must be considered before making any judgments about how and when it would be appropriate to involve him. **Chapters 3 and 4** will discuss two empirical studies that were conducted in order to learn more about the family context, outside of medical decision-making. **Chapters 5 and 6** will then explore how this information might be applied to the clinical context and thereby help to improve the way in which the concept of assent in paediatric medical research is approached.

Chapter 3. THE FAMILY CONTEXT: A SERIES OF FOCUS GROUPS

3.1 Introduction

The previous chapter offered an examination of the ethical and philosophical theory that supports the existence of assent. The primary justification for assent is found in the fact that it holds an important pedagogical role for the child. The child's involvement in the decision-making process not only allows him a participatory function, but it also teaches him how the decision is made, helping him to become a better decision-maker in the future. This pedagogical role lies primarily with the parents who are ultimately responsible for teaching their child to become an autonomous adult. However, the researcher has an obligation to the parents to respect this role, thereby involving the child in such a way as to support the parents' ongoing pedagogical plan. A secondary justification for assent arises from the child's own moral worth. Through the child's inclusion in the decision-making process he is being treated as a individual of worth and therefore he is learning that he does have self-worth.

If the justification for assent stems primarily from the pedagogical role of the parents towards their child, then it is necessary to examine the family dynamic between parents and children to learn more about their daily interactions. As discussed in **Chapter 1**, a child's family context has a substantial influence on his ability to take part in the decision-making process for research participation[61,65,90,119], but further research on how children are involved in daily decision-making within their families is needed. This chapter will describe a series of focus groups that were convened with children, parents, and primary school educators. These focus groups were designed to learn more about children's daily decision-making within the context of their family. Therefore the focus was on the typical

interactions between a child and his family members within the context of their daily lives, rather than specifically concentrating on medical decision-making.

3.2 Focus Group Study

3.2.1 Introduction

In order to learn more about daily decision-making within the family context, a questionnaire survey of children and their parents was planned. However, it was necessary to ensure that the questions posed in the questionnaire were both meaningful and appropriate for the established research purposes. Therefore, a series of focus groups was conducted with the aim of learning what topics would be most useful to explore further in the questionnaire study.

The primary objective of this focus group study was to explore different perspectives on the decision-making power and ability of children aged 5-12 years old. To get an accurate picture of a child's decision-making throughout his normal daily life, the focus groups were conducted with three different peer groups: children aged 5-12 years old, parents of children aged 5-12 years, and primary school educators. Conducting focus groups with these three peer groups allowed for an investigation of issues related to daily childhood decision-making from three different perspectives. While primary school educators are not part of the child's family context, they do spend a substantial amount of time with children in their daily lives and therefore they might have been able to offer an interesting and useful perspective on children's decision-making ability and experience.

As stated, this study concentrated on children aged 5-12 years old. Assent is a process that includes children up to the age of majority, however a teenager's decision-making ability is not usually considered to be under debate. In fact, there is a general consensus that teenagers should at least be included in decision-making for paediatric research[15,40,91,104], if not deemed a mature minor and granted the ability to provide their own fully informed consent. It is also generally accepted that infants and toddlers are too young to make a meaningful contribution to the decision-making process[21,113,116]. In the current medical literature, the group of children for whom it is unclear if they can and should be included in the decision-making process includes primary school-aged children (approximately 5 years old) through mid-adolescence (approximately 14 years old)[104,123]. When designing the empirical research to be described in this thesis, this age range was modified slightly to include only those children between the ages of 5 and 12 years old, as stated above. This is not to say that children aged 13-14 would not have been appropriate participants for this research. However for the sake of study recruitment, it was decided to limit the participant age range to the expected ages found among primary school children, in the hopes that the research on their daily decision-making within their family context will shed some light on the future involvement of this age group in the decision-making process of overall enrolment proceedings.

3.2.2 Methods

3.2.2.1 Study design

This qualitative research study was an exploratory and descriptive study. Study participants took part in a focus group of their peers (children aged 5 to 12 years, parents, and primary school educators). Study participation was the duration of the focus group discussion, approximately 1 hour. Several focus group discussions were conducted for

each peer group however an individual study participant was only allowed to join one focus group discussion. Upon the conclusion of each focus group, participants were compensated for their time spent in the study. Child participants received a certificate and stickers while parents and primary school educators received a £20 gift card to a local grocery store. Light refreshments were also available for all focus group discussions.

3.2.2.2 Ethical approval

Ethical approval for this study was granted by the University of Oxford Social Sciences and Humanities Inter-divisional Research Ethics Committee.

3.2.2.3 Recruitment

Purposive sampling was used. Recruitment for the study was achieved through posters and flyers advertising the study as well as direct mail-out via email to parents at several local schools in Oxford and to staff members at the University of Oxford. Information about the study was presented to the Head Teacher at 12 local primary schools. Of those schools, four agreed to distribute information about the study to the parents of their students. Potential participants who were interested in one of the focus groups registered their interest at the Oxford Vaccine Group, at which time the participant was scheduled for a specific focus group discussion. A participant information sheet and informed consent form were sent to the potential participant prior to the scheduled focus group discussion. After receiving the information sheet and informed consent form, potential participants were able to call the study Principal Investigator at the Oxford Vaccine Group to discuss the study in more detail prior to attending the focus group.

Child participants were healthy children between 5 and 12 years old, who were willing to participate, and for whom a parent gave written informed consent. Parent participants were healthy adults between 18-80 years old, who had custody of a child between 5-12 years old, and who gave written informed consent. Primary school educator participants were healthy adults between 18-80 years old, who worked with children aged 5-12 years old, and who gave written informed consent.

It was originally anticipated that three focus groups from each peer group would be conducted, however per the protocol the number of focus groups conducted could vary based on when saturation was achieved, meaning when no additional information was gained from the conduct of further focus groups. There were less primary school educator focus groups than originally planned as no additional information was gained from the educator group, beyond what was already learned through the parent groups. Conversely, there were more child focus groups than originally planned. The child groups were divided based on child age and therefore additional groups were necessary to reach saturation. The determination of when saturation was reached for each peer group was made based on the analysis of each focus group discussion upon its completion. Analysis was not conducted solely after all focus groups had been completed. Instead, the content of each focus group discussion was conducted soon after its conclusion. In this way it was very clear when an additional focus group added new information to the analysis of that peer group.

3.2.2.4 Consent

Written consent was given by each adult participant prior to the beginning of each focus group discussion. Parental consent was given prior to each child focus group, with the

verbal assent of each child participant verified by the moderator and/or assistant moderator. This verbal assent was documented on the consent form for each child. (A version of the consent form for child participants is included in Appendix 1). All consent forms were signed and dated by the adult participant or the parent of a child participant and then were counter-signed and collected by the focus group moderator or assistant moderator.

3.2.2.5 Development of Questioning Routes

Individual focus group discussions were conducted using specific questioning routes designed for that peer group. The questioning routes were developed in several steps. A comprehensive literature review was conducted, covering the subject of paediatric assent, child rights, child development, and the conduct of focus groups. Secondly, a draft questioning route for each peer group was developed. The draft questioning routes were then reviewed by the supervisory committee, prompting additional revision based on their comments. Finally, these drafts were reviewed by paediatric doctors and nurses with final modifications made based on their comments.

These questioning routes were used by the moderator as a guide for conducting the focus groups and were followed as closely as possible. Depending on the nature of the individual focus group discussions, questions were modified, added, or removed. However the discussions remained within the general context of those listed in the questioning routes. For the child focus groups, participants were placed in a group of similarly-aged children to facilitate the discussion[174]. Examples of the three questioning routes are included in Appendices 2-4.

3.2.2.6 Moderation

Each focus group was led by a trained moderator. The author acted as moderator for all adult focus groups, while Elizabeth Davis, a Paediatric Nurse, led all child focus groups. In addition, an assistant moderator was always present during the focus groups. The moderator was responsible for directing the focus group discussion, ensuring that the conversation ran smoothly. The assistant moderator was responsible for taking detailed notes of the proceedings as well as operating the digital audio recorder. After each focus group discussion, both the written notes and the audio recording were used to aid in the analysis.

3.2.2.7 Questioning Routes for Child Focus Groups

At the beginning of the child focus groups, children were asked a few introductory questions to build their comfort in the group setting. They were asked to share with the group their name and favourite food, and then to describe what they like to do with their free time. Once the children were comfortable with the format of the focus group discussion, the moderator moved on to cover more in-depth questions. They were first asked to define what it means when they are asked to choose something, in order to determine whether they understood the concept and therefore would be able to answer the remaining questions. Then, the children were asked a series of questions about potential decisions to which they might be accustomed in their daily lives, such as who chooses the food they eat, the clothes they wear, and the activities in which they participate. As stated above, these questions varied slightly depending on the nature of the discussion in each group. The child participants were also asked to discuss how they make decisions, what happens when their parents disagree with their decisions, and whether they have an

interest in making more decisions, or having more autonomy, in their daily lives. (The questioning route for child focus groups is included in Appendix 2).

3.2.2.8 Questioning Routes for Parent Focus Groups

Parent participants were first asked to state their names and then to share an activity that they enjoy doing with their child or children. The moderator then asked the parents if their children were given pocket money. These introductory questions were designed to start the group discussion and help to develop a sense of comfort among the participants in order to prepare them for the group discussion that was to follow. The moderator then asked a general question of whether the participants considered age to be an appropriate measure of a child's developmental abilities. Afterwards, the moderator asked a series of questions to foster a discussion of their individual experiences, including whether their children make decisions in their daily lives, if they guide their children's decisions, what happens if they disagree with a decision that their child has made, and whether they believe that their individual children would be capable of making a decision about their health care. (The questioning route for parent focus groups is included in Appendix 3).

3.2.2.9 Questioning Routes for Primary School Educator Focus Groups

To start off the discussion with the primary school educator focus group, the participants were asked to state their name and what they enjoy about working with children. They were then asked to share how they evaluate the progress of students in their classes. Then, similar to the parent focus groups, the moderator asked the participants a general question of whether they considered age to be an appropriate measure of a child's developmental abilities. Once the participants were comfortable with the group discussion format, the moderator moved on to the more central questions, including what types of decisions they

see children making in the school environment, what happens if they disagree with a decision their student has made, and whether they think that children would be capable of making a decision about their health care. (The questioning route for primary school educator focus groups is included in Appendix 4).

3.2.2.10 Transcription

All focus group discussions were audio-recorded using a digital audio recording device. Upon the conclusion of each focus group, a complete transcript of the focus group discussion was typed, using the audio recording of the focus group discussion as well as detailed written field notes taken by the assistant moderator and the audio recording of the debriefing session. Transcripts of the focus groups were then entered into the computer program NVivo 8 for analysis. At this point the audio recordings and written transcripts were compared in order to verify that the transcripts were correct and to become fully immersed in the data prior to analysis. Once the transcript was verified as accurate, the data was ready to be coded and analysed.

3.2.2.11 Member Checking

In addition to the audio recording, the assistant moderator took comprehensive written notes of the focus group discussions as they occurred. At the conclusion of each discussion, the assistant moderator briefly summarized the topics that were discussed, based on these written notes. The moderator then asked the participants to confirm whether it was an accurate summary of the focus group discussion. Participants were also given the opportunity to mention additional comments or thoughts that they believed should have been covered during the discussion. This allowed the moderator to verify the accuracy and completeness of each focus group discussion.

3.2.2.12 Post-Focus Group Debriefing

Immediately after each focus group discussion ended, the moderator and assistant moderator conducted a focus group debriefing session. This session was also recorded with the digital audio recording device used during the focus group discussion. The moderator first confirmed that the field notes were complete at which point the moderator and assistant moderator discussed what they heard during the focus group discussion, including:

1. Major themes and important topics that emerged during the focus group discussion;
2. Any surprising or unexpected comments or views voiced during the discussion;
3. Similarities and differences between this focus group and previous focus groups; and
4. Any changes that should be made to the questioning route before the next focus group was convened.

3.2.3 Results

3.2.3.1 Participants

Focus groups were held in University meeting rooms, a primary school, and participant homes. 9 focus groups were held between December 2010 and February 2011. At the end of data collection there had been 5 child focus groups, 3 parent focus groups, and 1 primary school educator focus group conducted with a total of 45 participants across all groups (23 children, 17 parents, and 5 educators). Table 1 shows basic demographic information on focus group participants. The individual focus groups included between 3 and 7 participants per group, with an average of 5 participants per group. The average age of the 23 child participants was 8.13 years old. Age was not collected from the primary

school educators or the parent participants. There were more female than male participants across all peer groups: 33 (73%) of all participants were female. This split was slightly less pronounced among the child participants, with 14 (61%) female and 9 (39%) male participants. Of the parent participants, there were 14 (82%) female and 3 (18%) male. There were 5 primary school educator participants and all 5 (100%) were female. It is interesting to note that all 3 male adult participants took part in the same focus group discussion (Parent Group 1). This was purely coincidental, based on the availability of the participants and is not a reflection on the recruitment methods for this group. In fact, the participants in Parent Group 1 were recruited through three of the different recruitment methods described in section 3.2.2.3 of this thesis.

Table 1 – Focus Group Study: Participant Demographics

Group	Age Range	Number of Participants	Gender
Child			
Child Group 1	5-8[1]	5	2 female, 3 male
Child Group 2	8-11[2]	5	5 female, 0 male
Child Group 3	5-6	3	1 female, 2 male
Child Group 4	7-9	6	3 female, 3 male
Child Group 5	10-12	4	3 female, 1 male
Parent			
Parent Group 1	18-80	4	1 female, 3 male
Parent Group 2	18-80	6	6 female, 0 male
Parent Group 3	18-80	7	7 female, 0 male
Teacher			
Teacher Group 1	18-80	5	5 female, 0 male

[1] This group was originally planned several weeks earlier for children aged 5-7 years, but was rescheduled due to scheduling conflicts during the holidays. Three weeks later when the group was rescheduled, one participant had turned 8 (her brithday was nine days prior to the focus group date).
[2] As above, this group was planned for children aged 8-10 years but was rescheduled. Three weeks later when the group was rescheduled, one participant had turned 11 (her birthday was two weeks prior to the focus group date).

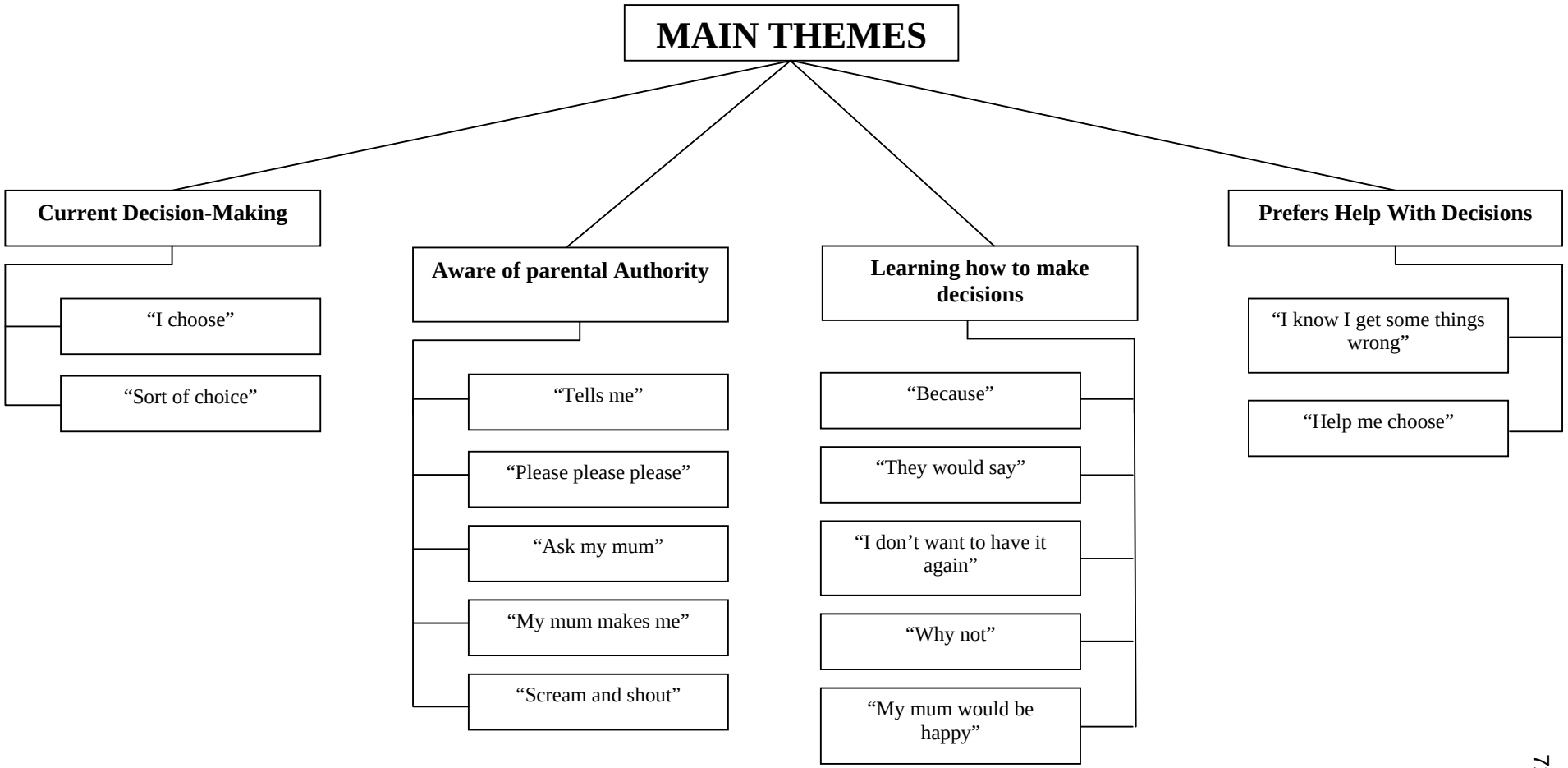
3.2.4 Analysis

A transcript-based thematic analysis was conducted, allowing themes to emerge from the text. The focus group discussions were coded and then those codes were arranged into wider themes. Focus group discussions were analysed first within each peer group, to identify the main themes that emerged during the focus group discussions and to determine whether saturation had occurred. Secondly, an analysis was conducted across peer groups to explore the similarities and differences between the main themes from each peer group. All focus group discussions were coded by the same person in order to ensure that there was no variation in the coding methods. However, throughout the coding process the coding definitions and any ambiguous responses were discussed with the rest of the research team.

3.2.4.1 Child groups

The main themes that emerged from the child focus groups centred on the child's perception of his decision-making power and ability. They also illustrated the pedagogical nature of the family context, as children were aware of their parents' viewpoint on important issues, clearly having learned from past decision-making within their family unit. (See Figure 1 for a chart of all themes from the child focus groups).

Figure 1 – Focus Group Study: Themes from Child Focus Group



Child participants in the focus group discussions admitted that they did make some choices in their daily lives. All of the decisions that were mentioned were related to the clothes that the children wore, how they spent their free time, and, in some cases, the food that they ate. One child shared with the group what she usually would do upon returning home from school:

> "*Child: I sometimes go to after school club, after, but most days I just go home and watch telly for a bit.*
> *Moderator: Ok and who decides what telly to watch?*
> *Child: Me, because I'm the only one home at that time.*" (girl, 9 years old)

It is important to note here that this statement could have raised safeguarding concerns as a 9 year old girl was seemingly reporting that she was regularly left at home alone. It was determined by the moderator and the assistant moderator, however, that this was not a concern for this specific individual as the parents were known and the child was most likely stating that she was the only one of her siblings who would be home at that time. Nonetheless this would not change the overall meaning of her statement, as, regardless of whether she was the only family member in the room or in the house, she still considered that the television programme that she would watch was due to her individual choice.

Another girl also spoke about the choices that she made regarding her free time:

> "*Child: I usually go home and have a snack, and then I play, either play Lego or read a book.*
> *Moderator: Ok, and what book do you read? Who decides what book you read?*
> *Child: Me. I usually read loads of different sorts of books.*" (girl, 8 years old)

Some of the child participants discussed the choices that they made regarding their clothing. As opposed to the discussions of their after school activities, children who stated that they chose their clothes also mentioned that they were not always allowed to do so.

> "*Moderator: And do you always get to choose what you want to wear?*
> *Child: Normally, but sometimes I don't.*" (girl, 8 years old)

> "*Moderator: And do you get to choose what you wear all the time or does your mum normally?*
> *Child: For parties my mum chooses it for me but other days I choose what I want to wear.*" (girl, 10 years old)

One child shared that she could periodically choose her dinner:

> "*Child: I sometimes get to choose what to have for supper.*
> *Moderator: Ok, and how do you choose?*
> *Child: Um, well I choose, I sometimes choose my favourite meal, but when we haven't had something healthy for a really long time then I might choose something a bit healthier than sausages and chips.*" (girl, 8 years old)

In this example, although she admitted to being able to choose an unhealthy option such as "sausages and chips", it also seems likely that she was not often given the opportunity to choose her dinner. Another child stated that after coming home from school he would watch television until tea time. The moderator then asked him if anybody would tell him to do this. He responded:

> "*No, I know when it's tea time.*" (boy, 5 years old)

In this response, the boy demonstrated that although he would make the decision to watch television until tea time, he was working around an already set schedule, presumably dictated by his parents. In most of these situations it was clear that, while the children mentioned instances in which they were able to make choices in their daily lives, they made these decisions because they knew they were allowed to make them, rather than truly choosing for themselves. It is also important to note that these decisions could all be described as having little or no consequences. Past research with children and adolescents has shown that parents are more likely to allow their children to make "soft" decisions, where the consequences of a potentially incorrect decision are minimal[108,170,175,176].

Throughout the focus group discussions, children also referred to a different type of choice that they would make: a "sort of choice". This describes situations where the child could make a choice among limited or set options. Once again, the examples given by child participants for these limited choices involved their choice of clothes, activities, and food. One boy described what he would do after school in the afternoons:

> *"I go straight home from school and then I have a sort of choice whether to go on the computer or my TV or my DSi. It's quite a hard choice but I normally choose the computer or the DSi.*" (boy, 7 years old)

Here he clearly made a choice between three different entertainment options, but he described it as "a sort of choice" because he had to choose between only those three options, rather than any extra-curricular activity. The limited range of choices also extended to decisions of what food the children consumed at meal times. Two girls in two different focus groups discussed their choice for what they would eat at breakfast:

> "*Child: I have two choices.*
> *Moderator: Two choices. And have you gone to the shop and chosen them?*
> *Child: No.*
> *Moderator: No, so mummy will say you can have this or this.*
> *[Child nods]*" (girl, 8 years old)

> "*Child: We have cereals but we have options like there's a cereal-full cupboard and there's like healthy stuff like Shreddies and Alpine and Muesli and stuff. But mum also lets us, we don't have Nutella or chocolate sauce but we have it like for Christmas. And we have to have either like 2 pieces of toast or a bowl of cereal something like substantial.*" (girl, 11 years old)

In these situations, the girls admitted that, while they were able to choose what they ate for breakfast, they were choosing from a limited range of options that had been chosen for them by their parents. Similarly, many of the children stated that they would decide what clothes they wore, however this was also usually a limited choice as the clothes were purchased by their parents with varying amounts of input from the children at the time of

purchase. For example, one girl mentioned that she would shop for clothes with her mother, while a boy stated that he let his mother decide what clothes to buy for him.

> *"Moderator: Ok, in the morning when you're not at school, who chooses what you wear?*
> *Child: Me.*
> *Moderator: And have you gone and bought those in a shop on your own?*
> *Child: No.*
> *Moderator: No, so who comes shopping with you to get your clothes?*
> *Child: Mum.*
> *Moderator: And does she let you choose a bit or totally?*
> *Child: Yes, a bit. Sometimes she like puts in her opinion.*" (girl, 12 years old)

> "*Child: Um, I choose what I wear but I hate shopping so my mum just chooses it all for me, what she buys. But I'm not really bothered about fashion.*" (boy, 10 years old)

Throughout the focus group discussions the children shared examples of decisions that they would make during their daily lives. Some of these were choices that the children made on their own with no input from their parents, although many of these were decisions that the children knew that they were allowed to make rather than true independent choices. However more often than not, the examples given by the child participants were illustrations of guided decisions such as those described above.

In fact, during the child focus groups the pedagogical role of parenthood and child-rearing became evident. Throughout the discussions, it was clear that the children were actively learning about decision-making from exposure to the overall decision-making process within the family. The children were aware of the parental viewpoint on a range of topics from their daily lives, and where they were unsure, they expressed a desire to understand why the decision had been made. Furthermore, some of the children gave examples of how they had learned from past experience and the effect that would have on future decisions of a similar nature.

First of all, the child participants seemed to be very aware of their parents' views. They clearly had acquired the skills to see situations from the parental viewpoint, even if they were not yet ready or willing to adopt that viewpoint as their own. Therefore, they were learning correct behaviour from past experiences with more paternalistic decision-making within the context of their family. For example, the moderator asked the children what they would choose for their lunch if they could go into the shop and buy whatever they wanted. After giving their responses, the moderator then asked them if their parents would be happy with what they chose. Some children chose items that they knew their parents would approve of, such as one girl who explained why she would buy a sandwich and yogurt for her lunch:

> "*Well, um, they're healthy and plus my mum would probably be happy with it.*" (girl, 8 years old)

Other children chose items that they knew were less healthy, and were well aware of the fact that their parents would not have approved of their choices:

> "Moderator*: And would your mum and dad be really happy with what you chose for your lunch?*
> Child*: Maybe not the sweets.*" (girl, 6 years old)

> "Moderator*: Why do you think she'd not be happy that you'd bought sweets and chocolate?*
> Child*: Because it isn't healthy.*" (boy, 5 years old)

This knowledge of the parental viewpoint was not limited to food. The children also discussed their use of television and computers within their homes. One child understood why a rule existed, even though he did not agree with its wide-spread application. In this instance, he described why his parents would make him ask permission before using the television or computer:

> "Moderator*: Your house rules, ok and do you know why you have those house rules?*
> Child*: Um, to keep us safe when, if it's like a new computer game, I still have to ask even though there's no danger about going on it.*" (boy, 7 years old)

Although this child did not always agree with his parents' rule that he must ask permission for television and computer usage as he did not see how a new computer game would be dangerous, he did understand the reason behind the rule. In contrast, an older child was allowed to choose her own television programmes, without parental supervision, because she already knew what she would be allowed to watch. Therefore she was not only aware of the parental viewpoint, she understood the reason behind it and was willing to adopt it in the choices that she made.

> "*I like choose stuff that I know that I'm allowed to watch and it's like still appropriate.*" (girl, 12 years old)

However, some children who participated in the focus group study, while they recognised and understood the parental viewpoint, were not necessarily willing to adopt it, but instead only did so when encouraged or mandated by their parents:

> "Moderator*: And what if you were going out of the door and it's really windy and really cold and your mom says you've only got a long-sleeved t-shirt on?*
> Child*: She'll make me put my coat on.*
> Moderator*: And why would she be doing that?*
> Child*: Because she won't want me to get cold.*
> Moderator*: And what about you, would you rather not wear your coat?*
> Child*: No.*" (boy, 7 years old)

Beyond their awareness of the parental viewpoint, some of the child participants mentioned clear instances where they actively learned about decision-making through asking their parents for explanations regarding a decision that had been made or by calling on their own past experience with a specific situation.

> "Child*: I'd probably ask them, um, give me quite a lot of good reasons why you don't want me to do this and I'll decide whether they're like good things, like say I'm not steady on my feet but like say I know I am, I can run and jump and do stuff, so, like I just want to know why they would.*
> Moderator*: And if you thought that their reason why was a good reason, would you then be happy not to do it?*
> Child*: Yeah.*" (girl, 10 years old)

> "Moderator*: Excellent, ok, and would you wear a coat if you were going out of the door?*
> Child*: Yeah.*
> Moderator*: And why is that?*
> Child*: Because I catch cold really easily in the cold, so I just like don't want to be ill.*
> Moderator*: Ok, and is it that you don't want to be ill, or do you mind being cold?*
> Child*: Um, not really but then I don't really want to be ill so...*" (girl, 10 years old)

Through these examples the children demonstrated some of the ways in which they would learn about decision-making in the context of their daily family lives. If they did not initially agree with a decision reached by their parents, they would ask for an explanation to help them understand why that decision was made. This is not to say that the explanation would always change the child's mind, however. One child described what would happen in her household if her parents denied her the opportunity to do something in which she had an interest:

> "Child*: I'd start screaming and shouting and if they still said no I'd go off in a big strop and wouldn't come out of my room.*
> Moderator*: And if they explained to you why, does that make you better?*
> Child*: A bit but I wouldn't talk to them.*" (girl, 8 years old)

Nevertheless, the act of learning the art of reasoning from their parents and the ability to recall past events are clearly skills that these children learned in the context of their daily family life that will aid them in developing a more robust capacity for decision-making. This ability of children to learn from past experience is supported in the existing literature

on medical decision-making. Studies have suggested that a child's decision-making ability is improved through past decision-making experience[91]. The statements from the children in this focus group study illustrate that the act of learning from past experience with decision-making, either through their own decisions or through understanding those of their parents, is not unique to medical decision-making but also occurs in their daily family lives.

During childhood, while they are actively gaining decision-making skills, children are often aware that those skills are not yet fully formed and therefore they sometimes lack confidence in their decision-making abilities[119]. In fact, the majority of child participants in the focus group study articulated some doubt regarding their own capacity to make decisions. To compensate for this self-doubt, many of the children expressed interest in receiving help from their parents when making a decision. For example, when asked if they would prefer to make their own decisions, several participants said no because they did not always feel able to make decisions alone:

> "*Sometimes I can't make my decision myself*" (girl, 10 years old)
>
> "*Sometimes I really can't decide and stuff*" (girl, 8 years old)

Following on from this belief in their incapacity to decide, many children conveyed satisfaction with their parents making some decisions with them or on their behalf.

> "*Child: I know I get some things wrong and also, um, I'm not the best at making decisions, so I sometimes I don't know what to do so I'd like my parents to help me.*" (girl, 11 years old)
>
> "*Child: Because if you did some stuff it might not have been a wise decision where if you like ask your mum and dad they can have their input as well as your own and then like see what's better.*" (girl, 12 years old)

Through their discussion, it seemed as though the children trusted their parents to make good decisions, recognising their superior decision-making abilities, and therefore they were happy to receive help from them. In fact, some children explained that although they would know they were making the wrong decision, they were not always able to stop themselves from making it. In these cases they were happy that their parents were there to step in and guide them in the right direction.

> "*I'd probably want somebody to choose for me because um, I know that I don't make the right decisions for some things and even though I know that I'd be doing the wrong thing, I sometimes still do it. So, um, I just like, cause if there's nobody to stop me I would like go on with that, and if it's something really silly I want somebody to tell me don't do that*". (girl, 10 years old)

Of course, throughout childhood there are plenty of instances when children desire independence and consequently resent or fight against advice from their parents. However, based on the focus group discussions, it would seem as though these children were receptive at least some of the time to obtaining decision-making guidance from their parents. Existing literature on paediatric medical decision-making suggests similar findings. Past research studies have stated that children prefer making joint decisions with their parents rather than being left to make a decision themselves[108,163,177,178]. This is often due to a desire for support in the decision-making process[108,163,178], or even sometimes to counteract the child's own belief that he lacks the competencies required to formulate good decisions[108,165]. Nonetheless, regardless of the impetus for seeking it, it would seem that this willingness to accept assistance not only helps children to reach a decision on the specific example in question but has the long-term effect of teaching the children how to make a good decision, thus helping to develop their decision-making capacities for the future.

Beyond these instances of guided decision-making, many of the children participating in the focus group study seemed very aware of the fact that in their daily lives their parents held the ultimate decision-making power. They mentioned many instances when they were told by their parents what to do. For example, when asked why she had to go to school even if she did not want to, one child responded:

> "*Because my mummy tells me I have to*" (girl, 8 years old)

Other children gave examples of their parents dictating what food they would eat for meals. Two children from different families described what would happen at their houses if they were given a food for dinner that they did not like:

> "*Well, kind of my dad's motto is you don't have to like it you just have to eat it so I'd probably eat it.*" (girl, 11 years old)
>
> "*My mum always makes me eat it. If I don't eat all of it, I don't get anything after*." (boy, 7 years old)

Participants also gave examples of situations when their parents dictated what clothes they could wear or how they could spend their time.

> "Child*: I have good clothes and I have mucky everyday clothes.*
> Moderator*: And…who says those are your good clothes and these are your play clothes?*
> Child*: Well, my mum told me which ones are good and which ones are everyday muck around clothes.*" (girl, 6 years old)
>
> "Moderator*: Ok, and does anybody say you can't have that book or do you always get a choice?*
> Child*: Um, no I get to decide, but if I don't want a book but my mum wants me to have it I have to get it*." (girl, 8 years old)

In these situations, the children were aware of the fact that their parents had already made a decision and there was no opportunity for the child to negotiate that decision. Here, it is evident that the children recognised the ultimate decision-making authority held by their parents. In addition to instances where the children were told what to do by their parents,

some children also gave examples of times they were required to obtain permission from their parents prior to partaking in new activities or buying new items. Some children may have expressed a desire to their parents to participate in an activity, however they were aware of the necessity for their parents to agree to this before it would become a genuine possibility.

> "Moderator*: Who chose for you to do karate?*
> Child*: Um, well, me, I did.*
> Moderator*: And did you just say I'm going to do karate and go off to a karate lesson?*
> Child*: Um, no I just said Mum can I do karate and she asked my karate teacher.*
> Moderator*: Excellent, ok. Would you have been able to do karate without asking her?*
> Child*: No.*" (boy, 7 years old)
>
> "*I get to choose what clubs I do at school but I've got to ask my mum first whether she thinks it's alright*" (girl, 8 years old)

This parental acquiescence was necessary in other situations as well, beyond participation in extra-curricular activities. For example, one girl described the process by which she could buy a new book:

> "Child*: I'll ask my mum so if I want to buy this book of some sort, my mum will tell me if it's appropriate or not. She'll have to go to the shop with me and buy it.*
> Moderator*: And what do you mean by appropriate? What do you think that means?*
> Child*: Like, not feisty books, and just adventurous books and stuff like that really.*" (girl, 10 years old)

In these examples, it is clear that the children recognised the requirement for parental permission in the context of their respective families. However, that knowledge also prompted them to develop various methods that they would employ to influence or change their parents' minds about a decision, including nagging and begging.

> "Moderator*: Ok, if you decided you were going to, you really wanted to do something and mummy said absolutely no. What would you do?*

> Child*: I would scream and start saying please please please?*" (boy, 9 years old)

Several children described a lingering persistence when asking their parents for permission, confident in the knowledge that if they persevered, it was likely that they would be able to wear their parents down. In some cases their nagging would last the duration of a night. For example:

> "*Cause we share it like the computer and if it's one of my brother's turns I'll say oh just 5 more minutes please I didn't go on straight away so I haven't had my full time. And so yeah, eventually I'll turn it off but most of the time I'll just keep nagging and nagging til she gives in and lets me have another half an hour*." (girl, 11 years old)

In other cases, however, children stated that they would continue their tactics for long periods of time, such as weeks or perhaps even many months.

> "Child*: I would beg for weeks.*
> Moderator*: And if they still said no what would you do?*
> Child*: Still beg them for weeks*." (girl, 8 years old)

> "Moderator*: If somebody said no and you really want it what would you do?*
> Child*: Go and ask my dad.*
> Moderator*: Ok and what if he says no too?*
> Child*: Wait til they've forgotten about it and then ask them again.*
> Moderator*: And what if they say no?*
> Child*: Keep pestering them.*
> Moderator*: Ok, til you get what you want?*
> Child*: Yeah. But if it goes on for more than a year I'll give up."*
> *(boy, 10 years old)*

These scenarios illustrate that although these children were aware of their lack of ultimate decision-making power within their family, they had also learned ways in which they could impact or change their parents' decisions.

On the other hand, there are instances when no amount of begging, nagging, or pleading is successful in changing a parent's decision. While in general the children in this study

stated that they accepted, and sometimes even appreciated, the fact that their parents had decision-making authority in their family, this knowledge could also cause frustration for the children when they disagreed with the parental decision and were unable to change it. Therefore the children plainly admitted that their frustration would manifest itself in temper tantrums, yelling, and crying. One boy explained what would happen if he asked permission for something and was denied:

> "*I would go in a sulk and I would cry in my room*." (boy, 9 years old)

Another child, in response to a similar question, described not only his physical reactions in the temper tantrum but also how this lack of power would make him feel:

> "*I would just start screaming and run up to my room and if she came I would just keep my door shut and wedge it but if she gets it open she would come talk and explain it to me, but it never makes it better.*" (boy, 7 years old)

These examples illustrate that the children in these focus groups were well aware of their place within the hierarchy of their family context. This did not present a problem for them for the most part, however when confronted with a disagreement over a specific decision, they knew that they had no power to overrule the decision and therefore their only outlet was to express their frustration in the form of a temper tantrum. This type of reaction is also documented throughout the literature regarding childhood decision-making in the medical context, where children have reported feelings of anger or sadness when they felt powerless and excluded from the decision-making process[108,163,165-170].

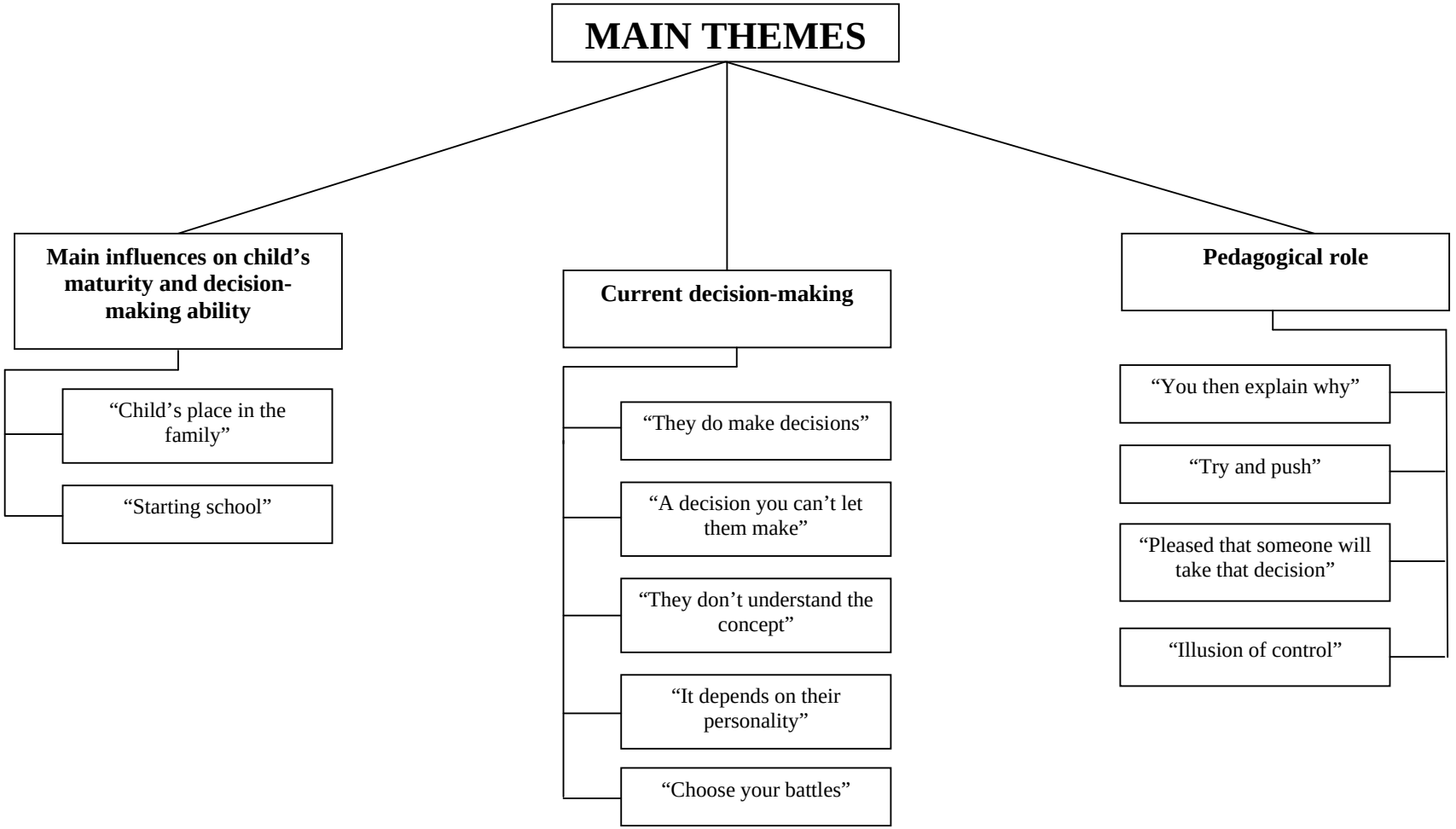
The child focus group discussions demonstrated that the assent process would be appropriate, at least for the child participants in this study. None of these children, regardless of their age, expressed a desire to make all decisions for themselves. While they

unsurprisingly did not necessarily always agree with their parents, they were happy to accept their help with many daily decisions. The children expressed satisfaction with their ability to make some choices for themselves, however much of the time those decisions were not made at random. Instead, many of the children allowed their decisions to be influenced either by what they believed their parents would have chosen or by their own past experience. As discussed in this section, these findings are supported by previous research within the context of medical decision-making. While the children in this study were asked about daily decision-making within the context of their families, the similarity in their responses when compared to past studies of medical decision-making lends credence to the idea that these phenomena can be applied to childhood decision-making in general, and not to one specific category of decisions. With the clear influence that a child's family has on the development of his decision-making skills, it would therefore seem reasonable that the family context should be a factor taken into consideration when the child's developmental capacity is assessed in the context of childhood assent.

3.2.4.2 Adult groups

In the parent and primary school educator focus groups, the main themes dealt with the various influences on a child's decision-making experience and ability. The adult participants discussed the principal external influences that affect a child's maturity and thus their decision-making capacity. They also shared opinions on parental involvement in a child's decision-making, covering their views on their child's current decision-making experience within their family dynamic as well as their own methods that they use as parents to guide their children's decisions. (See Figure 2 for a chart of all themes from the adult focus groups).

Figure 2 –Focus Group Study: Themes from Adult Focus Groups



Most of the adult participants agreed that the two main influences on a child's maturity and decision-making ability were siblings and the school environment. There was a general consensus that children were affected by the existence of siblings. Those children with older siblings were thought to be influenced positively in terms of their maturity, whereas those with only younger siblings might have been influenced in the opposite direction.

> "*I think they probably mature a bit quicker because they've got, they see you know what a 10 year old is doing. She will see what a 10 year old's doing and will be influenced by that, and almost pick things up quicker.*" (father of 2 children, aged 5 and 10 years)

> "*I think [my daughter]'s a bit young for her age partly because she's interacting with [my son] who's only 4 and they're playing a lot together and so, and when one of her school friends comes around who has an 11 year old brother, you know the whole sort of dynamic changes. I thought that was probably a birth order effect coming through quite strongly.*" (father of 2 children, aged 4 and 8 years)

Some of the adult participants also discussed how the lack of siblings might affect a child's maturity.

> "*Me and [my son] are on our own most of the time so he spends all his time apart from at school, with an adult so he comes across as quite mature, he might not be mature, but the things he says and some of the things he does seem quite mature but it's just learned behaviour from me.*" (mother of 1 child, aged 5 years)

> "*I wonder whether I do involve her more in decision making as she's an only child. Because I only have her to think about.*" (mother of 1 child, aged 10 years)

In these examples of single children, the parents believed that their children were actually more mature as their main interactions in the family context were with adults. Consequently they were more exposed to mature behaviour and autonomous decision-making than they might have been in a larger family environment. The possibility of siblings having an affect on a child's maturity and developmental capacity has also been discussed elsewhere, with potential explanations being credited to the influence of the

siblings themselves, or to a change in the amount of time and attention given to a particular child within the larger family[105,145,179-182].

Beyond the potential influence of siblings within the home, the adult participants cited school as a second key influence on a child's maturity and decision-making ability. The two main time periods that they discussed were the beginning of primary school and starting secondary school. Primary school was mentioned as the representation of a time when a child's perspective of the world would change. Prior to beginning school his family would be the main, if not only, influence on his world-view. Yet once the child would attend primary school, he would spend much of his waking life at school, where he would be influenced by teachers as well as other children[105].

> "*I think another time is when they start school, that's a massive, you know, it goes from you being almost the centre of their universe and then suddenly they're away from you and they're so impacted by other people's influences and that's you know that's a really big change I think.*" (mother of 2 children, aged 6 and 10 years)

In discussing the influence that primary school would have on a child's development, one educator made the observation that it is through school that a child would learn how to negotiate his new role as a member of society rather than merely a member of his immediate family, which is likely all he would have known up to that point.

> "*Year 1, I think because they're developing the strategies to work with other people, they're developing strategies of how to be part of the bigger wider community*" (primary school educator)

The participants also commented on the effect of secondary school on a child's development. One parent mentioned that it is at secondary school where a child would experience a greater amount of independence. While children in primary school might still

have been much more under the influence of parents or other adults, children in secondary school would usually experience more opportunities for autonomy in their daily lives. This autonomy could range from their transportation, their choice of friends, or how they would spend their time.

> "*I think secondary school makes a difference. There's a definite shift when they go to secondary school. So that you're not taking them, that communication they're more independent, they're more allowed to do their own thing or they make their own decisions or their own friends whereas you've quite controlled them at primary school I think.*" (mother of 4 children, aged 6-12 years)

In addition to the influence of siblings and school on a child's decision-making ability, participants also talked about their own interactions within their families, discussing how they shared decision-making with their children. All of the adult participants agreed that their children, or their students in the case of the primary school educator participants, made some decisions in their daily lives. However, the types of decisions that were made varied substantially based on the individual child, family, and decision in question. When asked about their children's decision-making, two parents in different groups shared similar responses, stating that their children definitely did make decisions in their daily lives:

> "*Lots of things, what they're going to have food for breakfast, what they're going to have for...what they're going to wear. Um, yeah all sorts of things. Yeah, I mean we sort of encourage it, generally*." (father of 2 children, aged 6 and 8 years)

> "*I think they do make decisions, from quite early on in what they like and what they don't like*." (mother of 4 children, aged 6 to 12 years)

Another parent explained why, in her opinion, it was important for children to be given the opportunity to develop their decision-making skills:

> "*Eventually they've got to make some decisions, haven't they. You're not always going to be there*." (mother of 2 children, aged 6 and 10 years)

Clearly in these families a child would be encouraged to participate in decision-making on a regular basis. But this would depend not only on the family dynamic but also the individual child's disposition as well as the specific situation. Parents with more than one child discussed the differences that they noticed in both decision-making interest and ability between their children. For example:

> "*I suppose my kids they're all very different characters and so, they make decisions about different things. Like they might be, one's quite, the second one's very particular about her friends and she's quite choosy about her friends; the eldest one's much more easy-going and more easily led. So I think they're just quite different in character themselves*." (mother of 4 children, aged 6 to 12 years)

Another mother explained that her son had a hard time making decisions, and in some situations she would feel forced to take the decision away from him.

> "Parent*: [My son] finds it very very hard to make a decision…cause he wants them both and it's really hard for him. He cannot make a decision.*
> Moderator*: So what do you do, do you end up making it for him?*
> Parent*: Yeah I have to. I do you know, after a while I try to be calm but sometimes you just can't...the clock's ticking and you've got to get to school...I have learned...just to say alright this is what you're having and that's it*." (mother of 2 children, aged 2 and 5 years)

So, although this parent would like her son to make some decisions, she was not always able to cultivate his burgeoning decision-making skills, as other factors, such as availability of time, were periodically more important. Through these examples it is evident that the opportunities for decision-making that these parents chose to provide to their children were determined largely by parenting style, although with some influence from other factors in specific situations. This trend has been seen in other studies as well, illustrating that the family context truly can have a significant effect on a child's prospect for developing decision-making capacity[165,183].

While for the most part the adult participants agreed that they encouraged their children to

make at least some decisions within the context of their family life, during the discussions it became clear that there were certain types of decisions that they were more comfortable with their children making. In general, they were happy for children to make decisions that they deemed less important and therefore not associated with potentially large consequences. The adult participants viewed these types of decisions as learning experiences for the children.

> "*It depends how important it is. Like sometimes they need to make the mistake and realise, or sometimes it's not, their idea was fine and you know it doesn't matter that it's not what you thought. If it's something important, then you can talk it through with them and help them to see, you know, the other side of whatever they're deciding about.*" (primary school educator)

Allowing children to make the less important decisions thus became a pedagogical tool for these parents to use in helping their children develop decision-making skills. However, with important scenarios, the parents definitely expressed a desire to be the final decision-making authority. As mentioned in the discussion of the child focus groups, this tendency for parents to allow their children to make "soft" decisions that are not associated with large consequences while retaining their own parental authority on more important decisions has been documented in other studies[108,170,175,176]. Decisions that were deemed "important" to participants in this study were related to the child's health and well-being, or more generally were just described as those decisions that carried larger consequences.

> "*I think the lesser decisions, the less important decisions, about maybe what he has for breakfast, is up to him…On the important decisions we would always, you know, make sure that the right decision was made.*" (father of 2 children, aged 5 and 10 years)

> "*If it's something like if it's going to be cold and she's going somewhere out I then step in and definitely take that choice away from her, because I said I'm dealing with you coughing during the night, so if I'm bearing the consequences I'm sorry but you're not allowed to have a decision*" (mother of 1 child, aged 10 years)

> "*So I allow her to make that level of decision, but there's not going to be any dreadful consequences from that. I would if it was something more serious I would take control*." (mother of 3 children, aged 7 to 11 years)

In fact, one of the parent participants viewed this parental decision-making authority as an essential part of parenthood. While it may be important to allow a child to make some decisions as a learning experience, for the important decisions she saw it as her duty as a parent to insist on what she believed to be the correct decision.

> "*And it's your job as a parent to make decisions about your children that you feel are important, that's part of being a parent... So, if you believe it's something really important, in the end it doesn't matter what they believe, they're going to have one way or another, if it's important enough to you you're going to enforce it aren't you.*" (mother of 1 child, aged 5 years)

While the participants in this study provided examples of times when they felt it necessary to exert their authority regarding a specific decision, they were also very aware of the fact that their children were not always receptive to this occurrence. In fact, every parent focus group mentioned the need to "choose your battles" when dealing with children. This phrase represented a strategy by parents to let children make some of their own decisions, even if the parents might have disagreed with those choices, in order to avoid fighting with the child about every decision in their life.

> "*I try not to fight over everything. So it's just, you do let things slide with it.*" (mother of 4 children, aged 6 to 12 years)

> "*You pick your fights don't you, or else you'll have confrontation about everything as they start getting older*." (mother of 4 children, aged 9 to 16)

By "choosing their battles", these parents were giving in to some of their children's wishes, in order to save up the time, energy, or parental authority that would be necessary to enforce the decisions that they, as parents, deemed important.

> "*Some things just aren't worth the battles.*" (mother of 5 children, aged 3 to 16 years)

> "*And in the end you do like you say, pick your battles, is it worth fighting every Friday. No.*" (mother of 2 children, aged 5 and 8 years)

Thus, based on the discussions it would seem that the participants in the adult focus groups encouraged their children to make decisions in their daily lives, but only so far as their health and safety would allow. When a decision would need to be made that might carry larger consequences, the participants were clearly ready to step in to ensure that the best decision for that child would be made.

Another major theme discussed in the adult focus groups pertained to the pedagogical role of parenthood. Participants discussed methods that they employed in their daily lives to teach their children how decisions were made and to actually guide their children in their own decision-making. First of all, participants stressed the importance of explaining decisions to their children.

> "*I think, yeah, I certainly think that children have the capacity to understand and reason through…so they like that, if you explain, if you've got the time to explain, that's the difficult bit.*" (father of 2 children, aged 5 and 10 years)

> "Parent 1*: I think you can explain lots of things to them.*
> Parent 2*: Yeah, I think if they've got the knowledge, at a level that they understand, then they're capable of making, not, you know, I'd trust that they'd make quite good decisions, as a very vague, general thing. I think it's about them having the knowledge, and then from that they would, you know, be able to make [decisions]*" (mother of 2 children, aged 5 and 8 years; mother of 2 children, aged 6 and 10 years)

Following on from providing their children with explanations of their own decisions, the adult participants stated their belief that when their children were asked to make decisions, they liked to be guided at least some of the time. While their children were learning about their developing autonomy, both within their family and in their external lives at school, the adult participants felt that they were not yet ready for and would not be interested in

taking on full decision-making responsibility in their lives. Instead, they felt that their children generally would welcome input or authority from their parents. As mentioned above in relation to the child focus groups, past research has illustrated that children do indeed desire assistance with at least some of the decisions that they encounter[108,163,177,178]. Here, two parents mention their beliefs regarding guided decision-making with their children:

> "*They're pleased that someone will take that decision if it's a clear one.*" (father of 2 children, aged 5 and 10 years)

> "*Most of the time they are relieved that somebody is quite firm with their decisions, and even if it's not a decision that they like, somehow the consistency is a little bit more important.*" (mother 1 child, aged 10 years)

Furthermore, while the parent participants admitted their willingness to enforce decisions that they viewed as "important", they also discussed some of the methods that they used to guide their children's decision-making. In this way, they were able to provide input to their children, moulding their decisions without needing to resort to a strict enforcement that may have caused arguments or rebellion. Similar to letting their children make some of the less important decisions, these methods of guiding their children's decision-making were pedagogical tools that were used within the family context on a regular basis to help refine their child's decision-making skills. These methods ranged from the extreme to more subtle techniques. The more extreme methods that were mentioned as examples of persuasive techniques were less learning experiences than ways in which the parents convinced their children to go along with their decision, such as emotional blackmail and coercion.

> "*Tried everything, emotional blackmail, bribery*" (mother of 2 children, aged 5 and 8 years)

> "*A little bit of emotional blackmail works quite well I've found as you move up to the older age group*" (mother of 4 children, aged 9 to 16)

> "*There's times when you really push them, really coerce*" (mother of 2 children, aged 5 and 8 years)

A few of the parents also mentioned sanctions as a method they used to convince their children to go along with a decision, or to punish them for a conflicting decision.

> "*Well if it's a conflict then it's down to you know what's your punishment, putting them in their room or taking a toy away or that sort of thing.*" (father of 2 children, aged 6 and 8 years)

> "*As a parent you fill your life with possible scenarios to try to motivate your child to make the right choices, by either making it interesting for them to go the route that you think is going to be more positive for them, or somehow you know resorting to you know strictness and somehow you know withdrawing of you know, rewards or consequences sometimes*" (mother of 1 child, aged 10 years)

Some of the more democratic methods of persuasion techniques that were mentioned by the adult participants were discussion and compromise. These methods clearly acted as ways in which an adult could guide the child's decision-making while simultaneously teaching him how that decision was made.

> "*They need reasons. You can't just say don't do that. You need to explain why and the full context*" (primary school educator)

> "*If it's a decision that you think, that in their best interests isn't, um, what they should be doing, you use all of your persuasive techniques that you possibly have to try and give them the right view, or the view that would be best for them.*" (primary school educator)

While discussing the need to compromise in some of their family dynamics, parent participants mentioned a key aspect of their daily interactions with their children: "the illusion of control". Similar to discussion and compromise, the illusion of control was a way in which a parent could give his child a choice, allowing him to make a decision, but within a range that had been pre-selected by the parent. This method was mentioned in every parent focus group and participants explained that it could be used in many aspects of their daily lives, from food to extra-curricular activities.

> "*Compromise. Concede a little bit on the, on what you were trying to achieve to give that illusion of control back again.*" (mother of 4 children, aged 9 to 16)

> "*To restrict them by choosing for them what you are selecting for them to choose from… Selecting a range of choices that I'll find good and then gently I introduce that…without saying how many things she might do but I am not offering her*" (mother of 1 child, aged 10 years)

> "*Cereals in the morning, that's fine, choose your own, because I've made the decision about which ones to buy*" (mother of 3 children, aged 5 to 10 years)

The benefits of this technique were threefold: the child would think he was making a decision and therefore was content in his newfound independence; the child was exercising his decision-making abilities and therefore learning how to become a better decision-maker; and thirdly the parent was satisfied that the child would be safe and not suffer any large consequences, regardless of his decision, as all of the choices had already met with the parent's approval. The parent participants were aware that this method may seem to be slightly manipulative but they were not bothered by this fact. Some parents even viewed the utilisation of the "illusion of control" as a key aspect of parenting.

> "*If you're a shrewd parent you can create a situation where a child feels that they're making a decision.*" (mother of 3 children, aged 7 to 11 years)

> "*The art is making them think they've made the choice*." (mother of 1 child, aged 10 years)

Thus, these parents were illustrating their desire to provide their children with opportunities to make decisions in their daily lives, while at the same time retaining some measure of control over the final decision that was reached.

Similar to the child focus group discussions, the focus groups conducted with parents and primary school educators seem to support the use of the assent process when enrolling a

child in medical research. The adults in this study all thought that children were capable of making some decisions in their daily lives. They also expressed their desire to help guide children in their decision-making, helping them to learn how to make their own good decisions. Due to the fact that they felt like this in general, within the context of their own family's daily life, it is reasonable to assume that they would have a similar desire to include their children in the decision-making process within the context of enrolment in a medical research study. Given that each family's approach to childhood decision-making was different, and that the participants in this study agreed that a child's decision-making capacity was dependent upon his individual personality, it would also seem reasonable that some assessment of the child and his individual family context should occur when deciding how to involve a child in the decision-making process for medical research.

3.2.4.3 Comparison between child and adult focus group analysis

Although the child and adult participants discussed childhood decision-making from very different perspectives, there were quite a few similarities in the topics that were covered. The adults and children both stated that children did, in fact, make some decisions within the context of their daily lives. They also both discussed that the children liked to be guided by their parents in their decision-making. In fact, many of the children admitted that they had no interest in making all decisions for themselves, preferring to rely on their parents for help with some decisions, while depending on them completely to make other decisions. Parents mentioned that they would often limit a child's choices, giving the child the "illusion of control" as he would be allowed to make a decision between those specific pre-selected options. When this was discussed in the adult focus groups, it seemed as though the parents thought that this was done without the child's knowledge. However, in the child focus groups, children mentioned that they would often make "sort of choices",

where they would decide between several set options allowed by their parents. Granted, this does not mean that these children were aware of every time their parents gave them the “illusion of control”, but it does illustrate that they were cognizant of the existence of this phenomenon and were not necessarily unhappy about it. Secondly, both adults and children mentioned that children desire some guidance from their parents when making decisions. They were also both well aware of the fact that parents held the ultimate decision-making power within the family context. They discussed that this imbalance of power was sometimes cause for disagreements between children and their parents. Children talked about their tactics for trying to change their parents’ decisions in their favour, and admitted their frustration when unsuccessful in that endeavour. On the other hand, adult participants agreed that it was necessary for them to sometimes “choose their battles” to avoid potentially constant fights with their children over every decision. Therefore these parents were likely to give in to their children’s wishes on what they considered to be the less important subjects, while saving the true battles for the most important decisions. Finally, both child and adult focus groups discussed how children would learn about decision-making through the example of their family members, such as siblings and parents. It would seem therefore, from the participants in this study, that all stakeholders in this family dynamic share the belief that a child’s development of his decision-making capacity is directly affected by his family context. Once again this supports the idea of considering the family context in any assessment of a child’s ability to participate in the decision-making process for medical research.

3.3 Conclusion

The assent process is a way in which a child can be involved in the decision-making process for medical treatment or research. Given that the primary ethical justification for

the concept of assent is derived from a parent's pedagogical obligation to teach his child how to become an autonomous being, and that a child's family context directly affects his development of decision-making skills that are essential for him to become autonomous, it is reasonable to surmise that the family context should be examined in more detail before any attempt is made to improve the assent process. This focus group study was designed, therefore, to learn more about children's daily decision-making within the context of their families. Three different groups of participants were included in this study in order to explore different perspectives on the decision-making power and ability of children between the ages of 5 and 12 years old. Upon analysis of the study data, however, it became evident that, while the participants did have different perspectives on the subject, their views were actually complementary and in harmony with each other. The main themes that emerged during analysis illustrate areas that should be explored in more detail in order to better understand the family context and its affect on a child's decision-making ability. For example, it is interesting that the children expressed a desire, not for decision-making autonomy, but for decision-making guidance from their parents. Similarly, while the adults were aware of the children's ability to make some decisions, they also liked to guide them in decision-making, often providing the children with limited options from which to choose.

As stated above, only one focus group was held with primary school educators as it was determined that this group had not added new information beyond what had already been learned in the parent focus groups. It is possible, however, that there were deficiencies in the questioning route developed for the primary school educators and that is why new information was not gained from the conduct of this focus group. To guard against this

possibility in future studies, it would be useful to discuss the study objectives with one or more primary school educators prior to designing the questioning route for this group. This would likely lead to the development of a much more useful questioning route that would be relevant to the experience of primary school educators regarding daily child decision-making. It also might have been interesting to collect more demographic information from participants, especially the age of parents and primary school educators. Finally, it was not a requirement for this study that there be a connection between child and parent participants. Had there been a link them, it might have been possible to conduct an analysis of individual family dynamics within these family groups. However, the fact that this was not possible in this study does not subtract from the usefulness of the data analysis within each peer group.

While the results from this qualitative study are interesting, it would be improper to draw any generalised conclusions regarding child decision-making within their families due to the study's small sample size. It is possible that any trends that have been identified in the data are purely representative of the participants who chose to take part in this study. Therefore, these qualitative results were used to develop questionnaires for a larger quantitative study that can give more insight into the family context. Exploring these ideas in a quantitative questionnaire study will allow us to reach constructive conclusions regarding the family context of childhood decision-making. The following chapter will discuss the results from a questionnaire study that was developed as a continuation of this focus group research.

Chapter 4 – The Family Context: Parent and Child Questionnaires

4.1 Introduction

The previous chapter presented data from a focus group study with children aged 5-12 years, parents of children aged 5-12 years, and primary school educators. That study allowed for the identification of important themes or issues related to childhood decision-making that warrant further in-depth research before that information can be applied to the assent process in medical research. During the child focus groups, the major recurring themes dealt with the children's perceptions of their own capacity for making decisions, as well as their decision-making power within their families. Based on their discussion, it became clear that the child participants learned about decision-making through becoming aware of their parents' perspective on a particular issue, as well as learning how their parents came to make these decisions. During the parent and educator focus groups, the participants discussed what could influence a child's decision-making ability, from attending school to the family dynamic. In addition, adult participants elaborated on methods that they currently used to guide their children's decisions, thus actively honing their children's decision-making skills.

The results from the focus group study seem to support that a child's family context has a serious influence on his decision-making ability and experience. The study results also give weight to the concept of a parent's pedagogical role in developing a child's decision-making skills as both children and adults provided data related to this idea. The main themes that developed from this study may well be indicative of many children and their families, however due to the small sample size from this qualitative study they may also only represent the specific family dynamics from the study participants. In order to learn

more about the family context and its effect on a child's decision-making ability, it was necessary to examine some of these issues in more detail in a larger, quantitative study. Furthermore, while research on childhood decision-making has been conducted, very few studies have been conducted that specifically asked children about their desire to make decisions in relation to their lives[108]. Therefore, a study was designed consisting of complementary questionnaires that were delivered to parents and children aged 5-11 years. It is important to note that one of the findings from the adult focus groups was that starting school, both primary and secondary, was considered to have a big influence on a child's maturity. However, similar to the focus group study, the age group for this questionnaire study included only those children who were of primary school age. This decision was made in order to aid in the recruitment process as well as to maintain consistency with the previous study. These questionnaires explored daily decision-making within the family context, drawing on the themes that emerged from the focus group discussions, including questions specifically geared towards learning whether children want to be involved in the decision-making process.

4.2 Questionnaire Study

4.2.1 Study Objectives

This questionnaire study had two objectives. The primary objective was to explore daily child decisions within the family context, from two perspectives, both child and parent. The secondary objective was to explore potential trends in how individual parent/child pairs perceive decision-making power in their daily family context. This study was focused on children of primary school age only, therefore the age range for child participants was five to eleven years old, rather than five to twelve years old in the focus group study. The adult participants in the focus group study stated that starting secondary

school was a big influence on a child's maturity and independence. If this were true for child participants in this questionnaire study, the results could have been skewed accordingly. Thus, in order to avoid a potential bias, the age range was modified for this study in order to include only primary school aged children.

4.2.2 Methods

4.2.2.1 Study Design

This research study was a questionnaire study. Adult study participants were asked to complete a paper questionnaire which they returned to the study team either in person or via the post in a prepaid envelope. It was estimated that the time required to complete this questionnaire would be approximately 20 minutes. Child study participants answered the questionnaire in an individual or small group session with a member of the study team lasting approximately 40 minutes. Child participants were given specific questionnaires designed for their age range, and small group sessions were conducted with children of a similar age so that the session could be modified to suit the age and development of the specific child participants. These child questionnaire sessions were held in locations such as University meeting rooms and offices, local schools, community centres, and participant family homes. While the child questionnaire was fairly long (73 questions), most of the questions were quite short and uncomplicated, and many of them were follow-on questions related to previous questions so when one question was not relevant to a particular child he was able to skip the next few related questions. Therefore, while some small group sessions with younger children may have lasted slightly longer than 40 minutes, most of the older children were able to complete their questionnaires quite quickly in as little as 30 minutes.

Study participation for adult and child participants was the length of time necessary for the completion of the questionnaire. As parent and child participants were members of family groups, parents were asked not to discuss their questionnaire responses with their children and the child's interview was conducted away from his parents. This was in order to ensure that each participant's responses were not influenced by responses of their family members and that the presence of an adult authority figure would not affect the child's responses.

Adult participants did not receive compensation for their participation as the completion of the questionnaire was not anticipated to be a time-consuming process. Child participants in the study received a certificate and stickers to thank them for their time spent during the investigator-led questionnaire session.

4.2.2.2 Ethical Approval

Ethical approval for this study was granted by the University of Oxford Social Sciences and Humanities Inter-divisional Research Ethics Committee.

4.2.2.3 Sample size

Approximately 200 participants were expected in this study, in order to recruit at least 100 participants in each of the two peer groups: parents and children aged five to eleven years. While only one parent from a family group was allowed to be enrolled in the study, more than one child from the same family group could participate. Therefore, the projected

study enrolment was 100 family groups which would include 100 parent participants, and at least 100 child participants.

This sample size was chosen so that for each question within a peer group the 95% Confidence Interval around the percent agreement per response would be a maximum + or - 10%. For example, if 80% of respondents within a peer group gave the same answer to a particular question, the 95% Confidence Interval would be + or – 8%, or between 72-88%[3].

4.2.2.4 Recruitment

Recruitment for the study was achieved through posters and flyers advertising the study, in-person recruitment at local community activities and primary schools in Oxfordshire, and direct mail-out to parents at local primary schools, staff members at the University of Oxford, and families participating in Oxford Vaccine Group studies. Information about the study was presented to the Head Teacher at 44 local primary schools. Of those schools, five agreed to distribute information about the study to the parents of their students. Although this was not a large response rate, this recruitment method was still likely to be the most efficient, given the resources available to conduct this study.

Participants were recruited within two distinct categories: children aged between 5-11 years old, and parents of children aged between 5-11 years old. One parent and at least one

[3] Calculation based on the Normal approximation to the binomial distribution.

child were recruited from each participating family. Child participants were healthy children between 5 and 11 years old, who were willing to participate, and for whom a parent gave written informed consent. Parent participants were healthy adults between 18-80 years old, who had custody of a child between 5-11 years old, and who gave written informed consent.

Written consent was given by each adult participant prior to receiving an adult questionnaire. Parental consent was given prior to each child questionnaire session, with the verbal assent of each child participant verified by a member of the study staff and documented on the consent form. (A version of the consent form for child participants is included in Appendix 5). All consent forms were signed and dated by the adult participant or the parent of a child participant and then were counter-signed and collected by a member of the study staff.

4.2.2.5 Development of the questionnaires

The questionnaires were developed in several steps. A literature review was conducted, covering the subject of paediatric assent, child rights, child development, and the creation and implementation of questionnaire studies. Secondly, draft questionnaires were developed for parent and child participants. The draft questionnaires were then reviewed by the supervisory committee, as well as paediatric doctors and nurses, prompting additional revision based on their comments. Finally, the draft questionnaires were used in a pilot test with adults and children in order to ensure that the questions were clear and that the child questions were appropriate for the age range of the intended participants, with final modifications made based on these pilot tests. Questionnaire questions were

created to cover several main categories of daily family life: demographic information, health, family life and interaction, activities, meals and food, clothes, and current decision-making. (Examples of the questionnaires are included in Appendices 6-7)

Upon enrolment in the study, adult participants were provided with a paper copy of the parent questionnaire which they were allowed to complete in person or return via post in a pre-paid envelope. Child participants completed the questionnaire in individual or small group sessions with a member of the study staff. The children were offered assistance from study staff members where appropriate. All paper questionnaires, for both adult and child participants, were entered into the computer program SPSS for analysis.

4.2.2.6 Planned analysis

4.2.2.6.1 Primary Analysis

The primary data analysis examined total pooled child responses and total pooled parent responses to all of their respective questionnaire items. Analysis focused on the individual questions within each peer group, and attempted to identify any noteworthy trends. Analysis was also conducted on the overall topic categories of daily family life: demographic information, health, family life and interaction, activities, meals and food, clothes, and current decision-making.

4.2.2.6.2 Secondary Analysis

An exploratory analysis was conducted to compare individual parent-child pairs wherever possible. This analysis examined the correlation between the responses of parent-child pairs in order to observe what proportion of time the parent and child agreed on each

related question. The purpose of this secondary analysis was to identify any trends which may lead to larger follow-on studies in the future. If the analysis seemed to demonstrate a large gap between the way children and their parents perceived a given situation, this could be worth further investigation.

4.2.3 Results and Analysis

4.2.3.1 Data entry

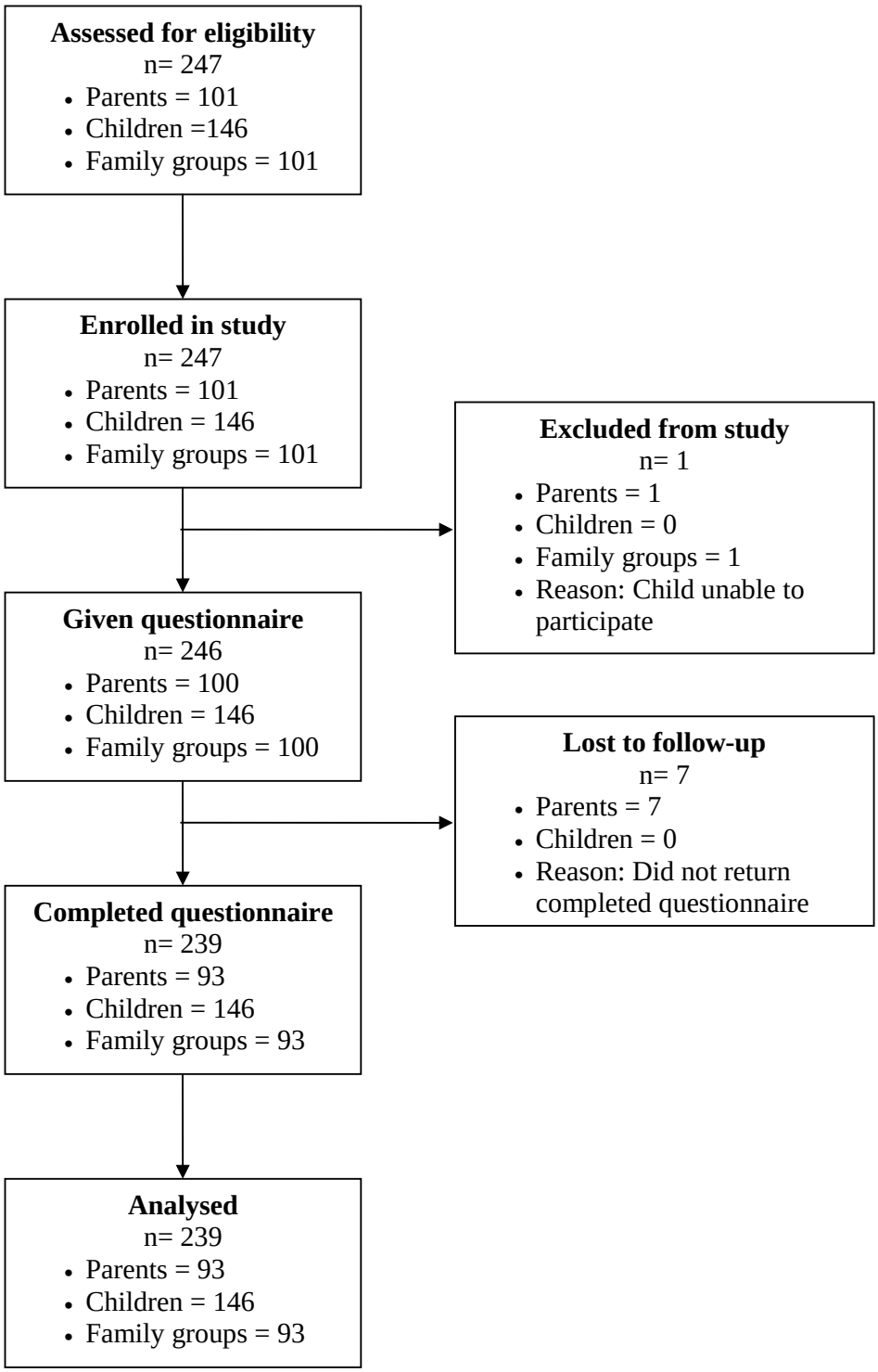
All questionnaires were completed by study participants on a paper version of the questionnaire. All data entry of the questionnaire responses and subsequent analysis was conducted by the same person. During data entry, a list of self-evident corrections for both the parent and child questionnaires was compiled. These documents tracked the coding of questionnaire responses when there was an exception to the expected responses. Some participants answered questions through a write-in response rather than or in addition to one of the provided responses on the questionnaire. For example, children were asked “Do you have family days out” and were given two possible responses: “yes” and “no”. A child wrote in the answer “sometimes” rather than checking one of the provided responses. As the question was aimed to find out if the child did or did not have family days out, and not to determine the frequency of these occasions, the written answer of “sometimes” was coded as a “yes” answer for analysis. For other questions where the possible answers were “yes” and “no”, some children would check both responses. Where this occurred, the answer was assumed to be missing and not included in analysis. The complete list of self-evident corrections for the child and parent questionnaires can be found in Appendices 8-9.

Once all questionnaires were entered into SPSS, frequencies for each question were run to identify any outliers or errors due to data entry. Furthermore, a random sample of questionnaires and the corresponding data as entered were monitored by the Quality Assurance Manager at the Oxford Vaccine Group. The data entry was found to be correct, following the self-evident corrections listed above, and therefore any potential for data entry errors has likely been kept to a minimum.

4.2.3.2 Participants

There were 247 participants who were officially enrolled in the study. Of those 247 participants, 101 were parents, and 146 were children. One parent participant was excluded after enrolment as his child was unable to attend a questionnaire session and therefore he would have represented an incomplete family group. Of the 100 parent participants who were enrolled in the study and were not excluded, 7 did not return a completed questionnaire. Per the protocol, these participants were contacted three times, by phone and email, in an attempt to obtain their questionnaire data. When no reply was received after three attempts, these participants were considered lost to follow up. 146 child participants were enrolled in the study, and all of them completed a questionnaire. Ten of these children belonged to the 7 family groups for which parent data was unavailable. A sensitivity analysis was run, eliminating the 10 children for whom no parent data was available, and the main results and conclusions were not altered. Therefore the decision was made to include these 10 children in the pooled child data analysis. An enrolment diagram for this study can be seen in Figure 3.

Figure 3 – Questionnaire Study: Enrolment Diagram



Of the 100 enrolled parent participants, 92 were female. The 7 parent participants who did not return their questionnaires were female. Thus, of those parents who were enrolled in the study and returned a completed questionnaire, 85 were female (91%) and 8 were male (9%). The 146 child participants were evenly distributed between male and female: 72 child participants were male (49.3%) and 74 were female (50.7%). Data on participant age were collected from child participants but not parent participants. Child participant ages ranged from 5 to 11 years old. The mean age of all child participants was 7.82 years old and the ages were approximately normally distributed (see Figure 4 and Table 2).

Figure 4 – Questionnaire Study: Normal distribution of child ages

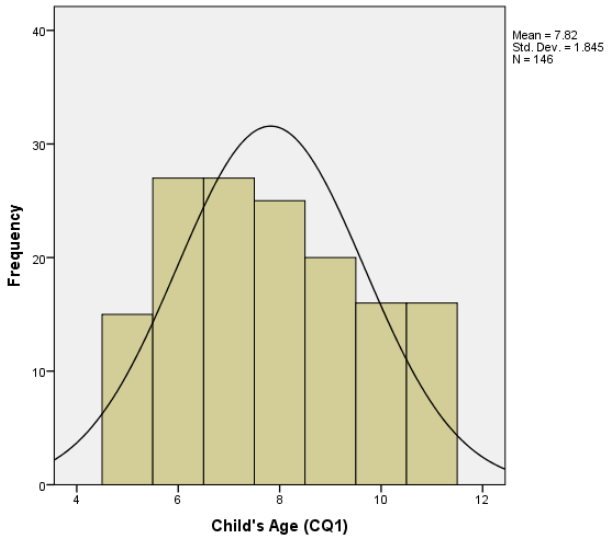


Table 2 – Questionnaire Study: Child participant age distribution

Child's Age	Freq. (%)
5	15 (10.3)
6	27 (18.5)
7	27 (18.5)
8	25 (17.1)
9	20 (13.7)
10	16 (11.0)
11	16 (11.0)
TOTAL	146 (100)

4.2.3.3 Primary analysis: Child Questionnaires

As described above, questionnaire questions were created to cover several main categories of daily family life, such as demographic information, health, family life and interaction, activities, meals and food, clothes, and current decision-making. Several types of questions within each category were asked in order to discover the overall picture of how decisions are currently made within the family. The children were first asked who would make the decision within their family for that specific question. The answers to these questions illustrated each child's perception of the current decision-making dynamic within his household. Then the children were asked if they would have to obey that decision. These questions demonstrated whether these children felt as though they still had a say in the enforcement of the decision. Finally, for each set of questions, the children were asked whether they would like to choose for themselves in that specific scenario, indicating whether these children had a preference for having decision-making power for that topic.

The analysis of the pooled child questionnaire data took place in three parts. First, frequencies and descriptive statistics were run on all individual questions. As data on child age was available, the mean age for each answer was also calculated in order to determine if there were any trends related to participant age. Secondly, questions were grouped together based on the type of question that was asked: for example, all questions that asked a child if he would like to be able to choose for that specific topic. Answers to all of these grouped questions were compared in order to examine the similarities and differences between them. Thirdly, questions were separated into the categories of daily family life such as demographic information, health, family life and interaction, activities,

meals and food, clothes, and current decision-making. Analysis was then performed to examine any trends that occurred between these categories.

The majority of child participants (n=121, 82.9%) in this study lived in a household with two parents, while 3 additional participants (2%) lived in a household with 2 adults but one of those adults being a step-parent. Twenty-two participants (15.1%) lived in single parent households (see Table 3). This proportion is lower than the UK average. According to the UK Office for National Statistics, in 2011 approximately 25% of families with dependent children were lone parents living with their dependent children[184]. Almost all child participants also lived in households with siblings. Only 11 participants (7.5%) were solitary children in their household, while the remaining 135 children (92.5%) lived with between 1 and 7 siblings (see Table 4). Therefore, the majority of child participants in this study lived in households with 2 parents and at least one sibling (n=116, 79.4%) (see Table 5).

Table 3 – Questionnaire Study: Number of parents in household of child participants

Number of parents with whom child participants live	**Total child participants n (%) [mean age[4]]**
1 parent	22 (15.1) [8.50]
2 parents	121 (82.9) [7.68]
1 parent + step-parent	3 (2.0) [8.67]
TOTAL	**146 (100) [7.82]**

[4] Mean age (years) of respondents in each category

Table 4 – Questionnaire Study: Number of siblings in household of child participants

Number of siblings with whom child participants live	**Total n (%) [mean age[5]]**
No siblings	11 (7.5) [8.82]
1 sibling	76 (52.1) [7.57]
2 siblings	49 (33.6) [7.92]
3 siblings	6 (4.1) [7.67]
4 siblings	2 (1.4) [10.00]
7 siblings	2 (1.4) [8.00]
TOTAL	**146 (100) [7.82]**

[5] Mean age (years) of respondents in each category

Table 5 – Questionnaire Study: Parent and sibling distribution in household of child participants

Parent and sibling distribution in child participant's household	**Total child participants n (%) [mean age[6]]**
1 parent, no siblings	6 (4.1) [9.00]
2 parents, no siblings	5 (3.4) [8.60]
1 parent + siblings	16 (11.0) [8.31]
1 parent + step-parent + siblings	3 (2.1) [8.67]
2 parents + siblings	116 (79.4) [7.14]
TOTAL	**146 (100) [7.82]**

[6] Mean age (years) of respondents in each category

In each subject area included in the questionnaire, children were asked the question "Would you like to choose..." to find out whether these children in general cared about having a choice for that topic. So, when asked about their usage of the television and who would decide what they watch, the children were then asked "would you like to choose what you watch on television". The idea behind these questions was to determine if there were specific subject areas where the child might have had more or less interest in making a decision himself, or if an individual child was likely to want more or less autonomy applied uniformly over all areas of his current daily life. The data from this range of questions show that these children did overwhelmingly want choice, across almost all topics, or sectors, of their life which were covered by this survey. This ranged from choice over what they ate for meals, their clothes, and how they spent their time. Of the 20 questions of this type that were asked, over 75% of children responded that they wanted to choose for themselves for 14 of them. In fact, 4 of the remaining 6 questions still had over 60% yes responses. There were only two questions where the tendency toward choice was equivocal, where the split between "yes" and "no" was approximately 50%: "Would you like to choose if you see the doctor" (54.9% responded yes) and "Would you like to choose for yourself if you clean your teeth" (48.3% responded yes). (See Table 6) While many studies have not specifically asked children if they would like to make a decision themselves, past research has indicated that children do have an interest in participating in decision-making about matters that affect them. The results from this range of questions in this questionnaire study appear to support this[108].

Table 6 – Questionnaire Study: How children answered questions regarding wanting a choice in aspects of their lives, ranked from the lowest to highest proportion answering affirmatively

Topics about which children were asked if they would like to have a choice	Yes n (%) [mean age[7]]	No n (%) [mean age[7]]	TOTAL n (%) [mean age[7]]
If you clean your teeth	70 (48.3) [7.44]	75 (51.7) [8.16]	145 (100) [7.81]
If you see the doctor	78 (54.9) [7.78]	64 (45.1) [7.80]	142 (100) {7.79]
To do something you're unsure about with a friend	88 (62.0) [8.22]	54 (38.0) [7.30]	142 (100) [7.87]
Bedtime on a school night	93 (65.0) [7.88]	50 (35.0) [7.74]	143 (100) [7.83]
To go to church/temple/mosque	97 (69.8) [7.96]	42 (30.2) [7.52]	139 (100) [7.83]
Breakfast from the shop	108 (74.0) [7.94]	38 (26.0) [7.50]	146 (100) [7.82]
To go food shopping[8]	110 (75.9) [7.99]	35 (24.1) [7.26]	145 (100) [7.81]
If you go on family days out[8]	109 (76.2) [7.82]	34 (23.8) [7.97]	143 (100) [7.85]
To do something fun with a friend[8]	110 (78.6) [8.09]	30 (21.4) [7.03]	140 (100) [7.86]
What you eat for dinner/tea[8]	115 (79.3) [7.78]	30 (20.7) [7.90]	145 (100) [7.81]
What you buy for snacks[8]	119 (83.8) [7.90]	23 (16.2) [7.48]	142 (100) [7.83]
If you help with household jobs (all participants) [8]	122 (87.1) [7.90]	18 (12.9) [7.50]	140 (100) [7.85]
What clothes to buy[8]	126 (88.1) [7.87]	17 (11.9) [7.35]	143 (100) [7.80]
If you go to a birthday party[8]	126 (88.7) [7.86]	16 (11.3) [7.50]	142 (100) [7.82]

[7] Mean age (years) of respondents in each category
[8] Over 75% of children responded that they wanted to chosse for themselves.

If you play games with your family (all participants) [8]	128 (88.9) [7.82]	16 (11.1) [7.75]	144 (100) [7.81]
Bedtime on weekend/holiday[8]	129 (89.6) [7.89]	15 (10.4) [7.47]	144 (100) [7.85]
To take part in activities/clubs (all participants) [8]	124 (90.5) [7.99]	13 (9.5) [6.69]	137 (100) [7.87]
What you play on the computer[8]	135 (93.7) [7.87]	9 (6.3) [6.89]	144 (100) [7.81]
What you buy with your pocket money[8]	97 (94.2) [7.89]	6 (5.8) [7.00]	103 (100) [7.83]
What you watch on television[8]	139 (95.2) [7.86]	7 (4.8) [7.14]	146 (100) [7.82]

When analysing this range of questions separated into the categories of daily family life, two interesting trends became apparent. Firstly, both questions pertaining to health were those for which fewer children expressed interest in making the choice for themselves. Secondly, there were three questions for which a small difference in mean age was observed. Children who responded that they were interested in making their own choice for participation in extracurricular activities, participating in fun activities with a friend, and participating in risky activities with a friend were slightly older than those who responded negatively. For the questions regarding participation in extracurricular activities, fun activities and risky activities the mean age of positive responders was 1 year greater than the mean age for negative responders, and the difference was found to be significant ($p<0.05$). All three of these questions were part of the activities category of the daily family life section. Clearly, based on the responses to this questionnaire, the children participating in this study were interested in having a choice about matters in their daily lives, and for the most part this interest was irrespective of the child's age. However the answers would also imply that there were some areas of their lives where the children were happier to relinquish decision-making authority, such as with health-related decisions, and that as the children grew older they may have exhibited greater interest in personally managing the way in which they spent their time. (See Table 7) This finding is in line with past research studies that have indicated that children will make a conscious choice to decrease their own involvement in the decision-making process in certain circumstances[185]. Nevertheless, it is important to note that the "health" category was based of responses to only two questions: "Would you like to choose if you see the doctor" and "Would you like to choose if you clean your teeth". In the case where a child is ill and his parents suggest visiting a doctor, the likelihood that the child will dissent is small. In retrospect, it would have been useful to include additional questions in this category in

order to ascertain whether the children were truly less interested in making health-related decisions. Possible questions could include the topics of visiting the dentist, eating healthily, and participating in regular exercise.

Table 7 – Questionnaire Study: Would Children like a choice (Mean % Response by Category of Daily Family Life)

Category of Daily Family Life	Mean % Response Yes	Mean % Response No
Health[9]	51.6%	48.4%
Family Life[10]	81.5%	18.5%
Activities[11]	84.8%	15.2%
Meals[12]	78.2%	21.8%
Clothes[13]	88.1%	11.9%

[9] Questions included in the Health category were "Would you like to choose...": "...if you see the doctor" and "...if you clean your teeth".
[10] Questions included in the Family Life category were "Would you like to choose...": "...your bedtime on a school night", "...your bedtime on a weekend/holiday", "...if you go to church/temple/mosque", "...if you go on family days out", "...if you play games with your family", "...what you buy with your pocket money", and "...if you help with household jobs".
[11] Questions included in the Activities category were "Would you like to choose": "...if you go to a birthday party", "...what you watch on television", "...what you play on the computer", "...to take part in activities/clubs", "...to do something fun", and "...to do something you're unsure about".
[12] Questions included in the Meals category were "Would you like to choose": "...to go food shopping", "...your breakfast from the shop", "...what you eat for dinner/tea", and "...what you buy for snacks".
[13] Questions included in the Clothes category were: "Would you like to choose what clothes to buy".

Child participants were also asked who in their current family dynamic would make the decision for each subject area. The children were able to choose all applicable answers from the following possibilities: “parent/guardian”, “brother/sister”, “me”, and “other”. For 6 of the 12 questions, covering the topics of doctor visits, bedtime, dinner, and household jobs, over half of the children stated that their parent alone would make the decision, with over 80% of the children stating this for the 3 questions related to doctor visits and bedtime. For the remaining 6 questions, regarding activities and clothing, over half of the children believed that they had at least some say in the decision, choosing the answer “me” or “me” plus some combination of the remaining possibilities. Furthermore, among those questions where children stated that they participated in the decision, there were only four topics for which a significant proportion of children stated that they alone made the decision: the choice of television programmes (48.3%), family games (50.8%), extracurricular activities (53.7%), and computer usage (71.9%). While children were allowed to choose any combination of answers to this question, the vast majority of their answers included “parent/guardian” as at least one of their choices. Only for the 4 questions described above was the “parent/guardian” option not selected as at least one of their responses by over 70% of children. In addition, very few children chose “brother/sister” as a response for most questions. There were only two questions where “brother/sister” was chosen in some combination with other responses by more than 10% of children: the choice of television programme (24.2%), and the choice of family games (29.6%). (See Table 8)

Table 8 – Questionnaire Study: How children answered questions regarding who in the family makes the decision about aspects of their lives, ranked from the highest to lowest proportion answering "parent"

Topics about which children were asked who in the family makes the decision	Parent alone n (%) [mean age[14]]	Parent + Sibling/ Other n (%) [mean age[13]]	Other / Sibling n (%) [mean age[13]]	Parent+Child (+Sibling / Other) n (%) [mean age[13]]	Child alone n (%) [mean age[13]]	Child + Sibling n (%) [mean age[13]]	TOTAL n (%) [mean age[13]]
Who chooses to take you to doctor when you are sick[15]	132 (90.4) [7.85]	6 (4.1) [7.00]	1 (.7) [5.00]	4 (2.7) [8.50]	3 (2.1) [8.33]	0	146 (100) [7.82]
Who tells you when you need injection[15]	115 (84.6) [7.90]	7 (5.1) [8.57]	10 (7.4) [7.70]	3 (2.2) [7.00]	1 (0.7) [6.00]	0	136 (100) [7.88]
Who tells you when it's your bedtime[15]	120 (83.3) [7.82]	8 (5.6) [7.75]	0	9 (6.3) [8.44]	7 (4.9) [7.71]	0	146 (100) [7.85]
Who decides when you help with household jobs[15]	80 (67.8) [8.16]	0	0	17 (14.4) [7.88]	20 (16.9) [7.05]	1 (.8) [10.00]	118 (100) [7.95]
Who chooses what you eat for dinner[15]	92 (63.0) [7.71]	5 (3.4) [8.00]	3 (2.1) [6.67]	26 (17.8) [8.54]	18 (12.3) [7.61]	2 (1.4) [7.00]	146 (100) [7.82]
Who chooses what you buy for snacks[15]	83 (56.8) [7.84]	1 (0.7) [7.00]	2 (1.4) [5.00]	24 (16.4) [8.88]	35 (24.0) [7.29]	1 (0.7) [6.00]	146 (100) [7.82]

[14] Mean age (years) of respondents in each category
[15] Over 50% of children responded that their parent alone would make the decision.

Who decides what clothes you buy	65 (44.5) [7.45]	0	2 (1.4) [10.0]	47 (32.2) [8.64]	32 (21.9) [7.25]	0	146 (100) [7.82]
Who decides if you go to a birthday party	47 (32.2) [7.15]	-	-	59 (40.4) [8.24]	40 (27.4) [8.00]	-	146 (100) [7.82]
Who chooses your activities	26 (21.1) [6.81]	0	1 (0.8) [6.00]	29 (23.6) [8.86]	66 (53.7) [7.95]	1 (0.8) [7.00]	123 (100) [7.90]
Who chooses what you play on the computer	16 (11.0) [6.94]	1 (.7) [9.00]	5 (3.4) [6.80]	13 (8.9) [8.62]	105 (71.9) [7.89]	6 (4.1) [8.00]	146 (100) [7.82]
Who chooses what you watch on TV	16 (11.0) [7.62]	2 (1.4) [8.00]	12 (8.3) [7.17]	24 (16.6) [8.46]	70 (48.3) [7.67]	21 (14.5) [7.95]	145 (100) [7.80]
Who chooses the game	9 (7.6) [6.67]	3 (2.5) [8.33]	15 (12.7) [7.93]	14 (11.9) [8.14]	60 (50.8) [7.62]	17 (14.4) [7.94]	118 (100) [7.71]

Looking at this range of questions from the standpoint of the categories of daily family life, the only clear area where these children believed that they were involved in the decision is regarding their activities. In this category, the proportion of responses that included “me” as at least one of the responses was 77.6%. On the other hand, well over half of the children responded that a “parent/guardian” would make the decision alone or was at least involved in the decision for all of the remaining categories: health (87.5% parent alone, 94.5% parent involved), family life (54.2% parent alone, 67.2% parent involved), meals (59.9% parent alone, 79.1% parent involved), and clothes (44.5% parent alone, 76.7% parent involved). These data would imply that the child participants in this study had the perception that, while they may have been involved in many of the decisions in their daily lives, their parents were even more involved. This illustrates that the children were aware of their parents’ influence over most areas of their lives, but that they felt some measure of control over decisions related to the activities in which they participated. (See Table 9) It has been suggested in past research that a family’s general decision-making dynamic can affect their approach to medical decisions in particular[179]. Based on the data from this set of questions, it would be a reasonable assumption that, while some of the child participants in this study might be invited to participate in decision-making within the medical context, it is likely that they would assume that their parents would retain the decision-making authority. This is reflected by the proportion of child participants who responded that their parents were at least involved in, if not solely responsible for, decision-making in almost all categories of daily family life.

Table 9 – Questionnaire Study: Who in the family makes the decision (Mean % Response by Category of Family Life)

Category of Daily Family Life	Parent alone	Parent + Sibling/ Other	Other / Sibling	Parent + Child (+ Sibling / Other)	Child alone	Child + Sibling
Health[16]	87.5%	4.6%	4.1%	2.4%	1.4%	-
Family life[17]	54.2%	2.5%	4.2%	10.5%	23.5%	5.1%
Activities[18]	18.8%	0.5%	3.1%	22.4%	50.3%	4.9%
Meals[19]	59.9%	2.1%	1.7%	17.1%	18.1%	1.1%
Clothes[20]	44.5%	-	1.4%	32.2%	21.9%	-

[16] Questions included in the Health category were: "Who chooses to take you to the doctor when you are sick" and "Who tells you when you need an injection".
[17] Questions included in the Family Life category were: "Who tells you when it's your bedtime", "Who chooses the game", and "Who decides when you help with household jobs".
[18] Questions included in the Activities category were: "If you get invited to a friend's birthday party, who decides if you go", "Who chooses what you play [on the computer]", "Who chooses what you watch [on TV]", and "Who chose these activities for you".
[19] Questions included in the Meals category were: "Who chooses what you eat for dinner/tea" and "Who chooses what you buy for snacks".
[20] Questions in the Clothes category were: "Who decides what clothes you buy".

For each subject area, after children were asked who in their family would make the decision, they were then asked to state whether they had to obey that decision. This series of questions was created to ascertain whether these children felt as though they had a say in the enforcement of the decision in question. There were four possible answers to these questions and children were asked to choose only one as an answer: “always”, “most of the time”, “sometimes”, and “never”. Four additional questions of a similar nature were also asked but with only two possible answers from which to choose: “yes” and “no”. For the sake of analysis, “yes” answers were assumed to be similar to a combination of “always” and “most of the time”, while “no” answers were assumed to be similar to a combination of “sometimes” and “never”. Over half of the respondents chose “always” or “yes” for five of the twelve questions: do you have to clean your teeth (80.1%), do you have to eat your breakfast (77.2%), do you have to practice for your activities (74.2%), do you have to go to church/temple/mosque (62.2%), and do you have to go to the activities (58.3%). Furthermore, if the “always” and “yes” answers were combined with “most of the time” answers, four further questions had well over 50% affirmative answers: do you have to eat your dinner (78.8%), do you have to go to the doctor (66.5%), do you have to check with a parent before using your pocket money (63.5%), and do they make you go to bed at this time (78.5%). The only three questions for which this was not the case were: do you have to go to the birthday parties (28.5%), do you have to go food shopping with your parent (47.9%), and do you have to play games with your family (38.4%). These answers illustrate that the children recognised that for most aspects of their lives their parents retained authority and therefore they, as children, had to comply (See Table 10). It is interesting to note that a significant difference in answers between girl and boy respondents was seen for only one of these questions: do you have to play games with your family ($p<0.05$). For this question, a much larger proportion of boy respondents

chose the answer “sometimes” (58.3% of boy respondents) while the answers from girl respondents were more evenly distributed between all four possible response.

Table 10 – Questionnaire Study: How children answered questions regarding whether they are made to obey a decision in aspects of their lives, ranked from highest to lowest proportion answering "always"

Topics about which children were asked if they must obey a decision	**Always (Yes)** n (%) [mean age[21]]	**Most of the time (-)** n (%) [mean age[19]]	**Sometimes (-)** n (%) [mean age[19]]	**Never (No)** n (%) [mean age[19]]	**TOTAL** n (%) [mean age[19]]
Do you have to clean your teeth[22]	117 (80.1) [7.80]	15 (10.3) [8.33]	10 (6.8) [7.70]	4 (2.7) [6.75]	146 (100) [7.82]
Do you have to eat your breakfast[22]	112 (77.2) [7.71]	-	-	33 (22.8) [8.12]	145 (100) [7.81]
Do you have to practice for the activities[22]	89 (74.2) [8.19]	-	-	31 (25.8) [6.94]	120 (100) [7.87]
Do you have to go to church / temple / mosque[22]	46 (62.2) [7.37]	13 (17.6) [8.08]	9 (12.2) [7.56]	6 (8.1) [8.17]	74 (100) [7.58]
Do you have to go to the activities[22]	70 (58.3) [8.11]	-	-	50 (41.7) [7.60]	120 (100) [7.90]
Do you have to eat your dinner[22]	69 (47.3) [7.55]	46 (31.5) [8.52]	26 (17.8) [7.54]	5 (3.4) [6.60]	146 (100) [7.82]
Do you have to go to the doctor[22]	68 (46.6) [7.60]	29 (19.9) [8.31]	45 (30.8) [7.84]	4 (2.7) [7.75]	146 (100) [7.82]
Do you have to check with parent/guardian before using pocket money[22]	44 (42.3) [7.32]	22 (21.2) [8.32]	24 (23.1) [8.88]	14 (13.5) [7.14]	104 (100) [7.87]
Do they make you go to bed at this time[22]	37 (31.9) [6.68]	54 (46.6) [8.57]	20 (17.2) [7.95]	5 (4.3) [6.00]	116 (100) [7.75]
Do you have to go to birthday parties	41 (28.5) [6.98]	-	-	103 (71.5) [8.17]	144 (100) [7.83]
Do you have to go food shopping with parent/guardian	31 (21.2) [6.97]	39 (26.7) [7.77]	67 (45.9) [8.37]	9 (6.2) [6.89]	146 (100) [7.82]
Do you have to play games with your family	15 (12.8) [6.67]	30 (25.6) [7.50]	48 (41.0) [8.31]	24 (20.5) [7.46]	117 (100) [7.72]

[21] Mean age (years) of respondents in each category
[22] Over 50% of children responded that they are made to obey a decision "always" or "most of the time".

This trend continues when analysing the results in categories of daily family life. The average percent response of “never” answers by category was relatively small (below 15%) for all categories except for activities. For the questions within the category of “activities”, the average percent response of “no” answers was 46.3%, implying that the children felt that they had more control over their activities than other parts of their daily lives. However, it is important to note that all three questions within the “activities” category had only two available responses (“yes” and “no”), rather than the usual four responses for this type of question (“always”, “most of the time”, “sometimes”, and “never”). Nonetheless, if the proportion of “never” and “sometimes” answers from the other categories are added together, the overall proportion would still be less than 46.3%, indicating that the “activities” category is indeed unique. The category of questions related to health represented the most extreme answers regarding the children’s perception of control over their lives. This category had the largest average percent response of “always” answers (63.4%) and the lowest average percent response of “never” answers (2.7%) when compared to the other categories. This may illustrate that the children in this study recognised that in matters of health, their parents allowed them less autonomy. On the other hand, the average percent response rates of overall answers in the category of family life were the most evenly spread between the four possible answers (37.3% “always”, 27.7% “most of the time”, 23.4% “sometimes”, 11.6% “never”) which may point to the fact that more variation can be seen between individual families in this sector of their lives. (See Table 11)

Table 11 – Questionnaire Study: Does child have to obey a decision (Mean % response by category of daily family life)

Category of Daily Family Life	Always (Yes)	Most of the time (-)	Sometimes (-)	Never (No)
Health[23]	63.4%	15.1%	18.8%	2.7%
Family life[24]	37.3%	27.7%	23.4%	11.6%
Activities[25]	53.7%	-	-	46.3%
Meals/Food[26]	48.6%	19.4%	21.2%	10.8%

[23] Questions included in the Health category were: "Do you have to go to the doctor even if you would rather not" and "Do you have to clean your teeth in the morning and evening".
[24] Questions included in the Family Life category were: "Do they make you go to bed at this time", "If your parent or guardians go to church/temple/mosque, do you have to go with them", "Do you have to play games with your family", "Do you have to check with your parents or guardians before using your pocket money".
[25] Questions included in the Activities category were: "Do you always have to go to the activities", "Do you have to practice for the activities", and "If you don't want to go to the birthday party do you have to go".
[26] Questions included in the Meals/Food category were: "If the person who looks after you needs to go food shopping, do you have to go with them", "Do you have to eat [breakfast]", and "Do you have to eat what you are given [for dinner/tea]".

Children were also asked a series of questions about whether they would seek permission to do two different types of activities with a friend: a fun activity and an activity about which they were unsure. During the questionnaire session, children were given additional information regarding the "unsure" activity: this was described as an activity that was potentially risky or dangerous. If they answered "yes" that they would seek permission, they were asked three additional questions: from whom would they ask permission, whether they would still do the activity even if permission were denied, and whether they would like to have the choice to do it themselves, without needing to obtain permission. The answers to these questions were illuminating, as the vast majority of children stated that they would seek permission before participating (84.8% for a fun activity, 82.6% for an unsure activity) (see Table 12). Furthermore, of those children who stated that they would seek permission, most would seek it solely from a parent (81.8% for a fun activity, and 88.2% for an unsure activity), while almost all of the remaining children specified that they would ask a parent and someone else such as another adult or a sibling (10.7% for a fun activity, 9.2% for an unsure activity) (see Table 13). Finally, the children were asked whether they would still do the activity if permission were denied, and the majority of these children answered that they would not (61% for a fun activity, 76.5% for an unsure activity) (see Table 14). As stated above (and seen in Table 6), the majority of these children would like to have the choice to do these activities (78.6% for a fun activity, 62% for an unsure activity) but by their answers to this series of questions it seems likely that they not only would expect to receive guidance from their parents but that they would follow it and would be unlikely to overrule their parents' wishes. These questions were all analysed by gender to determine whether any differences in responses might be apparent between boy and girl respondents. Interestingly, this analysis demonstrated no significant gender difference in their responses.

Table 12 – Questionnaire Study: Would child seek permission prior to engaging in activity with a friend

Type of activity	Yes n (%) [mean age[27]]	No n (%) [mean age[24]]	TOTAL n (%) [mean age[24]]
Fun activity	123 (84.8) [7.98]	22 (15.2) [7.00]	145 (100) [7.83]
Unsure activity	119 (82.6) [8.03]	25 (17.4) [6.92]	144 (100) [7.83]

[27] Mean age (years) of respondents in each category

Table 13 – Questionnaire Study: From whom would child seek permission prior to engaging in activity with a friend

Type of activity	Parent alone n (%) [mean age[28]]	Other adult alone n (%) [mean age[25]]	Parent + Other adult / Sibling n (%) [mean age[25]]	Sibling / Peer n (%) [mean age[25]]	Total n (%) [mean age[25]]
Fun activity	99 (81.8) [8.06]	0	13 (10.7) [8.08]	9 (7.4) [7.44]	121 (100) [8.02]
Unsure activity	105 (88.2) [8.07]	2 (1.7) [5.50]	11 (9.2) [8.00]	1 (.8) [9.00]	119 (100) [8.03]

[28] Mean age (years) of respondents in each category

Table 14 – Questionnaire Study: Would child still engage in activity with a friend if permission were denied

Type of activity	Always n (%) [mean age[29]]	Most of the time n (%) [mean age[26]]	Sometimes n (%) [mean age[26]]	Never n (%) [mean age[26]]	TOTAL n (%) [mean age[26]]
Fun activity	12 (9.8) [7.33]	6 (4.9) [8.83]	30 (24.4) [8.53]	75 (61.0) [7.80]	123 (100) [7.98]
Unsure activity	5 (4.2) [6.20]	4 (3.4) [7.00]	19 (16.0) [8.95]	91 (76.5) [7.98]	119 (100) [8.03]

[29] Mean age (years) of respondents in each category

At the end of the questionnaire were three questions to determine the children's overall perspective on their decision-making experience and ability. The children were first asked whether they thought that their parents or guardians let them make decisions. They were given four possible responses to this question ("always", "most of the time", "sometimes", and "never") and were asked to choose one. The majority of the children answered "sometimes" (36.3%) or "most of the time" (34.2%), while the answers from the remaining children were almost perfectly divided between "always" (14.4%) and "never" (15.1%). This shows that the vast majority of the children who participated in this study (84.9%) believed that they were given at least some opportunities to make decisions within their family context (see Table 15). The children were then asked if they sometimes needed help making decisions and an overwhelming majority admitted that "yes" they did need help (83.4%) (see Table 16). Finally, those children who said that they sometimes needed help making decisions were asked what helped them make the decision. They were able to choose one or more applicable answers from the following options: "understanding the problem", "talking to parent/guardian", "talking to brother/sister", "talking to friends", "remembering something good or bad that happened last time", and "remembering helpful comments from last time". An overwhelming majority of the children chose "talking to parent/guardian" (86.8%) and well over half of the children chose "understanding the problem" (63.6%) as one of their answers (see Table 17). These answers were also analysed by gender and only two of the responses demonstrated a significant difference between boy and girl respondents ($p<0.05$). A much greater proportion of girl respondents in this study chose the answers "understanding the problem" (73.4% of girls, 52.6% of boys) and "talking to brother/sister" (42.2% of girls, 15.8% of boys).The fact that most of the children in this study admitted that they relied on their parents first and foremost to guide them in their decision-making implies that, in addition to recognising their parent's

authority within the context of their family, they depended on it. This finding is supported by previous studies that have indicated children's preference for joint decision-making with their parents and the existence of child and adolescent self-doubt regarding their own decision-making abilities[108,163,165,177,178].

Table 15 – Questionnaire Study: Children's perception of decision-making opportunities within family context

	Always n (%) [mean age[30]]	**Most of the time** n (%) [mean age[27]]	**Sometimes** n (%) [mean age[27]]	**Never** n (%) [mean age[27]]	**TOTAL** n (%) [mean age[27]]
Do you think your parents or guardians let you make decisions	21 (14.4) [8.19]	50 (34.2) [8.02]	53 (36.3) [8.17]	22 (15.1) [6.18]	146 (100) [7.82]

[30] Mean age (years) of respondents in each category

Table 16 – Questionnaire Study: Children's perception of solo decision-making ability

	YES n (%) [mean age[31]]	**NO** n (%) [mean age[28]]	**TOTAL** n (%) [mean age[28]]
Do you sometimes need help making decisions	121 (83.4) [7.96]	24 (16.6) [7.25]	145 (100) [7.84]

[31] Mean age (years) of respondents in each category

Table 17 – Questionnaire Study: Distribution of child responses for what helps him make decisions

Decision-Making Aids	**Response** n (%) [mean age[32]]
Understanding the problem	77 (63.6) [8.17]
Talking to parent/guardian	105 (86.8) [8.05]
Talking to brother/sister	36 (29.8) [7.58]
Talking to friends	57 (47.1) [7.65]
Remembering something good or bad that happened last time	57 (47.1) [7.91]
Remembering helpful comments from last time	62 (51.2) [7.97]

[32] Mean age (years) of respondents in each category

The responses for these final questions illustrate that these children expressed a desire to have a choice in their daily lives, yet they recognised that their parents not only made most decisions within the context of their family but they also had the power to enforce those decisions. Based on the answers from child participants in this questionnaire study, it would seem reasonable that children of this age range should be involved in the decision-making process for medical research. The children want to have a say in the matters which affect them, and they want to be informed, but they do rely on their parents for guidance on most issues and therefore would most likely not expect or desire to make the final decision in a medical context.

4.2.3.4 Primary analysis: Parent Questionnaires

The parent questionnaire was composed of complementary questions to the child questionnaire. Therefore, the same basic questions were asked, but from the perspective of a parent. For each question topic, parents were asked several questions to understand the overall dynamic within that family unit. For example, parents were first asked if their child chose something or participated in something regarding a specific aspect of their daily life. They were then asked whether their child was required to participate. Finally, they were asked who in their family, if anyone, would enforce that original decision. Similar to the child questionnaire, the questions on the parental questionnaire were also divided into categories of daily family life, such as demographic information, health, family life and interaction, activities, meals and food, clothes, and current decision-making. Thus, analysis of the parent questionnaire data was conducted first on the overall questions, and then again on the categories of daily family life. It is important to note that for those parents who answered the questionnaire for multiple children, analysis was

conducted separately on the data provided for each individual child. Although there were 93 completed parent questionnaires, those 93 questionnaires contained responses pertaining to 140 children. Therefore, analysis was conducted on 140 sets of parent responses to the questionnaire questions.

The series of questions regarding whether their child was required to do something or participate in some aspect of daily life was designed in order to determine how much control these parents regularly allowed their children to have over different parts of their life. These questions ranged from more serious subjects such as whether their child was made to go to the doctor when unwell to questions of a more social nature, such as whether their child was required to attend birthday parties to which he was invited. Most of these questions were written so that parents were allowed to choose between four possible answers ("always", "most of the time", "sometimes", and "never), but a few of the questions allowed only "yes" or "no" responses. As stated above in the analysis of child questionnaire data, for the sake of analysis "yes" answers were assumed to be similar to a combination of "always" and "most of the time", while "no" answers were assumed to be similar to a combination of "sometimes" and "never". Well over half of the responses to the majority of these questions fell under the answers "always" and "most of the time". Of the 14 questions of this type on the parent questionnaire, all but 3 of them had greater than 60% responses as a combination of "always" and "most of the time", with over 85% of parents responding in this manner for 7 of the questions. In aspects of a child's health and well-being or nutrition, the majority of parents were likely to respond with either "always" or "most of the time" (e.g. going to the doctor: 92.1%; bedtime: 97.9%; eating dinner: 93.1%). This is in contrast with questions of optional activities for how children

spent their time, where parents were more likely to respond with “never” or “sometimes” (attending birthday parties: 66.4%; playing games with family members: 74.8%). When analysing these questions separated into categories of family life, over half of the responses in each category were “always” or “most of the time”, with the highest proportion of these responses seen in the categories of “health” (92.1%) and “family life” (77.9%). Variations to this pattern can be seen in two questions regarding whether a child needed permission to watch television or play on the computer, two common household activities which were mentioned during the focus groups. Only a small percentage of parents reported that their children “never” needed permission to watch television (5.8%) or play on the computer (3.7%). Interestingly, the responses to these two questions were very different on the opposite end of the spectrum. While the responses were fairly evenly distributed between “always”, “most of the time”, and “sometimes” regarding the television (26.1%, 36.2%, 31.9%), the majority of parents believed that their child “always” needed permission to play on the computer (68.4%). This is not surprising when we consider that parental controls are much more necessary on the computer where access to age inappropriate material would be more of a concern than through the television. However this is speculation only, as the parents were not asked the reasons behind their answers (see Tables 18-19). It is important to note that, similar to the child questionnaire, the category of family life was based on a limited range of questions, in this case the question “If your child refuses to go to the doctor would you make them go”. In this scenario, if a child were ill it is unlikely that a parent would allow the child to dictate whether or not he would be taken to the doctor. It would have been useful to include additional questions that could have been analysed in this category as well, such as whether the parent would insist that the child visit a dentist, eat healthy food, or participate in regular exercise.

Table 18 – Questionnaire Study: Parental view on whether child is required to do something

Topics about which parents were asked if child is required to do something	Always n (%) [mean age[33]]	Most of the time n (%) [mean age[30]]	Sometimes n (%) [mean age[30]]	Never n (%) [mean age[30]]	TOTAL n (%) [mean age[30]]
Does child have to go to bed at bedtime	24 (17.1) [7.17]	113 (80.7) [8.10]	3 (2.1) [8.33]	0	140 (100) [7.94]
Does your child have to go on the family day out	109 (78.4) [7.83]	25 (18.0) [8.44]	3 (2.2) [8.67]	2 (1.4) [7.50]	139 (100) [7.96]
Does child have to eat what is given at dinner (if did not choose it)	35 (30.2) [7.89]	73 (62.9) [7.90]	3 (2.6) [7.67]	5 (4.3) [8.20]	116 (100) [7.91]
Would you make your child go to the doctor if he/she refused to go	92 (65.7) [7.74]	37 (26.4) [8.46]	11 (7.9) [7.91]	0	140 (100) [7.94]
Does your child have to come with you to church / temple / mosque (for participants that go regularly)	28 (56.0) [8.11]	18 (36.0) [7.33]	1 (2.0) [8.00]	3 (6.0) [9.67]	50 (100) [7.92]
Does child have to eat breakfast (of those whose child does not choose breakfast)	7 (33.3) [7.71]	12 (57.1) [8.50]	0	2 (9.5) [8.00]	22 (100) 8.19
Does child need permission to play on computer	93 (68.4) [7.78]	26 (19.1) [8.23]	12 (8.8) [9.25]	5 (3.7) [7.20]	136 (100) [7.98]

[33] Mean age (years) of respondent's child in each category

Does child have to participate in activity	91 (73.4) [7.96]	-	-	33 (26.6) [8.12]	124 (100) [8.00]
Does child have to practice for the activity	81 (63.3) [8.22]	-	-	47 (36.7) [7.60]	128 (100) [7.99]
Does child need permission to watch television	36 (26.1) [7.11]	50 (36.2) [8.18]	44 (31.9) [8.45]	8 (5.8) [7.50]	138 (100) [7.95]
Does child have to eat what is given for snack (if did not choose it)	4 (6.2) [7.50]	35 (53.8) [8.09]	26 (40.0) [7.81	0	65 (100) [7.94]
Does your child have to attend the birthday parties they are invited to	11 (7.9) [7.82]	36 (25.7) [7.61]	36 (25.7) [8.08]	57 (40.7) [8.09]	140 (100) [7.94]
Does child have to go food shopping with you	3 (6.7) [8.67]	12 (26.7) [7.33]	29 (64.4) [7.48]	1 (2.2) [8.00]	45 (100) [7.53]
Does your child have to play the games	1 (0.7) [11.00]	33 (24.4) [8.03]	57 (42.2) [7.70]	44 (32.6) [8.07]	135 (100) [7.93]

Table 19 – Questionnaire Study: Parental view on whether child is required to do something (Mean % response by category of daily family life)

Category of Daily Family Life	Always n (%) [mean age[34]]	Most of the time n (%) [mean age[31]]	Sometimes n (%) [mean age[31]]	Never n (%) [mean age[31]]
Health[35]	65.7%	26.4%	7.9%	0%
Family life[36]	38.1%	39.8%	12.1%	10%
Meals/Food[37]	19.1%	50.1%	26.8%	4%
Activities[38]	47.8%	16.2%	13.3%	22.7%

[34] Mean age (years) of respondent's child in each category
[35] Questions included in the Health category were: "If your child refuses to go to the doctor would you make them go".
[36] Questions included in the Family Life category were: "Does your child have to go to bed [at bedtime]", "Does your child have to come with you [to church/temple/mosque]", "Does your child have to go on the family day out", and "Does your child have to play the games".
[37] Questions included in the Meals/Food category were: "Does your child have to go with you [food shopping]", "If no, does your child have to eat what is given to them [for breakfast]", "If no, does your child have to eat what is given to them [for dinner]", "If no, does your child have to eat what is given to them [for snacks]".
[38] Questions included in the Activities category were: "Does your child have to go to the birthday parties", "Does your child have to participate in the activity", and "Does your child have to practice for the activity".

Parents were also asked if they allowed their children to choose how they spent their pocket money. Of those parents who gave their children pocket money, the majority answered “most of the time” (59.7%), yet given that the proportion of parents who answered “always” was fairly small (16.7%), this indicates that most of the parents in this study preferred to at least have some input in how their children used their pocket money.

Parents were then asked who in the family would enforce specific decisions. They were given several possible answers (“me”, “other parent”, “child’s sibling”, and “other adult”) and were allowed to choose all applicable responses for each question. These questions were designed to explore the parent’s perception of the authority role in their family. No surprising results emerged in this group of questions. The vast majority of parents (over 80%) stated that one or both parents enforced decisions, across almost all subject areas. The only exception to this was for the question of who enforced the child playing games with his family. Only slightly more than half of parent participants responded that one or both parents enforced the child playing games with the family if the child was unwilling to play games (55.2%), while most of the remaining participants stated that one or both parents with the child’s sibling would enforce this (32.3%). However, even with this difference, the majority of parent participants still cited a parent as having the responsibility for enforcing this decision (see Table 20). When analysing this series of questions in categories of family life, this outlier response slightly lowers the proportion of responses that were one or both parent within the category of family life (86.2%), yet the overall proportion remains quite high as the other questions within this category are all heavily weighted towards this response (see Table 21).

Table 20 – Questionnaire Study: Person(s) responsible for enforcement of decisions (all results)[39]

Topics about which parents were asked who enforces the decision	One or both parents n (%) [mean age[40]]	Other adult n (%) [mean age[36]]	Parents with other adult n (%) [mean age[36]]	Parent(s) with child's sibling n (%) [mean age[36]]	Siblings alone n (%) [mean age[36]]	TOTAL n (%) [mean age[36]]
Who enforces child eating breakfast	126 (96.9) [7.96]	0	2 (1.5) [5.50]	2 (1.5) [7.50]	0	130 (100) [7.92]
Who enforces child's bedtime	135 (96.4) [7.99]	0	2 (1.4) [5.50]	3 (2.1) [7.67]	0	140 (100) [7.94]
Who enforces child eating dinner	132 (96.4) [7.97]	1 (0.7) [5.00]	2 (1.5) [5.50]	2 (1.5) [8.50]	0	137 (100) [7.92]
Who enforces child practicing for or participating in extra-curricular activities	105 (96.3) [8.17]	0	2 (1.8) [7.00]	0	2 (1.8) [7.50]	109 (100) [8.14]
Who enforces child eating snack	102 (96.2) [7.95]	1 (0.9) [8.00]	1 (0.9) [8.00]	2 (1.9) [6.50]	0	106 (100) [7.91]

[39] The possible responses for these questions in the questionnaire were: me, other parent, child's sibling, and other adult. Participants were allowed to choose more than one answer for these questions. Therefore, the responses in this table are organized in a slightly different format to better illustrate the range of responses.
[40] Mean age (years) of respondent's child in each category

Who enforces child attending birthday parties	73 (96.1) [8.16]	0	1 (1.3) [8.00]	2 (2.6) [8.00]	0	76 (100) [8.16]
Who would enforce child going to doctor	133 (95.0) [7.98]	0	1 (0.7) [7.00]	6 (4.3) [7.17]	0	140 (100) [7.94]
Who enforces child cleaning teeth	126 (94.7) [7.88]	0	1 (0.8) [6.00]	6 (4.3) [8.17]	0	133 (100) [7.88]
Who enforces child attending church / temple / mosque	35 (94.6) [7.80]	0	0	2 (5.4) [10.0]	0	37 (100) [7.92]
Who enforces child attending family day out	123 (93.2) [7.90]	0	1 (0.8) [8.00]	8 (6.1) [8.00]	0	132 (100) [7.91]
Who enforces child permission for playing on computer	121 (92.4) [8.02]	0	3 (2.3) [6.33]	6 (4.6) [8.50]	0	130 (100) [8.00]
Who enforces child helping with household jobs	114 (91.9) [8.02]	0	3 (2.4) [5.67]	7 (5.6) [8.29]	0	124 (100) [7.98]
Who enforces child permission for watching television	113 (91.1) [8.04]	0	5 (4.0) [6.20]	6 (4.8) [7.83]	0	124 (100) [7.95]
Who chooses clothes (if child does not choose)	62 (84.9) [7.47]	0	11 (15.1) [8.18]	0	0	73 (100) [7.58]
Who enforces child playing games	93 (55.2) [7.72]	0	4 (4.2) [8.00]	31 (32.3) [8.06]	8 (8.3) [8.38]	96 (100) [7.90]

Table 21 – Questionnaire Study: Person(s) responsible for enforcement of decisions (Mean % response by category of daily family life)

Category of Daily Family Life	One or both parents	Other adult	Parents with other adult	Parent(s) with child's sibling	Siblings alone
Health[41]	94.9%	-	0.8%	4.3%	-
Family life[42]	86.2%	-	1.8%	10.3%	1.7%
Meals/Food[43]	96.5%	0.6%	1.3%	1.6%	-
Activities[44]	94%	-	2.5%	3%	0.5%
Clothes[45]	84.9%	-	15.1%		

[41] Questions included in the Health category were: "Who would enforce [your child going to the doctor]" and "If your child is unwilling to clean their teeth, who enforces this".
[42] Questions included in the Family Life category were: "If your child is unwilling to go to bed then, who enforces this bedtime", "If your child is unwilling to go [to church/temple/mosque] who enforces this", "If your child is unwilling to go on the family day out, who enforces this", "If your child is unwilling to play the games who enforces this", and "Who enforces [your child helping with household jobs]".
[43] Questions included in the Meals/Food category were: "If your child is unwilling to eat their breakfast, who enforces this", "If your child is unwilling to eat their dinner, who enforces this", and "If your child is unwilling to eat their snack, who enforces this".
[44] Questions included in the Activities category were: "If your child is unwilling to go to the party, who enforces this", "If yes, who enforces [permission for watching television]", "If yes, who enforces [permission for playing on computer]", and "If your child is unwilling to practice for or participate in the activity, who enforces this".
[45] Questions included in the Clothes category were: "If no, who chooses [child's clothes]".

Beyond the questions pertaining to specific aspects of their child's daily life, parents were asked several questions to explore the pedagogical role of parents regarding daily decision-making. First, parent participants were asked whether they explained their decisions to their child, and they were allowed to choose one of four possible answers: "always", "most of the time", "sometimes", and "never". The vast majority of parents (87.1%) responded "always" or "most of the time" while none of the parents responded "never". This is illuminating as it clearly shows that the parents in this study actively taught their children about the decision-making process. (see Table 22)

Parents were also asked if they involved their children in decision-making for non-significant and significant decisions. Very few of the participants responded that they "always" involved their children in either of these types of decision-making (6.4% for non-significant decisions, 5% for significant decisions). However, as expected based on past research[108,170,175,176] as well as the focus group discussions, these parents were more likely to state that they involved their children at least some of the time in decision-making for non-significant decisions (62.1% responded "most of the time", 31.4% responded "sometimes") than for significant decisions (15.7% responded "most of the time", 60.0% responded "sometimes"). Furthermore, while none of these parents reported that they "never" involved their child in non-significant decision-making, 19.3% responded "never" regarding significant decision-making (see Table 22). This would imply that, while the majority of these parents did try to involve their children in at least some of the decisions in their daily lives, they showed greater willingness to involve a child in the decision-making process when there were not large potential consequences associated with those decisions. Tests of homogeneity on "Do you involve your child in

decision-making for significant decisions" and "Do you involve your child in decision-making for non-significant decisions" with "When you make a decision for your child do you explain why you have made that decision" showed a significant difference in both cases. However, the significant results seem to be driven by differences in the "sometimes" and/or "never" categories, rather than across all categories ("always", "most of the time", "sometimes", and "never"). In fact, parents who involved their children "always" or "most of the time" in decision-making, for significant or non-significant decisions, were likely to "always" or "most of the time" explain their own decision-making to their child.

Table 22 – Questionnaire Study: Pedagogical role of parents regarding child decision-making

Question	Always n (%) [mean age[46]]	Most of the time n (%) [mean age[42]]	Sometimes n (%) [mean age[42]]	Never n (%) [mean age[42]]	TOTAL n (%) [mean age[42]]
Do you explain your decisions to your child	61 (43.6) [8.30]	61 (43.6) [7.89]	18 (12.9) [6.94]	0	140 (100) [7.94]
Do you involve child in non-significant decision making	9 (6.4) [9.00]	87 (62.1) [7.99]	44 (31.4) [7.64]	0	140 (100) [7.94]
Do you involve child in significant decision-making	7 (5.0) [7.71]	22 (15.7) [8.41]	84 (60.0) [8.11]	27 (19.3) [7.11]	140 (100) [7.94]
Does your child need help making decisions	0	29 (20.7) [7.34]	103 (73.6) [8.07]	8 (5.7) [8.50]	140 (100) [7.94]

[46] Mean age (years) of respondent's child in each category

Those parents who involved their children in significant and non-significant decision-making were then asked to share how they involved them in both of these processes. They were given four options for their response to these two questions and they were allowed to select all applicable responses: “with positive rewards” (e.g. gift), “with negative rewards” (e.g. limit TV time), “with limited options”, and “negotiation”. The two most popular answers to these questions were “negotiation” (64.3% for non-significant decisions, 62.5% for significant decisions) and “with limited options” (47.9% for non-significant decisions and 48.33% for significant decisions) (see Table 23). These responses once again speak to the pedagogical nature of childhood decision-making within the family unit: when involving children in the decision-making process, these parents were likely to provide the child with limited options from which to choose, or to discuss and negotiate the decision with the child, thus teaching him how the decision was made without burdening him with the responsibility of making the full decision on his own.

Table 23 – Questionnaire Study: Methods used by parents to involve children in decision-making for non-significant and significant decisions

How do you involve child in non-significant decisions	**n (%)**
With positive rewards	44 (31.4)
With negative rewards	19 (13.6)
With limited options	67 (47.9)
Negotiation	90 (64.3)
How do you involve child in significant decisions	
With positive rewards	29 (24.2)
With negative rewards	12 (10.0)
With limited options	58 (48.33)
Negotiation	75 (62.5)

Finally, parents were asked if they thought their child needed help making decisions. The four possible answers from which they could choose were: “always”, “most of the time”, “sometimes”, and “never”. The majority of parents responded “sometimes” (73.6%), and almost all of the remaining parents responded “most of the time” (20.7%), with only 5.7% responding “never”. None of the parents responded “always”, implying that all participants in this study believed their children to be capable of making at least some decisions unaided (see Table 22). As in the child questionnaire, parents were asked what helped their child make decisions and they could choose any applicable answer from the following choices: “understanding the problem”, “talking with parent”, “talking with sibling”, “talking with friends”, “remembering past choices”, “remembering past advice”, and “other”. Over 90% of parents responded that what helped their child make decisions was “understanding the problem” (92.9%) and “talking with parent” (92.1%) (see Table 24). These answers were much more common than any of the other 5 choices. The results from this question are in line with the previous answers on this questionnaire: these parents recognised that their children relied on them for decision-making guidance.

Table 24 – Questionnaire Study: Distribution of parent responses for what helps child make decisions

Decision-Making Aids	Response n (%)
Understanding the problem	130 (92.9)
Talking to parent/guardian	129 (92.1)
Talking to siblings	46 (32.9)
Talking to friends	39 (27.9)
Remembering past choices	93 (66.4)
Remembering past advice	61 (43.6)
Other[47]	12 (8.6)

[47] There were 9 write-in responses for the category of "Other": "Explaining consequences/repercussions", "Understanding consequences/potential outcomes", "Talking about feelings", "Understanding consequences of decision", "Talking to Nana", "Scenario playing" (x2), "Talking as a family", and "Quiet time to think about it"

Overall, the data gathered from parents on this questionnaire seem to support the idea that children learn how to make decisions from their parents, within their family unit. As expected after the focus groups, parents in this study were more likely to involve their children in decisions about non-significant rather than significant issues. This was seen both in their responses to questions specifically about whether they involved their child in the decision-making process, as well as in their responses to whether the child was required to acquiesce to the parent's decision. These parents seemed to be aware of the fact that their children were capable of making some decisions, and could actively learn about decision-making through involvement in the decision-making process within the family, whether by being directly involved in a decision, or by hearing an explanation from their parents on why a particular decision had been made. These data, then, would seem to support the existence of an assent process for children in this age group: children who are used to being involved in some capacity in the decisions made within their family unit may be more likely to respond positively when accorded that same opportunity outside of the family unit.

4.2.3.5 Secondary Analysis

All participants enrolled in this questionnaire study had either a parent or a child who was also enrolled. This allowed an exploratory secondary analysis to be conducted, comparing parent-child pairs in order to discover any association between their answers. While all 146 child participants completed questionnaires, 7 of the 100 parent participants did not return their questionnaires; therefore for this analysis there were only 93 family groups, consisting of one parent and at least one child. These 93 family groups included 93 parents and 136 children.

A chi-square analysis was run for each related question from the parent and child questionnaires. This was conducted in order to observe the agreement between parent-child pairs on each related question and to identify any trends. There were a few questions where there seemed to be an association between parent and child responses based on a significant p-value associated with the chi-square test. Three sets of questions had highly significant p-values: the comparison between the child and parent answers for "Do you go to church/temple/mosque", "Do you get pocket money" vs. "Do you give your child pocket money", and "Do you have to practice for these activities" vs. "Does your child have to practice for the activity". This does indicate that there is an association between the answers of the children and their parents on these questions. However it is important to note that there is no control for type 1 error rate, so all p-values can be considered nominal. Furthermore, none of the questions for which there appeared to be an association between parent and child responses offered valuable insight into any apparent trends in childhood decision-making. Rather, most of these significant p-values seemed more likely to be related to the number of tests that were run, rather than from any essential relationship between the two datasets. Yet this does not mean that there is fundamentally no potential association between parent and child perception regarding a child's daily decision-making. While no overpowering trends emerged from the data in this study, taking into account that this secondary analysis was exploratory only, the study was not powered for this type of analysis, and there was no control for type 1 error, no permanent conclusions can be drawn from a lack of observable trends. (A table of tests of association between parent-child questions is included in Appendix 10)

4.2.3.6 Potential Biases

This study was a questionnaire study and therefore was vulnerable to a few different potential biases that must be mentioned in any discussion of data analysis. Possible biases for this study include selection, interviewer, and questionnaire biases. First of all, there could have been a selection bias present in the participants enrolled in this study. Participants were not identified or recruited through random sampling. Information about the study was presented to potential participants through in-person recruitment or direct mail-out. In addition, recruitment was conducted through local primary schools, with the approval of the school's head teacher. It is possible that the people who chose to enrol in this study differed in meaningful ways from those who did not choose to participate. It is also possible that those schools where recruitment was allowed differed significantly from the schools whose head teacher did not allow recruitment. Detailed demographic information was not gathered from participants in this study so a comprehensive comparison between study participants and the greater population of Oxfordshire was not possible. However, the primary schools where study recruitment was conducted covered a diverse demographic range: including state and private schools in Oxford (a more affluent town), Banbury (a less affluent town), and villages in Oxfordshire. Therefore, it is likely that these schools offered the possibility to recruit participants from diverse socio-economic backgrounds. Nonetheless, those families who chose to enrol in the study may still have been different from those who did not.

The questionnaires in this study were both interviewer-administered (child questionnaires) and self-administered (parent questionnaires). The child data thus may have experienced an interviewer bias. The fact that an adult was asking the questions during the child

questionnaire sessions may have caused some of the child participants to alter their answers in some way.

Several other biases were possible in association with the design of the questionnaires themselves. Many of the questions on both questionnaires used a scale of answers: “always”, “most of the time”, “sometimes”, and “never”. There was no explanation or definition given in relation to these terms, so it is possible that “most of the time” and “sometimes” may have been interpreted differently by various participants. These questions may also have introduced a bias of central tendency, where respondents might have avoided answering with the end of the scales (“always” or “never”), choosing instead an answer in the middle (“most of the time” or “sometimes”). Other questions on both questionnaires gave the respondents two choices for their answer: “yes” and “no”. These questions may have introduced a bias of faulty scale or forced choice as respondents were forced to choose between two responses, neither of which may have been correct. To avoid this problem, a third option of “don’t know” could have been offered to the respondents. However, given that both child and parent participants wrote comments and explanations next to many of their responses, including the comment “don’t know”, it is likely that these participants only answered questions when they felt secure in their answer.

A few of the questions were written as follow-on questions to previous items on the questionnaires. For example, a question on the child questionnaire asked participants if they had household jobs. The next question was then “If yes, which ones have you done”. Questions that began with “If yes…” or “If no…” were designed to be answered only by

those participants who had answered in that specific way for the previous question. However this was not clear to some participants who answered those questions, even when not relevant to their previous responses. While this does represent a flawed questionnaire structure as the instructions were apparently unclear to some of the participants, this should not have introduced a bias to the data analysis as data were only analysed from those participants who answered in the intended way for these questions.

Both parent and child questionnaires were fairly long. The parent questionnaire consisted of 59 questions printed over 3 double-sided pieces of paper, while the child questionnaire covered 7 double-sided pieces of paper with 73 questions (although some of its printed length was due to a much larger font and the inclusion of pictures). Due to the length of the questionnaires, there may have been some response fatigue, where participants paid less attention to their answers towards the end of the questionnaire.

Finally, some of the complementary questions on the parent and child questionnaires were written with a change of scale between them. For example, regarding birthday party invitations children were asked “If you don’t want to go to the party do you have to go” and were given the possible responses of “yes” and “no”. Parents, on the other hand, were asked “Does your child have to go to the birthday parties” and were given the possible responses of “always”, “most of the time”, “sometimes”, and “never”. This change of scale made it difficult to compare responses between parent and child pairs. This change of scale was also present in some of the pooled data analysis. For example, when comparing responses from child participants regarding whether they were made to obey a decision in aspects of their lives, some of the questions such as “Do you have to eat your

breakfast" had possible responses of "yes" and "no", while other questions such as "Do you have to clean your teeth" had possible responses of "always", "most of the time", "sometimes" and "never". In retrospect it would have been easier to only use binary options such as "yes" and "no" for all of these questions. However the decision to offer 4 possible answers was made in order to have more granularity in the results, which we felt was valuable within the context of the study. Forcing all variables into binary options from the outset would have reduced the granularity. Nevertheless, for the sake of analysis, and to reduce occurrence of questionnaire bias, all questions should have been written with the same scale if there was an intent to make comparisons across questions.

While it is possible that some of these issues may have introduced a potential bias to the questionnaire study data, this study was of a strictly exploratory nature. There is no attempt to generalise these results to a wider population. Instead, trends from the study data have been identified that may indicate areas for further research in a larger study.

4.3 Conclusion

The data from this questionnaire study further illustrate that a child's family context may have a great influence on the development of his decision-making abilities. The children in this study clearly desired to have some choices in their lives, across all aspects of daily life, however they did not seem to want to exert a blanket control over these choices. While they did express an interest in having some measure of control, particularly over their activities, they recognised that their parents had the ultimate authority over most aspects of their daily lives and that they were required to comply with those parental rules and wishes. In fact, it would seem from their responses to the child questionnaire, that

these children not only expected to receive decision-making guidance from their parents, but they were aware that they often needed guidance to make decisions, and furthermore they were relatively content to follow this guidance. The data from the parental questionnaires provided similar information, but from the opposite perspective. Parents confirmed that they were responsible for enforcing most decisions within the context of their families and that their children were usually required to acquiesce with their wishes. However they clearly had embraced the parental pedagogical role in nurturing their children's decision-making abilities. These parents actively taught their children how to make decisions by explaining their own decisions to their children, even when they were not allowed to participate in the actual decision-making process. Most of these parents did try to involve their children in some decisions within their daily lives, although they were much more likely to involve them in non-significant rather than significant decisions. Finally, even when involving their children in daily decision-making, the process for that involvement was geared towards maximum learning potential for their children by providing them with limited options from which to choose and fostering discussion and negotiation about those decisions.

This study clearly shows that the family context can play a crucial role in determining a child's decision-making abilities. While the results from this questionnaire study cannot be generalised to a wider population, they do provide some indication, especially when combined with the results from the focus group study, that these trends may not be unique to these study participants. In order to be sure that this is the case, a larger and statistically robust study would need to be conducted in which some of these concepts of child decision-making within the family context are examined in depth.

The ultimate goal behind this study and any similar study in the future, is to explore how knowledge of a child's decision-making experience within his family might help to influence when and how he should be involved in the decision-making process about medical research participation. Therefore, before recommending a larger questionnaire study regarding daily childhood decision-making, it was necessary to discuss these current findings with clinical professionals in the field of paediatrics in order to gauge their feelings on how it relates to their views on assent. The following chapter will present the outcome of a multi-disciplinary discussion panel where these issues were debated.

Chapter 5. APPLICATION TO CLINICAL PRACTICE: A MULTI-DISCIPLINARY PAEDIATRICS PANEL

5.1 Introduction

Chapter 2 outlined the ethical basis for why children should be involved in the decision-making process about their participation in medical research. Then, **Chapters 3 and 4** described two empirical studies, one focus group study and one questionnaire study, which were conducted in the attempt to better understand childhood decision-making in the family context. In paediatrics the family context is important, as past research has demonstrated that a child's decision-making role within his family unit has a direct influence on his interest in and capacity for participation in the medical decision-making process[22,25,110,120,129,131,132]. These studies were designed and conducted in order to examine the way in which children make decisions in their daily lives, in the hopes of learning more about the decision-making dynamic between parents and their children. With all of the confusion in the medical community surrounding the concept of assent, learning more about the child's role in decision-making within his family might aid clinicians in developing more detailed guidance on how and when to involve an individual child in the decision-making process about his participation in medical research. Therefore, if better understanding of how children are involved in daily decision-making within their families can be achieved, progress can be made in the development of improved guidelines for assent[20,123,135].

After concluding the analysis of study data from the focus group and questionnaire studies, a multi-disciplinary discussion panel was convened to present these research findings to experts within the field of paediatrics. This discussion panel was designed

primarily to determine whether these research findings may have implications for clinical practice. In addition, although there is a large body of literature regarding children's rights and the importance of involving children in medical decision-making, there is a shortage of data on whether there has been an appropriate translation to clinical practice[108]. Therefore, there were two objectives for the panel discussion: to learn from paediatric clinicians and nurses about their current assent practices for both treatment and research in comparison to existing recommendations in the various medical guidelines, and then to discuss what potential changes could be implemented in either their clinical practice or the guidelines to improve the overall process of child assent.

The information learned during this discussion panel represented an opportunity for quality improvement of a current clinical practice: assent. It was thus seen as a service development activity with NHS employees, rather than a formal study, and consequently no ethical approval was required. However, this should not indicate a lack of concern for the safeguarding of the panel participants. While there were no formal consent procedures followed prior to beginning the multi-disciplinary panel discussion, participation in the discussion was completely voluntary and participants were advised that they were free to leave at any time. When participants were invited to attend, they were informed of the objectives of the meeting, and they were reminded of these objectives at the beginning of the discussion. Furthermore, all participants were aware of the fact that an audio-recording was being made and that the issues under discussion would be used to form written recommendations regarding the improvement of the assent process, including but not limited to the completion of a Doctor of Philosophy degree from the University of Oxford. Given that all participants were experienced medical professionals who had familiarity

with consent procedures in clinical treatment or research, the objectives of the panel discussion were known to all participants, and their presence at the meeting was voluntary, the moderators felt comfortable proceeding with the panel discussion even in the absence of formal ethical approval or informed consent.

5.2 Multi-Disciplinary Discussion Panel

5.2.1 Methods

5.2.1.1 Moderation and facilitation

The multi-disciplinary panel was led by a trained moderator. The moderator was responsible for directing the discussion panel, ensuring that the conversation ran smoothly.

5.2.1.2 Topics covered by the discussion panel

The multi-disciplinary discussion panel had two components: a series of questions related to the concept of assent and a presentation of the research which has been described in this thesis. The questions that were posed to the panel participants belonged to four main topic groups: their current understanding of assent, the degree to which they currently involve children in the decision-making process in their respective clinical practices, what motivates them to involve a child in the decision-making process, and how the results from this research might be applied to clinical practice to improve the understanding or usage of assent. A list of the questions posed to the multi-disciplinary panel participants is included in Appendix 11. Participants in the discussion panel were specifically asked about their understanding of assent in order to explore one of the principal problems with assent in its current form: the accepted definition of assent does not provide sufficient

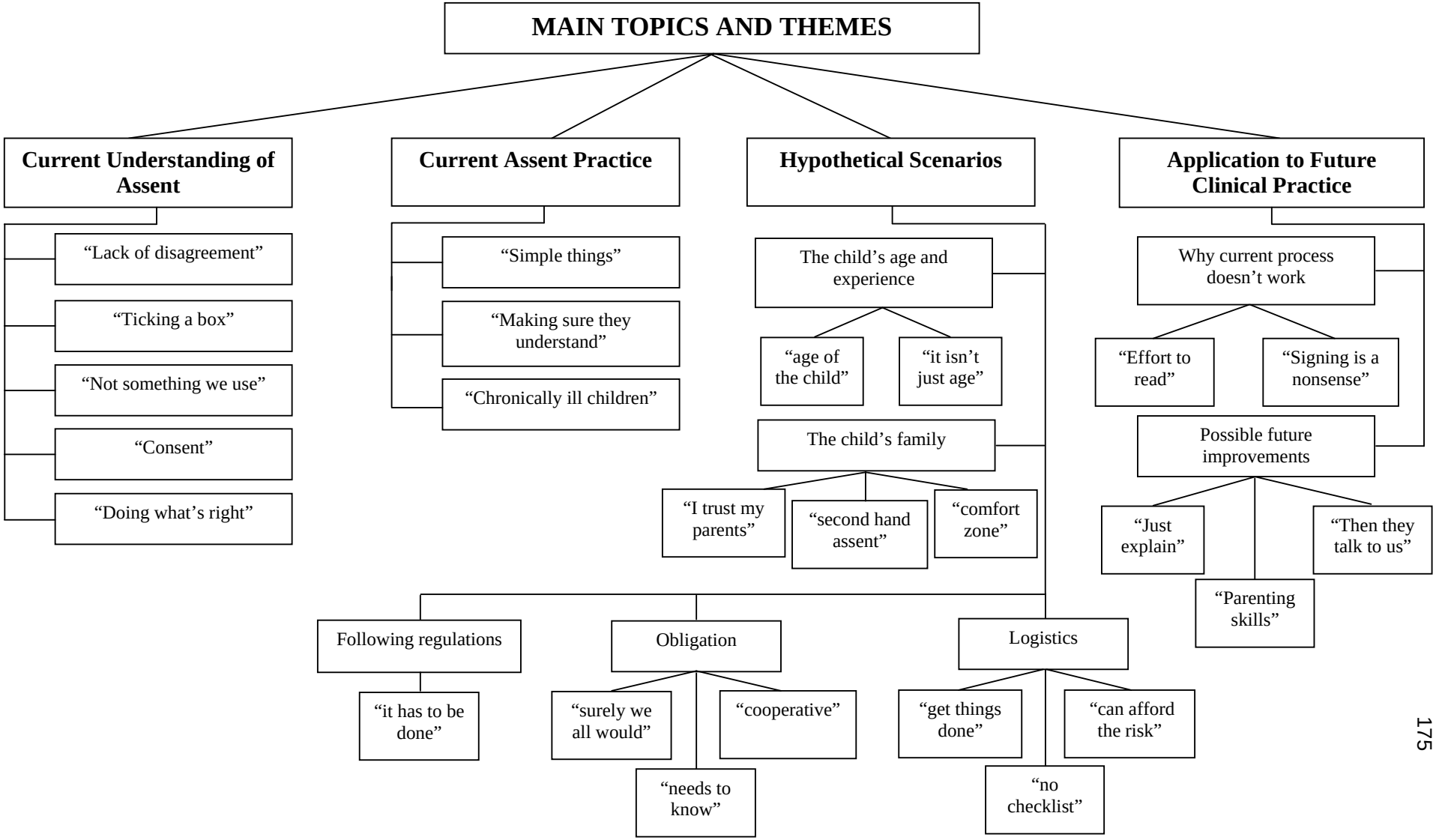
detail to ensure a standardized interpretation. It was also important to ask participants to discuss the ways in which they currently promote child decision-making within the medical context in order to get a sense as to whether they valued the true notion of assent. If the current guidelines are modified to clarify the definition and desired application of assent, it will lose its impact if the very people who are expected to implement those guidelines, medical professionals, do not believe assent to be an important part of the interaction with their paediatric patients. Finally, prior to developing recommendations for improved clinical practice it was essential to discuss the possibilities on a practical level with those who would be directly affected, thus elevating the issue from a purely theoretical level.

5.2.1.3 Transcription and analysis

The panel discussion was audio-recorded using a digital audio recording device. Upon the conclusion of the panel, a complete transcript of the discussion was typed, using this audio recording. The transcript was then entered into the computer program NVivo 8 for analysis. The audio recording was compared with the typed transcript to verify that the transcript was correct and to allow the listener to become fully immersed in the data prior to analysis. Once the transcript was verified as accurate, the panel discussion was ready to be coded and analysed.

Analysis of the panel data was conducted for each of the four main topic groups that were covered during the discussion. (See Figure 5 for a chart of all topics and themes from the multi-disciplinary discussion panel).

Figure 5 – Multi-Disciplinary Discussion Panel: Main Topics and Themes



5.2.1.4 Participants

The discussion panel was held at the John Radcliffe Hospital in Oxford on October 22, 2012. Participants were recruited through emails sent to doctors and nurses from the Department of Paediatrics at the University of Oxford and/or the Oxford Radcliffe Hospitals NHS Trust. There were 17 attendees of this panel, all of whom were associated with the Department of Paediatrics at one of these institutions. Of the 17 participants, 6 were Consultant Paediatricians, 4 were Junior Doctors (1 Clinical Lecturer, 1 Specialist Registrar in Paediatrics, and 2 Clinical Research Fellows), and 7 were nurses. These participants represented a breadth of paediatric specialities, from infectious diseases to haematology/oncology to paediatric intensive care. In addition to these clinical specialists, an Ethics Fellow from the Ethox Centre and the Institute of Science and Ethics at the University of Oxford was also in attendance as an observer.

The vast majority of the panel participants had clinical experience in both research and treatment settings, with the exception of 2 nurses. As discussed in **Chapter 1**, the concept of assent exists in both treatment and research. The important difference is that in the treatment setting, assent is a recommended practice but is not required for a treatment to go forward, as a child's assent can be overridden by parents and clinicians[84,104,105]. In the clinical research setting, on the other hand, a child's dissent should prevent him from being enrolled in the research study[84]. Clearly, based on the current debates about assent in the literature[20,22-44], the concept of assent is confusing enough to the medical community at large. The difference between how assent is involved in treatment and research further complicates the issue as many clinicians who are involved in clinical research also have duties in the treatment or non-research realm of paediatrics. Therefore, clinical specialists

from both treatment and research were included in this discussion panel, in order to get a complete picture of current assent practices and how these could be improved upon in the future.

5.2.2 Discussion Panel

5.2.2.1 Current Understanding of Assent

At the beginning of the meeting, prior to any presentation or discussion, participants were asked to share their understanding of assent. The definition of assent found in the literature is "a child's affirmative agreement to participate in research"[8]. However any review of the literature on assent will illustrate that, although this definition is accepted, in practice clinicians have numerous interpretations of assent beyond "a child's affirmative agreement to participate". The responses from the participants in this panel discussion were no different. Doctors who were involved in clinical research were familiar with the term assent, and had prior experience with obtaining assent from research participants, however their explanations of assent were not only different from the official definition in the literature but also different from each other's. One doctor stated that assent is "*a lack of disagreement*" (Consultant Paediatrician). This statement is actually in direct contrast to written guidance in the literature which specifies that assent is not just the lack of dissent[120,123]. Another doctor described her experience with assent on a previous clinical trial:

> "*We did assent them. We ticked a box…I was just making sure they understood what their parents were signing them up for*." (Specialist Registrar in Paediatrics)

Once again, this interpretation of assent is not in harmony with the actual definition of the concept in existing guidelines. Here, this doctor was describing what appears to be a pure

regulatory formality, rather than an opportunity for the child to be actively involved in the decision-making process and to voice his own opinion regarding the proposed research participation. Furthermore, this statement implies that the children in question were most likely led to believe that their parents were making the decision to "sign them up" for the study, without a possibility for them to disagree. This then could be seen as a form of coercion as past research has shown children to be very likely to obey adult authority: in this case their parents[20,45,52,68,80,126,133,134].

Although the definitions of assent that were provided by the doctors regarding clinical research may seem flawed in comparison with the guidelines, the information provided from the perspective of clinical treatment was even further from the accepted definition. One clinician with extensive experience in both research and treatment declared:

> "*I don't think I've ever heard the word being used on a ward in my life.*" (Consultant Paediatrician)

Another doctor elaborated on this thought, stating:

> "*It's not something we use in clinical practice…Instead of assent I think people use the word consent. Presumably they use those synonymously*." (Consultant Paediatrician)

As already discussed in **Chapter 1**, consent and assent are two very different concepts, regardless of whether they are used in the treatment or research settings. In fact, they are separate elements within the enrolment process. Yet this doctor voiced the opinion that they are viewed as synonymous or equal concepts in clinical practice, confusing them just as some researchers have in the literature[70,79-82]. A third doctor explained why she thought a difference in assent between treatment and research exists:

> "*In the clinical setting you're not really giving people much of a choice. This is what's in your best interests… I think a lot of clinical medicine's not about assent. It's about doing what's right for the person so that they get better*." (Specialist Registrar in Paediatrics)

This statement is a very practical view and illustrates why there is confusion regarding assent. Assent as "affirmative agreement" is essentially a choice made by the child, and therefore some clinicians may not see where assent fits into their clinical practice. In the treatment setting, a clinician aims to treat the child patient to improve his health in some capacity. Thus, there is not room for a child to choose whether or not that treatment should happen. On average, children are not emotionally or developmentally equipped to provide their own informed consent[3,4], and therefore the clinician, in cooperation with the parents, attempts to act in the best interests of that child to provide care with the aim of ultimately improving his health outcomes. The involvement of the child in the treatment decision may therefore seem less important to the clinician than the primary aim of treating what ails him.

5.2.2.2 Current assent practice

Based on the initial comments regarding assent in the treatment setting, it would seem as though children under the care of these paediatric specialists have very little voice in the treatment decisions made for their medical care. However, it was unclear whether the usage of the word "assent" may have been confusing the issue slightly, or whether these clinicians truly do not involve their child patients in the decision-making process. To discover which possibility was correct, the panel participants were instructed to forget for a moment the word "assent" and to comment on whether they involve children in the decision-making process in their clinical practice. As it turns out, when the participants spoke about their actual clinical practice, rather than concentrating on the specific word

"assent", they gave plenty of examples of opportunities when children might be allowed a voice, if not an actual choice, in their treatment decisions. One doctor described an example of the type of choice she often gives her paediatric patients:

> "*Simple things like which hand do you want me to put the cannula in? Do you write with your left or right hand? You don't give them that option [of saying neither]. It's left or right. Sometimes…they just pull their hand away. And you say, well we have to put it in but you get to choose which one*." (Clinical Lecturer)

Other basic choices that were given as examples were: "*the timing of a procedure being done or how long it's going to take*" (Senior Staff Nurse in Paediatric Intensive Care Unit), or "*do you want tablets or syrups*" (Clinical Lecturer). One doctor voiced a perfect summary of a child's potential involvement in decision-making within the typical treatment setting:

> "*You agree with the parents for the decision, the treatment plan, but the child is then given the choice within that, if it is possible to have a choice*." (Consultant Paediatrician)

The participants were in agreement that their child patients are not given the freedom to make the final decisions about whether they receive treatment for their ailment, but differences in their perspectives on the degree of the child's involvement in treatment decisions emerged based on their specific sub-specialities of Paediatrics. For example, a Specialist Registrar in Paediatrics who concentrates mainly in Emergency and Intensive Care described why she is less inclined to offer treatment choices to her patients:

> "*We make the decision that is clinically in the child's best interests and present that to the parents. Often there is no choice. This is the plan of action…So I don't think that the child's really involved. It's more that you're just explaining. Once you've got parental consent you're explaining what you're going to do which will hopefully reduce their anxiety*." (Specialist Registrar in Paediatrics)

From her standpoint, the number one priority is to treat the patient. In an emergency or more urgent setting, the clinician is more likely to concentrate on how to meet the clinical best interests of the patient, rather than risk the potential delay of treatment in the pursuit of a child's participation in the decision. On the other hand, another doctor described why this might be different when treating a child with a chronic or long-term illness:

> "*I think it becomes more relevant with…the chronic children who have long-term health issues and the diabetics. I think you'd be more likely to talk to them about options and involve them. Rather than the acute setting where it's not essentially relevant because you have to deal with an acute problem*." (Clinical Research Fellow)

A consultant who works mainly with chronic illnesses agreed with this point of view. When asked what methods she uses to involve children in the decision if it's a possibility within their treatment plan, she stated:

> "*Sometimes we say, well we could press on for another few months and see if this gets better if you really work hard at your drinking and toileting or we can add in some medicines now and the advantages and disadvantages. And quite often with children they'll have a strong view of what they want as much as the mother. A situation like that where it's not…urgent. You're just talking it through with them. It's a question of saying these are the options, this is what we can do for now, and…taking into account their views as much as their mum or dad's views*." (Consultant Paediatrician)

Even when an actual choice is not given to the child, the panel participants expressed their aim to involve the child by explaining to them the reasons why the treatment is being done:

> "*You have to explain what you are going to do. They may have had it done before and they don't want it, and you may have to sort of say look you have to do this and here's the reason why it has to be done and perhaps there might be some options on the way it's done, and a time that suits them as well*." (Senior Staff Nurse in Paediatric Intensive Care Unit)

This sentiment was echoed by one of the clinicians who stated:

> "*It's more about making sure that they understand in the clinical setting*." (Consultant Paediatrician)

Based on the dialogue during this discussion panel, it would seem that the first priority for these clinicians is to develop an appropriate treatment plan that serves the clinical best interests of their patients. If, when forming that treatment plan, an opportunity arises where a choice can be made that would not hinder or delay that treatment, they are then happy to let their paediatric patients make that decision. Past research with clinical staff has found similar results. In one study, clinicians reported that they were more likely to acquiesce to a child patient's wishes on decisions such as how they spend their time and what food they eat, but were much less likely to allow the child to make a decision related to his clinical care[176].

5.2.2.3 Hypothetical Scenarios

After this initial discussion of their current clinical practice regarding assent and child involvement in medical decision-making, several hypothetical scenarios were presented to the panel. These scenarios were designed to allow the participants to talk through whether they would involve the child in the medical decision-making process, and if so, what aspects of the child or the treatment would motivate the clinicians to do so. There were four scenarios presented to the participants:

1. A chronically ill child requires a planned or ongoing treatment/intervention that he has experienced before;
2. A child requires an immediate treatment that is not immediately life-threatening;
3. A child is a potential participant in a clinical research project for an experimental treatment, when all other treatment options have been exhausted; and

4. A child is a potential participant in a clinical research project that may not immediately or directly affect him.

Each scenario was presented to the panel, at which point there was a discussion regarding whether they would involve the child in the decision to begin the treatment or research regimen. In general the responses to these four different scenarios were fairly similar and followed five recurring themes regarding child involvement in the medical decision-making process: the child's age and experience, the child's family, following regulations or protocol, obligation, and logistics.

First of all, several participants mentioned a child's age as a factor behind their motivation to involve or exclude a child from the decision-making process. However age was mentioned more as a proxy measure for maturity or decision-making ability rather than as a specific cut-off point. In fact, a child's prior experience was also mentioned as a factor that is as important as a child's age, if not more so, in determining whether to involve him in the decision. This trend has been cited in prior research as well[108,167]. One doctor explained why a child's prior treatment experience is an important factor in whether she includes the child in the decision:

> "*Obviously age is relevant, but it isn't just age. Because if you've got a child who's been aware of and understood the treatment they've received before, then clearly you're going to be having a discussion with them about the fact that you're going to recommend they have some more treatment. So if you had a child who realised what they'd been through before you would always discuss it with them*." (Consultant Paediatrician)

In this example it is clear that the doctor recognizes that a child's past experience with a specific treatment will affect his ability to discuss the possibility of receiving additional treatment. Here, his prior knowledge of the treatment is likely to be more valuable in

enabling him to participate in any discussions about the treatment than his chronological age necessarily would be.

A second theme that emerged from the discussion was related to the child's family. In some cases the participants described how their involvement of the child in clinical decisions is often led by either the child or his family. One doctor described her experience with paediatric treatment discussions:

> "*There are some children I would say in my experience that are absolutely heads down and just want the communication to be with their parents, or their carers. Maybe it's a bit led by the parents who are then saying actually we don't want you to be involved, to the child. And then there's the complete opposite where the child is very involved and you have all your discussions together even though some of them may be quite tricky... Some of them make it very clear, maybe verbally or nonverbally that actually they don't want that discussion with you and that they'd like their discussions to be from their parents…some of them say well I know about this but I suppose they are saying but I trust my parents to make the right decision.*" (Consultant Paediatrician)

In this situation, this clinician is happy to follow the cues from the child himself, or from his parents, rather than make a blanket decision to include or exclude all children in the decision-making process based on age or any other piece of demographic information. Another doctor mentioned that he often seeks guidance from the parents regarding the child's involvement in the decisions:

> "*We do second hand assent as well because often they are too scared or nervous to talk to us so the parents will tell us yes they're fine or yes they prefer cold spray, or we've talked about this…The parents will say oh we've talked about this and I think the child will prefer this. Or, knowing them they would prefer this way.*" (Clinical Research Fellow)

These clinicians are clearly following what they think is the best course of action based on prompts from the child and/or his family. In fact, another doctor mentioned that by forcing

a child's involvement in the decision-making process, a clinician could actually cause more harm than good:

> "*You could potentially make it more traumatic for a child if you try and impose some sort of preconceived idea of the information they should have…that it turns out is not age appropriate. That child's greatest comfort zone with responsible parents is in their hands and not in your trying to get their assent. So you could, if you're not led by the parents, make it a more difficult and traumatic experience.*" (Consultant Paediatrician)

This viewpoint is quite interesting and is perhaps overlooked in much of the current debate over child involvement in medical decision-making. There is a strong emphasis on involving the child in the decision-making process because their involvement is seen as beneficial to the child in some way. However the statement from this doctor demonstrates that this involvement may not always be in the child's best interest. Another doctor shared a concrete example of how this could be true:

> "*Somebody was told that one of the drugs might affect his child's liver and then it was fed back to us that actually [the child] was very worried because he thought he was going to have to have a liver transplant.*" (Consultant Paediatrician)

This description of a recent misunderstanding by one of her paediatric patients is a clear illustration that providing a child with detailed information about his medical treatment is not necessarily acting in his best interests. In this situation the child was likely subject to additional stress and emotional trauma due to his confusion about the medical information that had been provided to him. If the clinician is allowed the freedom to follow cues from the child and his parents regarding whether the child should be involved in the decision-making process, it may well be easier to avoid potential misunderstandings such as in this example.

Participants in the discussion panel also mentioned that they are motivated to involve the child in the decision-making process purely in the interest of following regulations or the research protocol. It is important to note that these comments were made specifically in reference to the two scenarios involving research. No mention of rules or regulations was made regarding the clinical treatment scenarios. When asked what would motivate them to involve a child in the decision to enrol in a clinical research study, one Paediatric Research Nurse replied:

> "*The majority of the time you have to. You don't have a choice if it's a school-aged child then it would be in the protocol that you have to involve them*." (Paediatric Research Nurse)

Interestingly, this nurse did not mention anything regarding a benefit to the child or how any aspect of the child or his family would motivate her to involve him in the discussion regarding his proposed participation in the research study. Instead, the driving motivation for his involvement in the decision-making process is the assent requirement in the protocol. Another nurse mentioned a similar motivation for child involvement in the research enrolment process:

> "*Sometimes the studies specify that it has to be done. So whether or not the child is taking in the information for what they…say is appropriate for 6 to 10 year olds, they are still required to sign an assent form before they can take part in the study*." (Paediatric Research Nurse)

This description portrays one of the main problems with an age cut-off for assent. If assent is a mandated process for all children of a certain age, research study staff members would be forced to provide information to all children within that age range, regardless of whether the information is understood or desired by that child. As already mentioned above, some children do not want to be involved in the medical decisions that affect them and other children may be traumatised by receiving information that is misunderstood.

Requiring study staff members to provide previously determined information to the child and involve him in the medical decision removes their ability as paediatric professionals to judge whether those actions would be appropriate for that specific child and his family.

A fourth theme that emerged from the discussion of the hypothetical scenarios was the feeling of obligation regarding the involvement of children in discussions of their medical treatment. One doctor stated quite clearly that involving the child in the discussion about his clinical experience is presumably an obvious action by any clinical professional:

> "*Surely we all would involve a child in what we're doing to them. I would like to think that. And then when it becomes something where there isn't necessarily one right and one wrong way to do it then…give them an opportunity to maybe choose. Say choose a ward, choose how an antibiotic is given. You know, when it's not for certain that there's one better way or worse way*." (Consultant Paediatrician)

This comment demonstrates her assumption that all good clinicians should want to involve their paediatric patients to some degree in the discussion of their proposed treatment. However it is important to note that her definition of involvement does not necessarily mean that the child is given a choice. Rather, she is merely stating that the child is a person, not an object, and therefore should be recognised during the treatment discussion. She then clearly states that a child may be given an opportunity to make a choice regarding his treatment only in certain circumstances when there is not an obvious best course of action. Other participants mentioned the necessity of involving children with chronic illness in the discussions regarding their treatment. Their feeling was that involving the child will instil in him a sense of ownership over his treatment which may help with the child's long-term compliance.

> "*With children that are chronically ill, they're coming back over and over …you want them to be as cooperative as possible with all of the interventions that are going to happen so if you involve them then they are going to feel like they have more control and they are going to comply better with the treatment that you're actually offering, both in the hospital setting and at home*." (Paediatric Research Nurse)

> "*It's easy to make someone do something over a period of a few days, but if you have to get them to take the medication on time all the time for years on end, then part of it is to make them feel happy and be involved…So, it is actually looking after their best interests by not forcing them in some circumstances*." (Clinical Lecturer)

Here, these participants are discussing their obligation as clinicians and carers to involve the child in his treatment in order to safeguard his clinical best interests. However, just as in the previous example, neither one of these paediatric experts mentioned the word "choice" in their statements. They feel an obligation to involve the child in some capacity in his own treatment but only in order to gain the child's cooperation with the aim of ensuring his compliance to the treatment. Presumably, they are proposing the child's involvement with the established treatment plan, and are not seeking the child's opinions regarding what course of treatment should be pursued. On the other hand, in reference to the two scenarios involving clinical research, participants expressed a sense of obligation to involve the child in the actual decision to enrol in the proposed research study:

> "*I think it's more important that you involve the child in that scenario…because the child needs to know that it's not going to benefit him*." (Consultant Paediatrician)

> "*Especially if you have to do invasive things…extra blood tests that aren't clinically relevant. You wouldn't normally be doing all those blood tests but you're doing it as part of the trial*." (Clinical Lecturer)

Here these clinicians are describing how the nature of clinical research is a motivating factor for them to include the child in the decision-making process. In the clinical setting, the effectiveness of various treatment regimens is already identified; but in the research

setting, this information is not yet known. Therefore it is possible that a research participant may not gain any benefit from his inclusion in the study. Paediatric research is of course highly regulated to minimise any potential risks to the research participants. However, due to the fact that the study may not provide the child with a direct benefit to his health, and may also subject him to additional procedures that may not be clinically necessary, it is understandable why these clinicians would feel an obligation to include the child to some degree in the decision-making process.

The last theme that became apparent from the group discussion involved the logistics of involving a child in the decision-making process. When considering the treatment scenarios, several doctors commented that due to time constraints in the clinical environment, they are often only motivated to provide additional information to their paediatric patients in the presence of dissent:

> "*I think the reality is that we give much more information only when we encounter dissent in the immediate setting because you need to get things done. It's when you encounter dissent that you stop and you have to go back and say well this is why we're doing things and you go through a more detailed process.*" (Clinical Research Fellow)

> "*You would only do that if the child asked you why are you doing this. And you say it's to check your blood cells or it's to check on your kidneys or check to see if you have an infection or something like that. You would explain that to the child. But usually if they don't say anything then you just carry on.*" (Clinical Lecturer)

Their perspective is that if a treatment plan has already been established and the child appears satisfied to continue, there is no immediate need to delay the treatment to provide additional information to him. This is especially relevant in an urgent or emergency setting. Conversely, in the research setting there is not necessarily a time restraint

concerning the beginning of the intervention and therefore the clinician may feel more able to involve the child in the decision-making process:

> "*There's also less to lose from the clinical researcher's point of view at this stage. When you've got a child on the ward…trying to think of the optimum way of getting to the end that I think is right, with the least hassle, trauma, whatever else. [In research], if the child participates or not…you know it makes less difference. So you can afford to run the risk in a way of finding out about dissent or assent*." (Consultant Paediatrician)

These clinicians are expressing the very real logistical issue of time management that is an important indicator for the quality and breadth of any clinician-patient dialogue. While the participants in this discussion panel all expressed an interest in involving their child patients in some aspect of the treatment discussions, the fact remains that if there is an insufficient amount of time in which to engage the child, whether due to the urgency of the treatment or the schedule of the clinician, they are more likely to move forward with the treatment plans in the absence of child involvement in that decision. The research setting, on the other hand, is seen as a clinical area where there is potentially more time available, perhaps during the consent process, and therefore the clinician can make a greater attempt to start a dialogue with the child without the worry of treatment delay due to the child's possible dissent. Another logistical issue mentioned during the discussion was the difficulty for the clinician of judging an individual child's understanding of the material presented to him. One doctor expressed the following concern:

> "*I don't think all of the facts…about the treatment a 10 year old would want to have or even should have, but it's not like we have a checklist to see what they've understood*." (Consultant Paediatrician)

Paediatric specialists are accustomed to working with children, however that does not mean that they are specialists in child behaviour, psychology, or communication. Therefore, even when the clinician is motivated to include a child in the decision-making

process, he is not necessarily equipped to determine whether that child has actually understood the information presented to him.

5.2.2.4 Application to Clinical Practice

Once the discussion of the hypothetical scenarios was completed, there was a presentation of data from the ethical and empirical research on assent and child decision-making within the family context that has been described in this thesis. After the presentation, the final portion of this multi-disciplinary discussion panel was an opportunity for the group to consider how this information might be able to be applied to clinical practice. In the discussion that followed, the two main topics were related to the current assent process and why that system does not work and advice for the future and how the assent process might be improved.

First of all, panel participants discussed their thoughts on why the current assent process might not be successful. Several clinicians commented on problems they see with the methods used in the average research setting: providing the child with written information to read and asking the child to demonstrate his agreement by signing a form. In their experience, children do not always want to read the information provided to them:

> "*I had lots of children just hand it straight back and say I don't want to look at that because it had words on it which was effort to read*" (Consultant Paediatrician)

In clinical research, study teams often are expected to mirror the informed consent process when designing their plans for assent. So, just as an adult is provided with a written information sheet, a potential child participant is given written information that he is

expected to read prior to being asked to agree to study participation. While this information is expected to be written at an age-appropriate level, it may not be presented in a way that all children of that age group can understand or process. Furthermore, it is not clear that a written information sheet is the best way to provide children with information[101,133,186]. As this Consultant Paediatrician stated, in his experience not all children are interested in reading the information that is provided to them. If the child refuses to read the information about the proposed research study but is within the age range where assent is required, can it really be said that the child has granted "assent" if he agrees to participate in the study? Several clinicians also commented on the requirement by many ethics committees that a child document his assent by signing a form:

> "Consultant Paediatrician: *The process of signing is a nonsense, because that's not what it should be about. That's all to do with research protection so they can tell the ethics committee that they've done something*.
> Clinical Research Fellow: *How do you prove they were assented? A signature on a form doesn't prove anything*."
> Consultant Paediatrician: "*Particularly when it's a six year old's signature.*"
> (Clinical Research Fellow, Consultant Paediatrician)

Once again, these examples illustrate the attempt by many ethics committees to model assent after the current informed consent process. As these clinicians are rightly pointing out, it is unlikely that a young child will understand the meaning of placing their signature on a form, or that he will even have a signature to use. This aspect of the current assent process is purely a regulatory formality so that the research team can provide evidence that the required procedures were followed. Detailed paper documentation of clinical research is necessary in order to ensure the integrity of the research and the protection of the research participants, but it is also important that these procedures have a meaningful purpose. In this case, a child's signature on an assent form does not carry the same weight

as an adult's signature on a consent form due to the simple fact that most children will not comprehend the legal implications of placing a signature on a form[71,97].

The panel discussion also covered ideas for how the assent process might be improved in the future. One clinician suggested that agreement should be removed from the concept of assent:

> "*I don't like the bit about agreement being in it. Because if you're going to stick a needle in a child anyway why would you ever ask for their agreement because then you're just undermining them by still going ahead when they say no. Surely you've got to just explain to them what you're going to do and why, not ask for their agreement.*" (Consultant Paediatrician)

This comment was made in reference to the treatment setting, where a child's wishes can be overridden if the treatment is determined to be in the child's best interests, but this model could be applied to clinical research as well. The concept of assent could be changed to be the involvement of the child in the decision-making process, rather than the act of obtaining the child's agreement. The child's involvement could then be modified based on the clinician's judgment of the child's interest, maturity, and experience, the interaction with the parents, and the specific type of treatment or research in question. In fact, some of the participants stated that in their current practice, they judge a child's assent not by their agreement but by their actions. For example, one nurse described a common scenario in her experience when taking blood from a child:

> "*If they give you their arm, even if they're pulling away, I will say to them well you've given me your arm and if it doesn't hurt then would you be happy for me to do it and they'll say yes.*" (Paediatric Research Nurse/School Nurse)

A doctor shared a similar story regarding blood tests in young children:

> "*When we were doing blood tests on 5 year olds, the assent was that they weren't running away from you and you had 3 people holding their hand. So they might not be happy but if they did it they were assenting. But if you had to have a parent, an auntie and a neighbour holding the child down they probably weren't assenting*." (Clinical Lecturer)

These paediatric experts are describing interactions that they have experienced in their clinical practice where they used their best judgment of the child and the specific situation to determine whether to continue with the planned procedure, in these cases a blood test. They recognised that although the child in front of them might not be happy about the concept of a blood test, if he willingly offered his arm and did not attempt to escape from their presence, that behaviour could be considered assent, even in the absence of a verbal agreement from the child. This practice of evaluating a child's actions over his words has also been recommended in child protection literature[63].

Another idea that was shared as a possible way to improve assent in the future was to think of assent as an ongoing process that involves the wider clinical team, rather than a discrete event occurring between one clinician and the child. A Clinical Research Fellow stated his view of how, in his experience, assent includes the interactions between the nurse and the child as well as any communication that he has with the child.

> "*There's a gap…which I think is often made up by the nurses…The nurses will speak to the patient, and do a lot of it for us. So maybe we don't appreciate as much of the assent that goes on because a lot of it is done by the nurses. When they're putting the [anaesthetic] cream on…I think they're a big part of the assent process that happens*." (Clinical Research Fellow)

This clinician is recognising that there are other members of the clinical staff who are also interacting with the child and that this additional communication should be considered as

part of the assent process, rather than the one specific point in time where he as a clinician is supposed to be gaining the child's formal assent. Several of the nurses agreed with this statement, sharing examples from their experience regarding additional communication they had with children beyond the initial doctor to family interaction:

> "*You would go around the wards at night and that's when they'd talk to us and then we'd relay it back in the morning. So they are embarrassed to talk to doctors. They do sometimes see you initially as somebody you can't ask questions to, you're very high authority-wise. But then they talk to us and we relay it back…they just need to understand what's going on and then they're ok usually with it. I think we just explain it on their terms*." (Paediatric Research Nurse/School Nurse)

> "*I think whenever there's been a consultation or something being done to the child, you reiterate what the doctor said, perhaps slightly different language, you know a different point of view, just change it slightly so they can have a better understanding*." (Senior Staff Nurse in Paediatric Intensive Care Unit)

These examples illustrate that in current practice, assent is not the discrete event that it first appears to be. Although a clinician may be obtaining a child's assent before the commencement of a treatment or research study, it is likely that other members of the clinical team will also be interacting with the child during which time additional information may be exchanged. If that additional information is given to help inform the child and potentially make him more receptive to the intervention in question, then surely that communication should also be classified as part of the assent process. This is similar to recommendations from past research, suggesting that more members of the wider clinical team should interact and communicate with the child in the attempt to explain a specific treatment or procedure and consequently ease any of the child's potential anxiety[7].

Finally, several participants observed that the success of an interaction with a paediatric patient or research participant often hinges on his family dynamic. A consultant stated:

> "*It seems to me this is really sort of tied up with parenting skills…It's the sort of teamwork that you have, you know between professionals and the family which includes the child, or not, and it seems to me it's very integrally related to the parenting skills of the individual families*." (Consultant Paediatrician)

Another doctor agreed with this statement, adding a similar view from her experience:

> "*The kids that really struggle and play up it's often when you haven't got good support from the parents*." (Specialist Registrar in Paediatrics)

These views indicate that when attempting to communicate with a child regarding a potential treatment or research procedure, some sort of an evaluation of the family context is important before proceeding. As discussed during the hypothetical scenario, these paediatric experts often follow cues from the child and his family regarding how to involve the child in the overall decision-making process. Therefore this would seem to be a reasonable recommendation to include in any guidelines for the assent process. The child is accustomed to a specific communication and decision-making dynamic which is set by his parents or caretakers and dictated by their own personal parenting styles. For the communication between clinician and paediatric patient to be successful, it seems logical that the clinician should at least take into account the child's family dynamic and modify his communication style accordingly.

5.3 Conclusion

This multi-disciplinary discussion panel was an opportunity to discuss the concept of assent with working experts in the field of paediatrics. Through this discussion it was possible to learn about their current experiences with assent, and to examine ways in which the assent process could be improved. If the experiences shared by these paediatric specialists are any indication of the wider paediatric field beyond the Department of

Paediatrics at the Oxford Radcliffe NHS Trust or the University of Oxford, there are several clear ways in which the assent process could be improved as it relates to both treatment and clinical research.

In clinical practice, the clinician can provide treatment without the child's agreement, if he is acting in the child's best interests and has the consent of the parents[84,104,105]. Therefore it is understandable that many of the participants in this discussion panel do not use the term "assent" in their clinical practice, nor do they attempt to obtain the child's agreement prior to formulating the clinical treatment plan. As discussed, in situations where there is one clearly superior treatment available, the clinician does not want to ask the child's opinion. If the child's agreement is sought, the clinician then runs the risk of obtaining the child's dissent rather than assent, at which point he then must override the child's wishes in order to continue to offer the best clinical care possible. Instead, the participants in this discussion panel explained that they will try to involve the child in other ways: by explaining the proposed treatment plan and why it is necessary, or giving the child specific choices within the treatment plan such as which hospital ward he will stay in or from which arm a blood sample will be taken. In clinical research, on the other hand, regulations state that the research should not proceed in the face of a child's clear dissent, and therefore the research team is required to document the child's assent as part of the enrolment process[94,103]. This documentation is often alarmingly similar to informed consent, involving the provision of an information sheet to the child and the collection of his signature on an assent form. However it is unreasonable to expect that the assent process should mirror the informed consent process. Adults and children have different cognitive capacities and the expectations from informed consent and assent reflect that. As

with the treatment setting, it should be possible to involve the child in the decision-making process regarding his potential enrolment in the research study, without expecting that involvement to match the informed consent procedures. Instead, there should be a concentration on involving the child in the overall enrolment process so that he can learn about the decision that is being made. For example, when discussing the study with the family, the clinician can direct some of his speech towards the child rather than directing all of his communication to the parents. This interaction can be tailored to the individual child and situation and can also involve other members of the clinical team who may be able to describe the procedures in a slightly different way; with the result that the child may be able to process more of the information.

As part of the discussion of how the guidelines on assent could be improved, one participant made a simple comment:

> "*Surely the guidelines should just say something like you know, use your common sense and involve children as much as possible.*" (Clinical Lecturer)

This is, of course, an unrealistic suggestion as it would raise numerous logistical issues. Each clinician might have a different definition of "common sense" and in clinical research there still must be some recommendations in the guidelines for the appropriate procedures to follow as all aspects of a research project should be clearly documented and standardised as much as possible. However it seems that there should be some attempt to capture the sheer simplicity of this suggestion in any revision of the guidelines on assent. Rather than placing the emphasis on obtaining a child's agreement to procedures that he may not be equipped to fully understand and to which he may not be allowed to refuse due to the possibility of his wishes being overridden, why not instead define assent as the

involvement of a child in the decision-making process. The degree of that involvement could then be a judgment call on behalf of the clinical team, based on their impression of the child's ability and interest, the interaction with the parent and/or family members, the degree of urgency of the treatment or research, and the duration of the intervention. Perhaps if assent were considered to be merely a way in which a child can be involved in the discussion, without expecting a specific response from him, a higher quality and more rewarding interaction could be achieved between the clinical team and their paediatric patients.

Chapter 6. CONCLUSION

6.1 Setting the Scene for Future Research

The practice of assent in clinical research is a way in which some children are included in the decision-making process regarding their participation in a particular research study. While in theory this is a positive goal, current guidelines for paediatric clinical research do not provide clear directions for how the process of assent should be handled[10-13,17]. They recommend that the researcher obtain a child's assent based on his age, maturity, and capacity of understanding the research in question. Unfortunately they do not provide researchers with further instructions for how this should be accomplished. This lack of clarity has led some researchers to recommend different age-related cut-offs for when a child should be asked to assent[9,46], and has allowed individual researchers and local Research Ethics Committees to determine their own methods for how assent should be facilitated[68,69]. The current lack of standardisation in the guidelines and the widespread confusion among the very clinical personnel who are responsible for obtaining this assent, make it unlikely that the assent process will be successful as it is currently defined.

Establishing an age limit for assent would make it simple for clinicians to determine which of their patients and potential research participants should be asked to provide assent. Yet this would also remove the responsibility of the investigator to engage with each child during the overall enrolment process[62]. An age limit for assent would also mean that some children without the appropriate level of developmental capacity would be asked for their assent while other children for whom assent might be meaningful would be denied the opportunity to participate[1,16,31,59-61]. If children who are not capable of decision-making, whether due to immaturity, low cognitive function, or paternalistic family dynamic, are

asked for their assent, this assent will lack its current basic purpose, to gain a child's agreement to participate, and will become purely a regulatory formality[1,16,31,59-61].

The tendency for many researchers and ethics committees to conflate assent with consent is further confusing the current situation[70,79-82]. While it is understandable for the desire to establish some method of documenting assent as a component of the enrolment process for paediatric clinical research, it is a mistake to attempt to model assent after consent, complete with written information forms and the requirement of a child to sign an assent form as documentation of his assent. Assent is meant to serve a different purpose than consent[90]. The child is not expected to understand the details of the proposed research and its risks and benefits as he is not being asked to make an informed decision to participate. Instead, assent is a way in which the child can be involved in the discussion of matters that affect him, demonstrating respect for the child as a person, rather than respect for his various developmental processes such as his developing autonomy[66,120]. When working with children, the concept of respect for the person requires that a healthy balance be found between respect for the child's developing autonomy and the protection of the child's best interests[187]. Assent, or involving the child in the decision-making process, is essentially a compromise between these two positions: allowing a child to become involved in the decisions about matters which affect him, thus recognising his developing autonomy, while not actually granting him any additional self-determination rights, thus maintaining the overall protection of his best interests provided by his parents or caretakers. On the other hand, consent gives the clinician a legal right to proceed with the research and therefore it is reasonable to require detailed documentation of this process. Furthermore, an adult's signature holds a legal significance because he understands the

meaning of placing his signature on a document. As it has already been established that a child is not sufficiently competent to make his own legally binding decision to provide informed consent, it is not appropriate to assume that he will understand the legal significance of placing his signature on a form to document his provision of assent[71,97].

The existing uncertainty surrounding assent in paediatric clinical research has led to the conduct of a large body of research dedicated to the discovery of when a child should be asked for his assent to research participation. It is likely that additional research will continue to be performed in pursuit of an answer to this question. However it seems clear that no suitable answer will appear while assent remains in its present definition. If the main motivation for the existence of assent were to fulfil a regulatory requirement for research, then it would be reasonable to continue to aim for the establishment in the guidelines of a defined age limit for assent and a clear set of procedures to follow in the implementation and documentation of this process. Yet, in the analysis of the ethical grounding for assent presented in this thesis, it is evident that the actual motivation for assent stems not from the regulatory realm but from the philosophical. In fact, the ethical justification of assent arises from the researcher's dual obligations to the child's parents and to the child himself. A child's parents are responsible for determining when and how he will develop his decision-making ability throughout his childhood, and the researcher has an obligation to the parents to respect their pedagogical role, engaging with the child in a manner that compliments his parents' pedagogical style. At the same time, the researcher also has an obligation to the child to treat him as a being of moral worth, thus teaching him that he is of moral value.

Accepting this ethical justification for assent would lead to a different mechanism for determining which children should be asked to provide assent. If the ethical justification for assent were found in respect for the child's developing autonomy, it would then be reasonable to conduct further research with the aim of identifying an appropriate age limit for assent where the majority of children above that boundary would have sufficiently developed cognitive capacities to warrant asking them for assent. However, with the ethical justification for assent proposed in this thesis, that it allows the researcher to fulfil his obligations to both the child and his parents, the entire definition of assent as it is currently known would come into question. Instead of viewing assent as the "child's affirmative agreement to participate in research"[8], assent should be defined as the method by which the child is involved in the overall decision-making process, or the way in which the clinician engages with the child. The investigator would then be left to determine how that involvement would occur based on numerous factors including the child's age and experience, the nature of the proposed research, and the child's family context. The emphasis here would be on engaging with the child rather than an attempt to get the child to agree to the research. This revised definition would remove the focus on the search for a method to identify which children should be involved in the assent process. Instead, when confronted with the question of how we can determine a child's ability to assent, the clear answer would be that all children should be involved in the process, regardless of "ability". However the degree of that involvement would vary substantially between individual children, from a simple soothing interaction between the researcher and very young child prior to initiating a procedure to including a more developed child as an active participant in the discussion with his parents or caretakers. It would be impossible to completely standardise this process as the very factors on which the child's involvement would be based are individual to each child and each research study. Nonetheless, if the

guidelines were modified to clearly state this new definition of assent and that an investigator should aim to include all children in the decision-making process to some degree, as appropriate, this would go a long way toward resolving the current confusion regarding assent. Furthermore, this same definition of assent could easily be extended beyond clinical research to other disciplines involving children including clinical treatment and social science research.

The empirical research studies that were described in **Chapters 3 and 4** of this thesis were conducted in order to learn more about the family context of a child's daily decision-making. Past research has suggested that a child's family context can influence his ability to participate in decision-making within the medical setting and therefore it was necessary to explore how children are involved in daily decision-making within their families[20,123,135]. While the results of these studies cannot be generalised to all children, the common themes identified in the data analysis of both studies indicate that some of the identified trends may extend beyond this study population. The children in these studies clearly did make decisions in their daily lives and furthermore they desired to have the opportunity to make decisions about matters which affected them. On the other hand, they did not express an interest in having complete control over their daily lives. They recognized the ultimate authority of their parents and were often happy to accept decision-making guidance from them. Data collected from their parents provided a complementary perspective to this. The parents were aware of their authoritarian role within the family context however they also actively taught their children about decision-making by explaining their own decisions even when their children were not allowed to participate in the actual decision-making process. Most of the parents also tried to involve their children

in some decisions within their daily lives, although they were much more likely to involve them in non-significant decisions rather than significant decisions. This involvement was usually structured to provide their children with limited options from which to choose and to encourage discussion and negotiation between the parents and their children.

If the results from the focus group and questionnaire studies give any indication of potential trends in the wider arena beyond the participants in these studies, it seems clear that children should be involved in the decision-making process for research participation and that this involvement should be the extent of their assent, rather than expecting the children to make a specific decision. The children in these studies expected their parents to provide them with decision-making guidance in most aspects of their life. It would therefore be unreasonable to think that they would necessarily disagree with their parents regarding research participation. Instead they would be much more likely to acquiesce to the wishes and guidance of their parents, causing that affirmative agreement to participate to be less about actual agreement and more about meeting a regulatory formality. By changing the definition of assent to mean the involvement of a child in the overall decision-making process, without expecting an individual response, this will likely be mimicking a familiar decision-making setting from their family context where their parents will involve them in decision-making by guiding their decision and encouraging discussion and negotiation.

Based on the discussion with clinical experts in the field of paediatrics during the multi-disciplinary panel, clearly some clinicians in both treatment and research settings are already using a modified definition of assent in practice. Rather than treating assent as a

child's affirmative agreement, many of these clinicians described their current interactions with child patients and research participants in terms of simple involvement in the decision-making process. In most cases they did not actually state that the children were given a choice regarding the initiation of the treatment or research procedure in question. They did describe ways in which they might attempt to give children smaller decisions, where applicable, such as the arm used to provide a blood sample, or the method by which a medication was provided. However in most scenarios that arose during the panel discussion, the clinicians said that they did not expect a child to make an independent decision regarding his medical care. Instead, they described numerous factors that they as clinicians use to determine how and to what extent an individual child should be involved in the decision-making process: the child's age, experience, and interest in participating in the process, his interaction with his parents, and the specific type of treatment or research in question.

The current confusion surrounding the assent process has resulted in a broad divergence in the expectations of how assent should be approached and documented. This disparity can be seen both in the requirements of individual ethics committees and in the performance of individual researchers[20,22-44,78]. It is evident that in order to resolve this problem, the current guidelines on assent must be clarified and revised. The experiences described by the members of the multi-disciplinary panel discussion illustrate avenues that should be explored in the attempt to improve the assent process. Many of the clinicians admitted that they rarely, if ever, encountered the term "assent" in their clinical practice and furthermore that they were unlikely to document the solicitation of a child's agreement in their clinical notes. The clinical staff members who were active in clinical research, on the other hand,

stated that their practice of assent was dictated by the specific research protocol or instructions from the ethics committee. In an effort to reach some degree of standardisation in the practice of assent between treatment and research settings, and consequently improve both the understanding and implementation of assent within paediatrics, the existing guidelines should be modified to encourage clinicians to document their interactions and discussions with their child patients, both in the clinical notes in the treatment setting and in the clinical trial paperwork in a research study. The current expectation within clinical research of obtaining a child's signature on a form to document his assent does not prove anything other than that the child obeyed directions from his parents and/or doctor. Giving the clinician researcher the format to instead document the child's assent through a brief description of his interaction and/or discussion with the child would be much more successful in providing evidence that the process of assent actually took place. Furthermore, if this type of description were considered good clinical practice in both the treatment and research settings, it is likely that some of the current confusion surrounding when assent is required would be minimised.

Secondly, as mentioned in the discussion panel, dialogue with a child patient will often take place through several different staff members. For example, the treating physician may initially describe the treatment plan with a child, but a nurse is likely to explain the procedure again, in slightly different language, while interacting with the child at a different time such as during the administration of a blood test. The fact that this interaction already occurs on a usual basis within both treatment and research settings should be capitalised on in the implementation and documentation of assent. Allowing the child to interact with different members of the clinical team, and encouraging those

individuals to not only engage with the child and discuss the procedure, research, or treatment in question but also to document the nature of that discussion in the clinical notes or on clinical research paperwork, would ensure that an accurate picture of the entire assent process would be available. In this case, a formal assent form complete with signatures such as is commonplace in current clinical research would be unnecessary. Instead, the assent could be documented through a collection of notes from all of the clinical staff who engaged with the child in a discussion of the proposed research or treatment. These notes would serve as a much more accurate representation of the assent process that actually took place with that individual child.

Clearly, further research in the field of assent is necessary before any permanent changes to the guidelines or clinical practice will be made. The findings from this body of research merely shine a light on areas which would benefit from improvement. While we strongly believe that the definition of assent should be changed to mean the process by which children are involved in the decision-making process to some degree, this method would need to be tested in a formal research environment to ensure that its application to clinical practice was feasible and that all stakeholders in the clinician-child-parent communication triad were comfortable. Although the current literature illustrates the lack of consensus within the medical community about how assent should be facilitated, the amount of attention that it continues to receive is encouraging as this exemplifies the importance that children and their best interests hold to experts throughout paediatrics.

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Appendix 1 – Focus Group Study: Consent Form for Child Participants

Childhood Decision-Making: A Series of Focus Groups

Consent Form

Child's full name: Participant code: |____| |____| |____|

If you agree with each statement please initial in each box below;

I confirm that I have read *Childhood Decision-Making: A Series of Focus Groups Information Sheet – Parent of Child Participant, Version 3 dated 1st July 2010.* I have had the opportunity to consider the information, discuss the study, ask questions and have had these answered satisfactorily. ☐

I understand that data collected during the study may be looked at by authorised individuals from the University of Oxford, Research Ethics Committee, and study monitors where it is relevant to my child'staking part in this research. I permit these individuals access to my child's research records. ☐

I understand that my child's participation is voluntary. I am free to withdraw my child from the study at any time, without having to give a reason for leaving and without affecting my child's legal rights. ☐

I agree to the audio recording of the focus group discussion. ☐

I understand that the audio recording of the focus group discussion, any transcripts or notes taken by the moderator or assistant moderator, and any personal details will be stored in a secure location at the Oxford Vaccine Group. ☐

I understand that at the successful completion of the focus group discussion, my child will receive a certificate for participation. ☐

I have discussed the study with my child and they are happy to participate. ☐

If all of the above are initialled, meaning "yes", then please continue:

I voluntarily agree to my child taking part in this study. ☐

Name:

Relationship to Child:

Signature:..... Date: |___ ___| |___ ___| |___ ___|

I, ..., verify that the child has given verbal assent for participation.

Investigator's name:

Signature: ..... Date: |___ ___| |___ ___| |___ ___|

Appendix 2 – Focus Group Study: Child Questioning Route

1. Tell us your first name and what your favourite food is.

2. What do you like to do in your free time after school and on the weekends?

3. What does it mean if someone asks you to choose?

4. [Start discussing real-life examples when the children may have been asked to choose something]
    a. When you get ready to go play with your friends, how do you choose what you wear? Do your parents ever dislike the clothes that you choose?
    b. Do you choose what you eat for breakfast? For lunch? For dinner?
    c. Do your parents like you to eat some food that you don't like? What happens – do you eat that food? Why do your parents want you to you eat it?
    d. Do you want to eat other food that your parents don't like you to eat? What happens – do you eat that food?
    e. Do you watch TV or play computer games at home? Do your parents ask you to turn off the TV or computer while you are using it? When your parents ask you to turn it off, how long do you wait before turning it off?
    f. Have you ever missed a day of school because you were unwell? When that happened, who said you should stay at home – you or your parents?
    g. How do you decide what films you watch or games you play – do your parents rent/buy them for you or do you choose the ones that you want?

5. You've talked about a lot of choices that you make, with and without your parents. What happens when you choose – do you talk it over with your parents before you choose?

6. [If it hasn't been discussed already] What do you do when you want to make a different choice than your parents want?

7. Do you want to make more choices on your own without your parents' help?

8. [Moderator or Assistant Moderator summarises the discussion that has taken place] Is this what we talked about today? Did we talk about anything else?

9. Is there anything that you think we should have talked today but didn't?

Appendix 3 – Focus Group Study: Parent Questioning Route

1. Tell us your first name and something that you enjoy doing with your child or children.

2. Do you give your children an allowance and if so, at what age did you start this? How do your children decide what to spend their money on? [If there are parents of older children, prompt group to comment on any changes in spending patterns as children have matured.]

3. Would you say that a child's age is an appropriate measure of their developmental ability or maturity?

4. [Depending on the answers to the previous question: Are there certain ages where a shift in development or maturity seems more pronounced?]

5. Do your children make their own decisions about things in their daily lives? If so, what do they make decisions about?

6. Think about your daily lives with your family – do you guide your children's decision-making process, letting them think they are making a decision when in fact you led them to make that decision?

7. What do you do when you and your children disagree on a decision?

8. Do you think children are capable of making decisions about their healthcare?

9. [Moderator or Assistant Moderator summarises the discussion that has taken place] Was this an accurate summary of what we discussed today?

10. Is there anything that you think we should have talked about in this discussion but didn't?

Appendix 4 – Focus Group Study: Primary School Educator Questioning Route

1. Tell us your name and what you most enjoy about working with children.

2. How do you evaluate your students' progress in your classes?

3. Think back over the classes you have taught in the last few years. Would you say that a child's age is an appropriate measure of their developmental ability or maturity? [Prompt for details in answers, beyond yes and no.]

4. [Depending on the answers to the previous question: Are there certain ages or grade levels where a shift in development or maturity seems more pronounced?]

5. In your experience as an educator, do you see children making decisions? If so, tell us some examples of decisions that they make. [Prompt for examples at different grade levels, depending on the experience of the group.]

6. What do you do if you disagree with one of your students about a decision that they have made?

7. In your opinion, are children capable of making decisions about their healthcare? [Prompt for details in answers, beyond yes and no.]

8. [Moderator or Assistant Moderator summarises the discussion that has taken place] Was this an accurate summary of what we discussed today?

9. Is there anything that you think we should have talked about in this discussion but didn't?

Appendix 5 – Questionnaire Study: Consent Form for Child Participants

Childhood Decision-Making: Parent and Child Questionnaires

Consent Form

Child's full name: Participant code: |____| |____| |____| |____|

If you agree with each statement please initial in each box below;

I confirm that I have read *Childhood Decision-Making: Parent and Child Questionnaires Information Sheet – Parent of Child Participant, Version 2 dated 22nd September 2011*. I have had the opportunity to consider the information, discuss the study, ask questions and have had these answered satisfactorily. ☐

I understand that data collected during the study may be looked at by authorised individuals from the University of Oxford, Research Ethics Committee, and study monitors where it is relevant to my child'staking part in this research. I permit these individuals access to my child's research records. ☐

I understand that my child's participation is voluntary. I am free to withdraw my child from the study at any time, without having to give a reason for leaving and without affecting my child's legal rights. ☐

I understand that the paper questionnaire and any personal details will be stored in a secure location at the Oxford Vaccine Group. ☐

I understand that at the successful completion of the questionnaire small group session, my child will receive a certificate and stickers for participation. ☐

I have discussed the study with my child and they are happy to participate. ☐

If all of the above are initialled, meaning "yes", then please continue:

I voluntarily agree to my child taking part in this study. ☐

Name: Relationship to Child: Signature:..... Date: |___ ___| |___ ___| |___ ___|
I, ..., verify that the child has given verbal assent for participation. Investigator's name: Signature: ..... Date: |___ ___| |___ ___| |___ ___|

Appendix 6 – Questionnaire Study: Child Questionnaire

1. How old are you? _____

2. Are you a boy or a girl?
   - ☐ Boy
   - ☐ Girl

3. Who lives in your house? (tick all boxes that apply)
   - ☐ Mum
   - ☐ Dad
   - ☐ Step-mum
   - ☐ Step-dad
   - ☐ Grandmother
   - ☐ Grandfather
   - ☐ Aunt
   - ☐ Uncle
   - ☐ Brother. If yes, how many brothers? ____

   How old are your brothers? _____

   - ☐ Sister. If yes, how many sisters? ____

   How old are your sisters? _____

   - ☐ Other_____

4. Who chooses to take you to the doctor when you are sick?

   - ☐ parent/guardian
   - ☐ brother/sister
   - ☐ me
   - ☐ other_____

5. Who tells you when you need an injection?
   - ☐ parent/guardian
   - ☐ brother/sister
   - ☐ me
   - ☐ other_____

6. Do you have to go to the doctor even if you would rather not?
   - ☐ Always
   - ☐ Most of the time
   - ☐ Sometimes
   - ☐ Never

7. Would you like to choose if you see the doctor?
   - ☐ Yes
   - ☐ No

8. Do you have to go to bed at a certain time?
   - ☐ Yes
   - ☐ No

9. Who tells you when it's your bedtime?
   - ☐ parent/guardian
   - ☐ brother/sister
   - ☐ me
   - ☐ other_____

10. Do they make you go to bed at this time?
    - ☐ Always
    - ☐ Most of the time
    - ☐ Sometimes
    - ☐ Never

11. Would you like to choose what time you go to bed on a school night?
    - ☐ Yes
    - ☐ No

12. Would you like to choose what time you go to bed on a weekend or holiday?

- ☐ Yes
- ☐ No

13. If the person who looks after you needs to go food shopping, do you have to go with them?

- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

14. Would you like to choose whether you should go food shopping with them?

- ☐ Yes
- ☐ No

15. Do you choose your breakfast from the shop or the cupboard?

- ☐ Shop
- ☐ Cupboard

16. Do you have to eat it?

- ☐ Yes
- ☐ No

17. Would you like to choose your own breakfast from the shop?

- ☐ Yes
- ☐ No

18. Who chooses what you eat for dinner or tea?

- ☐ parent/guardian
- ☐ brother/sister
- ☐ me
- ☐ other _____

19. Do you have to eat what you are given?

- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

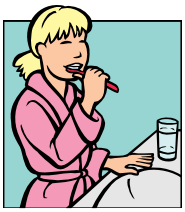
20. Would you like to choose what you eat for dinner or tea?
- ☐ Yes
- ☐ No

21. Who chooses what you buy for snacks?
- ☐ parent/guardian
- ☐ brother/sister
- ☐ me
- ☐ other _____

22. Would you like to choose for yourself what you buy for snacks?
- ☐ Yes
- ☐ No

23. In the morning and evening, do you always remember to clean your teeth?
- ☐ Yes
- ☐ No

24. Do you have to clean your teeth in the morning and evening?
- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never



25. Would you like to choose for yourself if you clean your teeth?
- ☐ Yes
- ☐ No

26. Do you go to church/temple/mosque?
- ☐ Yes
- ☐ No

27. If your parents or guardians go to church/temple/mosque, do you have to go with them?
- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

28. Would you like to choose if you go to church/temple/mosque?
- ☐ Yes
- ☐ No

29. If you get invited to a friend's birthday party, who decides if you go?
- ☐ parent/guardian
- ☐ me
- ☐ both

30. If you don't want to go to the party, do you have to go?
- ☐ Yes
- ☐ No

31. Would you like to choose if you go to the party?
- ☐ Yes
- ☐ No

32. Do you have family days out?

- ☐ Yes
- ☐ No

33. Do you choose where to go on family days out?

- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

34. Do you like spending time with just your family?

- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

35. Would you like to choose if you should go on family days out?

- ☐ Yes
- ☐ No

36. Do you often play games with your parents and brothers or sisters?

- ☐ Yes

☐ No

37. Who chooses the game?

☐ parent/guardian

☐ brother/sister

☐ me

☐ other_____

38. Do you have to play games with your family?

☐ Always

☐ Most of the time

☐ Sometimes

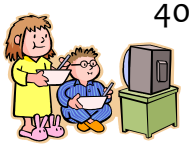
☐ Never

39. Would you like to choose if you play games with your family?

☐ Yes

☐ No

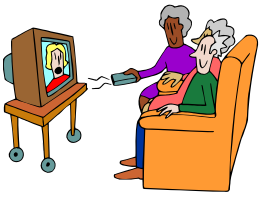
40. Do you need permission to watch television/DVDs?



☐ Yes

☐ No

41. Who chooses what you watch?



☐ parent/guardian

☐ brother/sister

☐ me

☐ other_____

42. Would you like to choose what you watch on television?

☐ Yes

☐ No

43. Do you need permission to turn on the computer?

☐ Yes

☐ No

44. Who chooses what you play?

- ☐ parent/guardian
- ☐ brother/sister
- ☐ me
- ☐ other_____

45. Would you like to choose what you play on the computer?
- ☐ Yes
- ☐ No

46. Do you get pocket money?
- ☐ Yes
- ☐ No

47. Do you have to check with your parents or guardians before using your pocket money?

- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

48. Do you choose what to buy with your pocket money?

- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

49. Would you like to choose what you buy with your pocket money?
- ☐ Yes
- ☐ No

50. Do you do activities or clubs after school or at weekends? (e.g. sports, music, ballet)
- ☐ Yes
- ☐ No

51. Who chose these activities for you?
- ☐ parent/guardian
- ☐ brother/sister
- ☐ me
- ☐ other_____

52. Do you always have to go to the activities?
- ☐ Yes
- ☐ No

53. Could you stop the activities if you wanted to?
- ☐ Yes
- ☐ No

54. Do you have to practice for these activities?
- ☐ Yes
- ☐ No

55. Would you like to choose to take part in these activities?
- ☐ Yes
- ☐ No

56. Who decides what clothes you buy?
- ☐ parent/guardian
- ☐ brother/sister
- ☐ me
- ☐ other _____

57. Do you like the clothes?
- ☐ Yes
- ☐ No

58. Would you like to choose what clothes to buy?
- ☐ Yes
- ☐ No

59. Do you have household jobs?
- ☐ Yes

☐ No

60. If yes, which ones have you done? (tick all that apply)

☐ Helping with the dishes

☐ Take out rubbish

☐ Tidying room

☐ Laying the table

☐ Clearing the table

☐ Making my bed

☐ Dusting / Vacuuming

☐ Shopping

☐ Hanging the washing

☐ Other_____

61. Who decides when you help with household jobs?

☐ parent/guardian

☐ brother/sister

☐ me

☐ other_____

62. Would you like to choose if you help with household jobs?

☐ Yes

☐ No

63. If a friend asked you to do something fun that you wanted to do, would you ask anybody if you could do it?

☐ Yes

☐ No

64. If yes, who would you ask?

☐ Parent/guardian

☐ Brother/sister

☐ Other_____

65. If they said no, would you still do it?
- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

66. Would you like to have the choice to do it?
- ☐ Yes
- ☐ No

67. If a friend asked you to do something you were unsure about, would you ask anybody if you could do it?
- ☐ Yes
- ☐ No

68. If yes, who would you ask?
- ☐ Parent/guardian
- ☐ Brother/sister
- ☐ Other_____

69. If they said no, would you still do it?
- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

70. Would you like to have the choice to do it?
- ☐ Yes
- ☐ No

71. Do you think your parents or guardians let you make decisions?
- ☐ Always
- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

72. Do you sometimes need help making decisions?

- ☐ Yes
- ☐ No

73. If yes, what helps you make the decision?

- ☐ Understanding the problem
- ☐ Talking to parent/guardian
- ☐ Talking to brother/sister
- ☐ Talking to friends
- ☐ Remembering something good or bad that happened last time
- ☐ Remembering helpful comments from last time

Appendix 7 – Questionnaire Study: Parent Questionnaire

1. Who lives in your home? (tick all boxes that apply)

☐ Partner/Spouse ☐ Mother/Mother-in-law ☐ Father/Father-in-law ☐ Sister/Sister-in-law
☐ Brother/Brother-in-law ☐ Other adult _____
☐ Male Children If yes, how many? ____ Ages of male children: _____
☐ Female Children If yes, how many? ____ Ages of female children: _____

2. Please list your children's ages, and continue to answer questions for each child in the relevant column.	**Child 1 – ___ years old**	**Child 2 – ___ years old**	**Child 3 – ___ years old**
3. Who identifies that your child needs to see a doctor if they are unwell? (tick all that apply)	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____
4. If your child refuses to go to the doctor would you make them go?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
5. Who would enforce that decision? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
6. Does your child have a bedtime?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
7. If yes, does your child have to go to bed then?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
8. If your child is unwilling to go to bed then, who enforces this bedtime? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
9. When you go food shopping, do you often take your child with you?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

	Child 1	Child 2	Child 3
10. If yes, does your child have to go with you?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
11. Does your child choose what they eat for breakfast?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
12. If no, does your child have to eat what is given to them?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
13. If your child is unwilling to eat their breakfast, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
14. Does your child choose what they eat for dinner?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
15. If no, does your child have to eat what is given to them?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
16. If your child is unwilling to eat their dinner, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
17. Does your child choose what they eat for snacks?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
18. If no, does your child have to eat what is given to them?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
19. If your child is unwilling to eat their snacks, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____

	Child 1	Child 2	Child 3
20. In the morning and evening, do you have to remind your child to clean their teeth?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
21. If your child is unwilling to clean their teeth, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
22. Do you go to church/temple/mosque regularly?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
23. If yes, does your child have to come with you?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
24. If your child is unwilling to go, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
25. Do you let your child go to every birthday party they are invited to?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
26. Does your child have to go to the birthday parties?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
27. If your child is unwilling to go to the party, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
28. Do you have family days out?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
29. If yes, does your child have to go on the family day out?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
30. If your child is unwilling to go on the family day out, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____

	Child 1	Child 2	Child 3
31. Does your child play games with you or your other children?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
32. Who chooses the games? (tick all that apply)	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____
33. Does your child have to play the games?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
34. If your child is unwilling to play the games who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
35. Does your child need to check with you before watching a programme on television?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
36. If yes, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
37. Does your child need to check with you before playing on the computer?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
38. If yes, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
39. Do you give your child pocket money?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
40. If yes, do you let your child choose what to buy with their pocket money?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never

	Child 1	Child 2	Child 3
41. Does your child do extra-curricular activities? (e.g. sports, music, ballet)	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
42. If yes, who chose for your child to start the activity? (tick all that apply)	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child ☐ child's sibling ☐ other adult_____
43. Does your child have to participate in the activity?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
44. Does your child have to practice for the activity?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
45. If your child is unwilling to practice for or participate in the activity, who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
46. Do you let your child choose what clothes to buy?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
47. If no, who chooses them? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____
48. Does your child have to help with household jobs?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
49. If yes, which ones do they help with? (tick all that apply)	☐ Rubbish ☐ Tidying room ☐ Making bed ☐ Laying the table ☐ Clearing the table ☐ Washing up ☐ Dusting/Vacuum ☐ Shopping ☐ Laundry ☐ other _____	☐ Rubbish ☐ Tidying room ☐ Making bed ☐ Laying the table ☐ Clearing the table ☐ Washing up ☐ Dusting/Vacuum ☐ Shopping ☐ Hanging washing ☐ other _____	☐ Rubbish ☐ Tidying room ☐ Making bed ☐ Laying the table ☐ Clearing the table ☐ Washing up ☐ Dusting/Vacuum ☐ Shopping ☐ Hanging washing ☐ other _____
50. Who enforces this? (tick all that apply)	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____	☐ me ☐ other parent ☐ child's sibling ☐ other adult_____

	Child 1	Child 2	Child 3
51. If asked by a friend, would your child undertake a fun activity that they wanted to do without asking for your permission?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
52. If asked by a friend, would your child undertake an activity they were unsure about without asking for your permission?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
53. Do you involve your child in decision-making for non-significant decisions? (e.g. decisions without foreseeable large consequences)	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
54. How do you involve your child in decision-making for non-significant decisions?	☐ With positive rewards (e.g. gift) ☐ With negative rewards (e.g. limit TV time) ☐ With limited options ☐ Negotiation	☐ With positive rewards (e.g. gift) ☐ With negative rewards (e.g. limit TV time) ☐ With limited options ☐ Negotiation	☐ With positive rewards (e.g. gift) ☐ With negative rewards (e.g. limit TV time) ☐ With limited options ☐ Negotiation
55. Do you involve your child in decision-making for significant decisions (e.g. decisions with potentially large consequences)?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
56. How do you involve your child in decision-making for significant decisions?	☐ With positive rewards (e.g. gift) ☐ With negative rewards (e.g. limit TV time) ☐ With limited options ☐ Negotiation	☐ With positive rewards (e.g. gift) ☐ With negative rewards (e.g. limit TV time) ☐ With limited options ☐ Negotiation	☐ With positive rewards (e.g. gift) ☐ With negative rewards (e.g. limit TV time) ☐ With limited options ☐ Negotiation
57. When you make a decision for your child, do you explain to your child why you have made that decision?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never
58. Does your child need help making decisions?	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never	☐ Always ☐ Most of the time ☐ Sometimes ☐ Never

59. What helps your child make decisions?	☐ Understanding the problem ☐ Talking with parent ☐ Talking with sibling ☐ Talking with friends ☐ Remembering past choices ☐ Remembering past advice ☐ other _____	☐ Understanding the problem ☐ Talking with parent ☐ Talking with sibling ☐ Talking with friends ☐ Remembering past choices ☐ Remembering past advice ☐ other _____	☐ Understanding the problem ☐ Talking with parent ☐ Talking with sibling ☐ Talking with friends ☐ Remembering past choices ☐ Remembering past advice ☐ other _____

Appendix 8 – Questionnaire Study: List of Child Self-evident Corrections

1. Question 3 – "Who lives in your house".
    a. For the section which asks "How old are your brothers/sisters" - If a child writes in an answer between 0 and 1 year, this answer will be coded as 1 year old.
    b. If a child writes in "Step-brothers" or "Step-sisters" in the "Other" category, these answers will be coded as "Brothers" or "Sisters".
    c. If a child writes in "Aunt" in the "Other" category, this answer will be coded as "Aunt".
2. Question 4 – "Who chooses to take you to the doctor when you are sick".
    a. If a child checks "Other" and writes in "Mum or dad", this answer will be assumed to be "Parent/Guardian" and will be coded accordingly.
3. Question 7 – "Would you like to choose if you see the doctor".
    a. If a child writes in the answer "Maybe" this answer will be assumed to be missing and will not be coded.
    b. If a child checks both "Yes" and "No" this answer will be assumed to be missing and will not be coded.
4. Question 8 – "Do you have to go to bed at a certain time".
    a. If a child writes in the answer "Around a certain time" this answer will be assumed to be a "Yes" and will be coded accordingly.
    b. If a child writes in the answer "sometimes", this answer will be assumed to be a "Yes" and will be coded accordingly.
    c. If a child checks "Yes" and "No", this answer will be assumed to be a "Yes" and will be coded accordingly.
5. Question 9 – "Who tells you when it's your bedtime". If a child checks "Other" and writes in "Dad and mum", this answer will be assumed to be "Parent/guardian" and will be coded accordingly.
6. Question 10 – "Do they make you go to bed at this time". If a child checks 2 answers, one for their boarding school and one for their home, the answer given for their home will be coded.
7. Question 11 – "Would you like to choose what time you go to bed on a school night".
    a. If a child checks the answer "Yes" and writes in "Maybe because otherwise there will be consequences of what I look like", this answer will be assumed to be "Yes" and will be coded accordingly.
    b. If a child writes in the answer "Sometimes" this answer will be assumed to be "Yes" and will be coded accordingly.
8. Question 12 – "Would you like to choose what time you go to bed on a weekend or holiday". If a child writes in the answer "Sometimes", this answer will be assumed to be "Yes" and will be coded accordingly.
9. Question 15 – "Do you choose your breakfast from the shop or the cupboard".
    a. If a child chooses both answers, this answer will be assumed to be "Shop" and will be coded accordingly.
    b. If a child writes in "Mum chooses" this answer will be assumed to be missing and will not be coded.
10. Question 16 – "Do you have to eat it".
    a. If a child writes in the answer "mostly", or "most of the time", or "sometimes", this answer will be assumed to be a "Yes" and will be coded accordingly.

    b. If a child checks “No” and writes in “Not all of it” or “Not always”, these answers will be assumed to be “No” and will be coded accordingly.
11. Question 18 – “Who chooses what you eat for dinner or tea”.
    a. If a child checks “Other” and writes in “Mum” this answer will be assumed to be “Parent/guardian” and will be coded accordingly.
    b. If a child checks the answers “Parent/guardian” and “Me” and writes in “Sometimes” next to “Me”, this answer will be assumed to be “Parent/guardian” and “Me” and will be coded accordingly.
12. Question 20 – “Would you like to choose what you eat for dinner or tea”.
    a. If a child checks the answer “Yes” and writes in “Maybe because if I choose what I want to eat then I’ll choose my favourite but it will get boring after a while”, this answer will be assumed to be “Yes” and will be coded accordingly.
    b. If a child checks “Yes” and “No” this answer will be assumed to be missing and will not be coded.
    c. If a child writes in the answer “Sometimes” this answer will be assumed to be a “Yes” and will be coded accordingly.
13. Question 22 – “Would you like to choose for yourself what you buy for snacks”.
    a. If a child writes in the answer “sometimes”, or “maybe”, this answer will be assumed to be a “Yes” and will be coded accordingly.
    b. If a child checks “Yes” and “No” this answer will be assumed to be missing and will not be coded.
14. Question 23 – “In the morning and evening, do you always remember to clean your teeth”.
    a. If a child writes in “Sometimes” this answer will be assumed to be a “No” and will be coded accordingly.
    b. If a child checks “Yes” and “No” this answer will be assumed to be missing and will not be coded.
15. Question 24 – “Do you have to clean your teeth in the morning and evening”. If a child checks both “Most of the time” and “Sometimes” this answer will be assumed to be “Sometimes” and will be coded accordingly.
16. Question 25 – “Would you like to choose for yourself if you clean your teeth”. If a child writes in the answer “Maybe, but I would anyway”, or “Sometimes” this answer will be assumed to be a “Yes” and will be coded accordingly.
17. Question 26 – “Do you go to church/temple/mosque”.
    a. If a child writes in “Sometimes”, this answer will be assumed to be a “Yes” and will be coded accordingly.
    b. If a child checks “Yes” and “No” and writes in “School sometimes, not home”, this answer will be assumed to be a “No” (as this questionnaire is interested in the family context not the school context) and will be coded accordingly.
    c. If a child checks “Yes” and “No”, this answer will be assumed to be missing and will not be coded.
18. Question 27 – “If your parents or guardians go to church/temple/mosque, do you have to go with them”.
    a. If a child checks “Always” and “Most of the time”, this answer will be coded as “Most of the time”.

    b. If a child checks “Always” and “Never” this answer will be assumed to be missing and will not be coded.
19. Question 28 – “Would you like to choose if you go to church/temple/mosque”.
    a. If a child checks “Yes” and writes in “Sometimes” this answer will be assumed to be “Yes” and will be coded accordingly.
    b. If a child checks “Yes” and “No” this answer will be assumed as missing and will not be coded.
20. Question 29 – “If you get invited to a friend’s birthday party, who decides if you go”. If a child checks “Parent/guardian” and “Me”, this answer will be assumed to be “Both” and will be coded accordingly.
21. Question 30 – “If you don’t want to go to the party, do you have to go”.
    a. If a child writes in the answer “Not sure” this answer will be assumed to be missing and will not be coded.
    b. If a child writes in “Sometimes”, this answer will be assumed to be “Yes” and will be coded accordingly.
22. Question 31 – “Would you like to choose if you go to the party”. If a child writes in the answer “Sort of”, this answer will be assumed to be missing and will not be coded.
23. Question 32 – “Do you have family days out”. If a child writes in the answer “sometimes” this answer will be assumed to be a “Yes” and will be coded accordingly.
24. Question 33 – “Do you choose where to go on family days out”. If a child checks two answers, “Most of the time” and “Sometimes”, the answer will be assumed to be “Sometimes” and will be coded accordingly.
25. Question 34 – “Do you like spending time with just your family”. If a child checks the answers “Always” and “sometimes” and writes that it is a spectrum between the two, this answer will be coded as “Sometimes”.
26. Question 35 – “Would you like to choose if you should go on family days out”.
    a. If a child writes in the answer “Sometimes” this answer will be assumed to be “Yes” and will be coded accordingly.
    b. If a child checks “Yes” and “No”, this answer will be assumed to be missing and will not be coded.
    c. If the child checks “No” and writes “Don’t know” this answer will be assumed to be missing and will not be coded.
27. Question 36 – “Do you often play games with your parents and brothers or sisters”.
    a. If a child writes in “Sometimes”, this answer will be assumed to be a “Yes” and will be coded accordingly.
    b. If a child checks “No” but writes in “apart from scrabble”, this answer will be assumed to be a “Yes” and will be coded accordingly.
28. Question 37 – “Who chooses the game”. If a child checks “Other” and writes in “Both”, this answer will be assumed to be missing.
29. Question 38 – “Do you have to play games with your family”.
    a. If a child writes in the answer “no” this answer will be assumed to be a “Never” and will be coded accordingly.
    b. If a child writes in the answer “I want to play with them”, this answer will be assumed to be N/A and will be coded accordingly.
30. Question 39 – “Would you like to choose if you play games with your family”.
    a. If a child checks the answer “Yes” and writes in “Sometimes”, this answer will be assumed to be “Yes” and will be coded accordingly.

   b. If a child checks “Yes” and “No” this answer will be assumed to be missing and will not be coded.
31. Question 40 – “Do you need permission to watch television/DVDs”.
   a. If a child writes in “Sometimes” this answer will be assumed to be “Yes” and will be coded accordingly.
   b. If a child writes in “Yes to DVDs and No to TV” this answer will be assumed to be “Yes” and will be coded accordingly.
32. Question 41 – “Who chooses what you watch”.
   a. If a child checks the answer “me” but writes in “I have to ask if it is okay to watch what I choose”, this answer will be assumed to be both “me” and “parent/guardian” and will be coded accordingly.
   b. If a child checks the answer “Me” but writes in “If it is suitable”, this answer will be coded as both “Me” and “Parent/guardian” as it is the parent/guardian who decides whether the programme is suitable.
33. Question 42 – “Would you like to choose what you watch on television”.
   a. If a child writes in the answer “Sometimes”, this answer will be assumed to be “Yes” and will be coded accordingly.
34. Question 43 – “Do you need permission to turn on the computer”. If a child writes in the answer “sometimes”, this answer will be assumed to be “Yes” and will be coded accordingly.
35. Question 44 – “Who chooses what you play”. If a child checks the answers “Me” and “Other” and writes in “Me” next to “Other” this answer will be assumed to be “Me” and will be coded accordingly.
36. Question 45 – “Would you like to choose what you play on the computer”. If a child writes in the answer “Sometimes”, this answer will be assumed to be “Yes” and will be coded accordingly.
37. Question 46 – “Do you get pocket money”.
   a. If a child checks “Yes” and writes in “Very rarely”, this answer will be assumed to be a “Yes” and will be coded accordingly.
   b. If a child writes in the answer “Sometimes” this answer will be assumed to be a “Yes” and will be coded accordingly.
   c. If a child checks “Yes” and “No”, this answer will be assumed to be missing and will not be coded.
38. Question 47 – “Do you have to check with your parents or guardians before using your pocket money”. If a child checks “Always” and “Never” this answer will be assumed to be missing and will not be coded.
39. Question 48 – “Do you choose what to buy with your pocket money”.
   a. If a child checks the answer “Always” but writes in “Unless useless”, or “Unless not allowed” this answer will be assumed to be “Most of the time” and will be coded accordingly.
   b. If a child checks the answers “Always” and “Sometimes”, this answer will be assumed to be “Sometimes” and will be coded accordingly.
40. Question 50 – “Do you do activities or clubs after school or at weekends”. If a child writes in the answer “Sometimes”, this answer will be assumed to be a “Yes” and will be coded accordingly.
41. Question 51 – “Who chose these activities for you”.
   a. If a child checks “Other” and writes in “Me and parents” this will be assumed to be “Parent/Guardian” + “Me” and will be coded accordingly.

   b. If a child checks the answer “Other” and writes in “Discuss”, this answer will be coded as “Parent/guardian” and “Me” as the child meant it was a discussion between them.

42. Question 52 – “Do you always have to go to the activities”.
   a. If a child checks “yes” as an answer and writes in the answer “Usually” or “Sometimes”, this answer will be assumed to be a “Yes” and will be coded accordingly.
   b. If a child checks “Yes” and “No” this answer will be assumed to be missing and not coded.
43. Question 53 – “Could you stop the activities if you wanted to”.
   a. If a child checks “Yes” and writes in “After we’ve stopped paying”, this answer will be assumed to be “No” and will be coded accordingly.
   b. If a child writes in “Sometimes” the answer will be assumed to be missing and will not be coded.
   c. If a child checks “Yes” and “No” this answer will be assumed to be missing and will not be coded.
   d. If a child writes in “Don’t know” this answer will be assumed to be missing and will not be coded.
44. Question 54 – “Do you have to practice for these activities”.
   a. If a child checks “Yes” and writes in “Mostly” or “Sometimes”, this answer will be assumed to be “Yes” and will be coded accordingly.
   b. If a child checks “Yes” and “No”, this answer will be assumed to be missing and will be coded accordingly.
45. Question 57 – “Do you like the clothes”.
   a. If a child checks both “Yes” and “No”, this answer will be assumed to be missing and will not be coded.
   b. If a child writes in the answer “Sometimes” or “Some of them”, this answer will be assumed to be missing and will not be coded.
   c. If a child writes in the answer “They’re ok. Old fashioned though” this answer will be assumed to be missing and will not be coded.
   d. If a child checks the answer “No” and writes “I do like my football shirts though” this answer will be assumed to be “No” and will be coded accordingly.
46. Question 58 – “Would you like to choose what clothes to buy”.
   a. If a child writes in the answer “Sometimes” this answer will be assumed to be a “Yes” and will be coded accordingly.
   b. If a child checks “Yes” and “No” this answer will be assumed to be missing and will not be coded.
47. Question 59 – “Do you have household jobs”.
   a. If a child writes in “Sometimes”, this answer will be assumed to be a “Yes” and will be coded accordingly.
   b. If a child checks both “Yes” and “No” but answers the subsequent questions as if they do have household jobs, this answer will be assumed to be “Yes” and will be coded accordingly.
48. Question 60 – “If yes, which ones have you done”.
   a. If a child checks “Other” and writes in “Unloading dishwasher”, this answer will be assumed to be “Helping with the dishes” and will be coded accordingly.
   b. If a child checks an answer and writes in “Sometimes” next to it, this will be counted as a household job.

    c. If a child checks “Other” and writes in “I do lots” this will not be counted as a household job.
49. Question 62 – “Would you like to choose if you help with household jobs”.
    a. If a child writes in the answer “Maybe”, this answer will be assumed to be “Yes” and will be coded accordingly.
    b. If a child writes in the answer “Sometimes, when it seems like fun”, this answer will be assumed to be “Yes” and will be coded accordingly.
    c. If a child checks both “Yes” and “No”, and writes in the answer “I don’t like them, but I like being helpful”, or just checks “Yes” and “No”, this answer will be assumed to be missing and will be coded accordingly.
50. Question 63 – “If a friend asked you to do something fun that you wanted to do, would you ask anybody if you could do it”.
    a. If a child checks the answer “No” but writes in “But maybe mum and dad though”, this answer will be assumed to be “Yes” and will be coded accordingly.
    b. If a child writes in “Sometimes”, this answer will be assumed to be “Yes” and will be coded accordingly.
    c. If a child checks both “yes” and “no”, this answer will be assumed to be missing and will not be coded.
51. Question 64 – “If yes, who would you ask”.
    a. If a child checks “Other” and writes in “Me”, this response will not be coded as “Other”.
    b. If a child checks “Other” and writes in “Sister/Brother”, this response will be coded as “Brother/Sister”.
52. Question 65 – “If they said no, would you still do it”. If a child writes in “Try to do things sneakily” this answer will be assumed to be “Most of the time” and will be coded accordingly.
53. Question 66 – “Would you like to have the choice to do it”.
    a. If a child checks “Yes” and “No” and writes in the answer “Usually”, this answer will be assumed to be a “Yes” and will be coded accordingly.
    b. If a child checks “Yes” and “No” but doesn’t write in something to explain that, this answer will be assumed to be missing and will not be coded.
54. Question 67 – “If a friend asked you to do something you were unsure about, would you ask anybody if you could do it”. If a child writes in the answer “Sometimes” this answer will be assumed to be missing and will be coded accordingly.
55. Question 68 – “If yes, who would you ask”. If a child checks “Other” and writes in “Me”, this response will not be coded as “Other”.
56. Question 69 – “If they said no, would you still do it”. If a child checks both “Sometimes” and “Never” this answer will be assumed to be “Sometimes” and will be coded accordingly.
57. Question 70 – “Would you like to have the choice to do it”. If a child checks “Yes” and “No” and writes in the answer “Usually”, or “But maybe”, or “Sometimes”, this answer will be assumed to be a “Yes” and will be coded accordingly.
58. Question 73 – “If yes, what helps you make the decision”. If a child checks an answer and writes in “Sometimes” next to it, this will be counted as an answer.

59. General question – what to do about “sometimes” answers for the questions about “Would you like to choose…”. I have coded those answers as “Yes” for the moment but actually, I don’t think that captures it – the “sometimes” answers illustrate that kids want their parents to make some decisions for them and not others, or make decisions for them sometimes and not others. The proto-independence. Should I go back and recode them to be sometimes…?

Appendix 9 – Questionnaire Study: List of Parent Self-evident Corrections

1. Question 1 – "Who lives in your home". If a parent writes in "Mother" under "Other adult", this answer will be coded as "Mother" rather than "Other adult".
2. Question 5 – "Who would enforce that decision". If a parent writes in "husband" for "Other adult" (and the husband is the child's father), this answer will be coded as "Other parent".
3. Question 6 – "Does your child have a bedtime". If a parent checks the answer "Yes" but writes in "On school nights", this answer will be assumed to be a "Yes" and will be coded accordingly.
4. Question 7 – "If yes, does your child have to go to bed then".
    a. If a parent checks the answer "Always" but writes in "unless special/particular reason why not", this answer will be assumed to be a "Always" since it seems evident that the parent would still be the person deciding on the special exceptions to the normal bedtime.
    b. If a parent checks the answers "Always" and "Most of the time" and writes in "Most of the time – changes with activities", this answer will be assumed to be "Most of the time" and will be coded accordingly.
5. Question 9 – "When you go food shopping, do you often take your child with you". If a parent checks "Yes" and writes in "Sometimes", this answer will be assumed to be a "Yes" and will be coded accordingly.
6. Question 11 – "Does your child choose what they eat for breakfast".
    a. If a parent checks the answer "Yes" but writes in "From what is available", or "Given a selection to choose from", or "From a limited selection, e.g. 2 options", or "Within limits chosen by parents", or "from a limited choice", this answer will be assumed to be a "Yes" and will be coded accordingly.
    b. If a parent checks the answer "Yes" but writes in "Within limits", this answer will be assumed to be a "Yes" and will be coded accordingly.
7. Question 12 – "If no, does your child have to eat what is given to them". If a parent checks "Always" and "Most of the time", this answer will be assumed to be "Most of the time" and will be coded accordingly.
8. Question 14 – "Does your child choose what they eat for dinner". If a parent writes in "Sometimes" this answer will be assumed to be a "Yes" and will be coded accordingly.
9. Question 15 – "If no, does your child have to eat what is given to them." If a parent checks the answer "Always" but writes in "Though not necessarily all of it, but most of it", this answer will be assumed to be a "always" and will be coded accordingly.
10. Question 17 – "Does your child choose what they eat for snacks".
    a. If a parent writes in "Sometimes", this answer will be assumed to be a "Yes" and will be coded accordingly.
    b. If a parent checks "Yes" and writes in "Of a selection", this answer will be assumed to be a "Yes" and will be coded accordingly.
11. Question 18 – "If no, does your child have to eat what is given to them". If a parent checks "Always" and "Most of the time" this answer will be assumed to be "Most of the time" and will be coded accordingly.
12. Question 19 – "If your child is unwilling to eat their snacks, who enforces this". If a parent doesn't check an answer, but writes in "I don't enforce eating of

snacks. Snacks are optional", the answer will be assumed to be "N/A" and will be coded accordingly.

13. Question 20 – "In the morning and evening, do you have to remind your child to clean their teeth".
    a. If a parent checks the answer "Yes" but writes in "Not always", this answer will be assumed to be a "Yes" and will be coded accordingly.
    b. If a parent checks the answer "Yes" but writes in "I still clean his teeth for him", this answer will be assumed to be a "Yes" and will be coded accordingly.
    c. If a parent checks the answers "Yes" and "No" and writes in "morning" next to "Yes" and "Night" next to "No", this answer will be assumed to be a "Yes" and will be coded accordingly.
14. Question 24 – "If your child is unwilling to go, who enforces this". If a parent doesn't check an answer but writes in "N/A yet", this answer will be coded as "N/A".
15. Question 25 – "Do you let your child go to every birthday party they are invited to". If a parent checks the answer "Yes" and writes in "If we are available", this answer will be assumed to be a "Yes" and will be coded accordingly.
16. Question 26 – "Does your child have to go to the birthday parties". If a parent checks "never" but writes in "though I would encourage him", this answer will be assumed to be a "never" and will be coded accordingly.
17. Question 27 – "If your child is unwilling to go to the party, who enforces this". If the parent doesn't check an answer but writes in "If unwilling they don't have to go in some circumstances", this will be assumed to be missing data and will not be coded.
18. Question 29 – "If yes, does your child have to go on the family day out". If a parent checks "Always" and "Most of the time", this answer will be assumed to be "Most of the time" and will be coded accordingly.
19. Question 32 – "Who chooses the games". This question says "Tick all that apply". If a parent checks "child" but then writes in "Though I will give him the options to choose from", this answer will be assumed to be both "child" and "me" and will be coded accordingly.
20. Question 39 – "Do you give your child pocket money".
    a. If a parent writes in the answer "Sometimes" this answer will be assumed to be a "Yes" and will be coded accordingly.
    b. If a parent writes in the answer "Not regularly" this answer will be assumed to be a "Yes" and will be coded accordingly.
    c. If a parent writes in the answer "They earn money" this answer will be assumed to be a "Yes" and will be coded accordingly.
    d. If a parent writes in "From granny" this answer will be assumed to be a "Yes" and will be coded accordingly.
21. Question 41 – "Does your child do extra-curricular activities". If a parent checks "No" and writes in "Not at present", this answer will be assumed to be "No" and will be coded accordingly.
22. Question 43 – "Does your child have to participate in the activity".
    a. If a parent checks "Yes" and writes in "When available", this answer will be assumed to be a "Yes" and will be coded accordingly.
    b. If a parent deliberately checks between "Yes" and "No", this answer will be assumed to be missing data and will not be coded.

   c. If a parent writes in “Depends what it is – for example swimming – Yes because it’s a vital skill” this answer will be assumed to be missing data and will not be coded.
   d. If a parent checks both “yes” and “no”, this answer will be assumed to be missing data and will not be coded.
23. Question 45 – “Does your child have to practice for the activity”. If a parent checks “No” but writes in “Not regularly, I occasionally encourage him” this answer will be assumed to be a “No” and will be coded accordingly.
24. Question 46 – “Do you let your child choose what clothes to buy”.
   a. If a parent writes in “Sometimes” this answer will be assumed to be a “Yes” and will be coded accordingly.
   b. If a parent writes in “Bit of both” this answer will be assumed to be a “Yes” and will be coded accordingly.
   c. If a parent checks “Yes” and writes in “select items” this answer will be assumed to be “yes” and will be coded accordingly.
   d. If a parent checks “Yes” and writes in “but guided choice” this answer will be assumed to be “yes” and will be coded accordingly.
   e. If a parent checks “No” but they write in “Though may give him choice out of ones I have chosen”, this answer will be assumed to be a “No” and will be coded accordingly.
   f. If a parent checks “Yes” and “No” this answer will be assumed to be “Yes” and will be coded accordingly.
25. Question 48 – “Does your child have to help with household jobs”. If a parent checks the answer “No” but writes in “Occasionally”, this answer will be assumed to be a “Yes” and will be coded accordingly.
26. Question 51 – “If asked by a friend, would your child undertake a fun activity that they wanted to do without asking for your permission”.
   a. If a parent writes in “Not sure”, this answer will be assumed to be missing data and not coded.
   b. If a parent deliberately checks between “Yes” and “No”, this answer will be assumed to be missing data and will not be coded.
   c. If a parent doesn’t check an answer but writes in “Depends”, this answer will be assumed to be missing data and will not be coded.
27. Question 58 – “ Does your child need help making decisions”. If a parent checks both “Most of the time” and “Sometimes” this answer will be assumed to be “Sometimes” and will be coded accordingly.
28. General question – if a question says “If yes, then….” or “If no, then…”, and this is based on their response to the previous question, do I ignore the answers if technically based on their previous response they shouldn’t have answered the question?
29. General question – P003 says child makes choice about food but wrote in that the choice is out of a pre-selected group chosen by the parent, but then later says the child doesn’t make choice about clothes, but wrote in that the parent gives the child a choice out of ones the parent has pre-selected.
30. General question – if a parent checks “Other adult” as an answer but doesn’t write in who that is, it will still be coded for other adult – or do I need to say that is missing?
31. General question – for questions 35 and 37 about whether a child needs to check with a parent before watching TV or playing on computer – if a parent checks “never” (P037) but then writes in “but only watch cbeebies” or “but

only access to cbeebies", I am leaving this as "never" because it's the child's choice whether to turn on the TV or computer.

Appendix 10 – Questionnaire Study: Tests of Association between Parent-Child Questions

Question Descriptions	Pearson Chi-Square p-value
Who chooses doctor when you are sick vs. Who decides child to see a doctor	0.992
Who chooses doctor when you are sick (re-coded into categories of people) vs. Who decides child to see a doctor (re-coded into categories of people)	0.811
Who tells you when you need injection vs. Who decides child to see a doctor	0.462
Who tells you when you need injection (re-coded into categories of people) vs. Who decides child to see a doctor (re-coded into categories of people)	0.252
Who chooses doctor when you are sick (re-coded into categories of people) vs. Who tells you when you need injection (re-coded into categories of people)	0.027[48]
Do you have to go to the doctor vs. Would you make child go to doctor	0.797
Do you have a bedtime vs. Does child have a bedtime	
Who tells you it's bedtime vs. Who enforces this bedtime	0.999
Who tells you it's bedtime (re-coded into categories of people) vs. Who enforces this bedtime (re-coded into categories of people)	0.783
Do they make you go to bed at this time vs. If yes, does child have to go to bed then	0.512
Do you have to go food shopping with parent/guardian vs. If yes, does your child have to go with you	0.196
Do you have to go food shopping with parent/guardian vs. When food shopping do you take child with you	0.231
Do you choose breakfast from shop or cupboard vs. Does your child choose breakfast	0.474
Do you have to eat it vs. If no, does your child have to eat what is given to them	0.087
Do you have to eat it vs. If no, does your child have to eat what is given to them (If answer to "Does your child choose breakfast" was no)	0.823
Who chooses what you eat for dinner vs. Does your child choose dinner	0.949
Who chooses what you eat for dinner (re-coded into categories of people) vs. Does your child choose dinner	0.814
Do you have to eat it vs. If no, does child have to eat what is given to them	0.096
Do you have to eat it vs. If no, does child have to eat what is given to them (If answer to "Does your child choose dinner" was no)	0.288
Who chooses what you buy for snacks vs. Does your child choose snacks	0.205
Who chooses what you buy for snacks (re-coded into categories of people) vs. Does your child choose snacks	0.241
Do you remember to clean your teeth vs. Do you remind child to clean teeth	0.006[49]
Do you have to clean your teeth vs. Who enforces child cleaning teeth	0.896
Do you have to clean your teeth vs. Who enforces child cleaning teeth (re-coded into categories of people)	0.839
Do you go to church/temple/mosque vs. Do you go to church/temple/mosque	0.000
Do you have to go vs. If yes, does your child have to go with you	0.051
Do you have to go vs. If yes, does your child have to go with you (if answer to "Do you go to church/temple/mosque" was yes)	0.236
Who decides if you go to a birthday party vs. Do you let your child attend every birthday party they are invited to	0.501
Do you have to go vs. Does your child have to attend the parties	0.074

[48] 80% of cells have expected count less than 5, calling into question the validity of the result.
[49] 25% of cells had expected count less than 5, calling into question the validity of the result.

Do you have family days out vs. Do you have family days out	n/a[50]
Do you play games with your family vs. Does your child play games with you	0.044[51]
Who chooses the games vs. Who chooses the games	0.000[52]
Who chooses the games (re-coded into categories of people) vs. Who chooses the games (re-coded into categories of people)	0.858
Do you have to play games with your family vs. Does your child have to play the games	0.458
Do you need permission to watch TV vs. Does your child need permission to watch television	0.001[53]
Who chooses what you watch vs. If yes, who enforces child watching television	0.642
Who chooses what you watch (re-coded into categories of people) vs. If yes, who enforces child watching television (re-coded into categories of people)	0.132
Do you need permission to turn on computer vs. Does your child need permission to play on computer	0.000[54]
Who chooses what you play vs. If yes, who enforces child playing on computer	0.962
Who chooses what you play (re-coded into categories of people) vs. If yes, who enforces child playing on computer (re-coded into categories of people)	0.533
Do you get pocket money vs. Do you give your child pocket money	0.000
Do you have to check with parents before using pocket money vs. If yes, do you let your child choose what to buy with pocket money	0.537
Do you have to check with parents before using pocket money vs. If yes, do you let your child choose what to buy with pocket money (if answer to "Do you give your child pocket money" was yes)	0.191
Do you choose what you buy with pocket money vs. If yes, do you let your child choose what to buy with pocket money	0.876
Do you choose what you buy with pocket money vs. If yes, do you let your child choose what to buy with pocket money (if answer to "Do you give your child pocket money" was yes)	0.920
Do you do activities or clubs vs. Does your child do extra-curricular activities	0.008[55]
Who chose these activities vs. If yes, who chose for your child to start the activities (If answer to "Do you do activities or clubs" was yes AND "Does your child do extra-curricular activities" was yes)	0.978
Who chose these activities (re-coded into categories of people) vs. If yes, who chose for your child to start the activities (re-coded into categories of people) (If answer to "Do you do activities or clubs" was yes AND "Does your child do extra-curricular activities" was yes)	0.501
Do you have to go to the activities vs. Does your child have to participate (If answer to "Do you do activities or clubs" was yes AND "Does your child do extra-curricular activities" was yes)	0.063
Could you stop the activities vs. Does your child have to participate (If answer to "Do you do activities or clubs" was yes AND "Does your child do extra-curricular activities" was yes)	0.068
Do you have to practice for these activities vs. Does your child have to practice for the activity (If answer to "Do you do activities or clubs" was yes AND "Does your child do extra-curricular activities" was yes)	0.011
Who decides what clothes you buy vs. Does your child choose clothes	0.066

[50] No statistics computed because all parents answered the same way.
[51] 50% of cells had expected count less than 5, calling into question the validity of the result.
[52] 94% of cells had expected count less than 5, calling into question the validity of the result.
[53] 12.5% of cells had expected count less than 5, calling into question the validity of the result.
[54] 37.5% of cells had expected count less than 5, calling into question the validity of the result.
[55] 25% of cells had expected count less than 5, calling into question the validity of the result.

Who decides what clothes you buy (re-coded into categories of people) vs. Does your child choose clothes	0.020[56]
Who decides what clothes you buy vs. If no, who chooses them (If answer to "Does your child choose clothes" was no)	0.908
Who decides what clothes you buy (re-coded into categories of people) vs. If no, who chooses them (re-coded into categories of people) (If answer to "Does your child choose clothes" was no)	0.331
Do you have household jobs vs. Does your child have household jobs	0.643
If yes, how many do you have vs. If yes, which ones do they help with (If answer to "Do you have household jobs" was yes AND "Does your child have household jobs" was yes)	0.118
Who decides if you help with household jobs vs. Who enforces this (If answer to "Do you have household jobs" was yes AND "Does your child have household jobs" was yes)	0.000[57]
Who decides if you help with household jobs (re-coded into categories of people) vs. Who enforces this (re-coded into categories of people) (If answer to "Do you have household jobs" was yes AND "Does your child have household jobs" was yes)	0.150
Would you ask permission to do something fun vs. Would your child do fun activity without permission	0.408
Would you ask permission to do something you were unsure about vs. Would your child do unsure activity without permission	0.033[58]
Would you ask permission to do something fun vs. Would you ask permission to do something you were unsure about	0.079
Do you think your parents/guardians let you make decisions vs. Do you involve child in non-significant decision-making	0.205
Do you think your parents/guardians let you make decisions vs. Do you involve your child in significant decisions	0.126
Do you sometimes need help making decisions vs. Does your child need help making decisions	0.496
If yes what helps you make the decision, vs. What helps your child make decisions	0.000[59]
Do you sometimes need help making decisions vs. Do you explain your decisions to your child	0.740

[56] 25% of cells had expected count less than 5, calling into question the validity of the result.
[57] 90.5% of cells had expected count less than 5, calling into question the validity of the result.
[58] 50% of cells had expected count less than 5, calling into question the validity of the result.
[59] 100% of cells had expected count less than 5, calling into question the validity of the result.

Appendix 11 – Multi-Disciplinary Discussion Panel: List of Questions

1. What is your understanding of assent?

2. In your current practice, do you involve children in the decision-making process? If so, what methods do you use to involve children?

3. I will now present you with a few hypothetical that you might encounter in clinical practice. I have purposely left out details so that I am not planting ideas in your heads on how you might proceed. For each scenario, think about the following questions:
    a. Would you involve this child in the discussion of whether to start the proposed treatment?
    b. Would you always involve a child in the decision?
    c. Would you never involve a child in the decision?
    d. What would motivate you to involve one child but not another in this decision?

4. Scenario 1 – A chronically ill child requires a planned or ongoing treatment or intervention that he has experienced before.

5. Scenario 2 – A child requires an immediate treatment that is not immediately life-threatening.

6. Scenario 3 – A child is a potential participant in a clinical research project for an experimental treatment, when all other treatment options have been exhausted.

7. Scenario 4 – A child is a potential participant in a clinical research project that may not immediately or directly affect her.

8. Presentation of dissertation research (philosophy, focus groups, questionnaires)

9. Given what we have learned about the family context and its impact on a child's decision-making ability and desires, how can we apply this to clinical practice in terms of assent?