

Priscilla Alderson P (2007) Competent children? Minors' consent to health care treatment and research. *Social Science and Medicine* 65 2272-2283.

## **Abstract**

This paper concentrates on controversies about children's consent, and reviews how children's changing status as competent decision makers about healthcare and research has gradually gained greater respect. Criteria for competence have moved from age towards individual children's experience and understanding. Uncertain and shifting concepts of competence and its identification with adulthood and childhood are examined, together with levels of decision-making and models for assessing children's competence. Risks and uncertainties, methods of calculating the frequency and severity of risks, the concept of 'therapeutic research' and problems of expanding consent beyond its remit are considered. The paper ends by considering how strengths and limitations in children's status and capacities to consent can be mirrored in researchers' and practitioners' own status and capacities. Examples are drawn from empirical research studies about decision-making in healthcare and research involving children.

## **Introduction**

This paper relates consent to children's bodies, health and illness, their views and behaviours, (dis)abilities and experiences, their rights, relationships and status. The paper mainly considers current English/Commonwealth law and guidance, but also refers to some international influences and to historical examples that are basic to, or have developed towards, present policy. Guidance in law and ethics on healthcare and research has variously either ignored children (Nuremberg, 1947) or intensely discussed them (US, 1997; RCPCH, 2000; BMA, 2001; MRC, 2004), carefully protected them or entered them into high risk research (Beecher, 1966; Pappworth, 1967; Sharav, 2003), regarded them as either the last (RCPCH, 2000) or as the first (Nuffield, 1992) group to take part in research. This paper concentrates on controversies about children's consent. It reviews children's status and rights to consent, various definitions and assessments of their competence, and calculations of risk. Consent to healthcare treatment and consent to research often overlap when research investigates treatment, and the concept of 'therapeutic research' and the limited remit of consent are critically analysed. Finally, children's status and capacities to consent are reviewed as possibly a reflection, mirror image, or indicator of practitioners' and researchers' own status and capacities.

## **Children's status in decision-making: guidance in law and ethics**

### *Beyond an age of consent: the law*

There is a movement beyond an arbitrary 'age of consent' towards respect for individual children's abilities. This is partly because, as will be illustrated in later sections, contingencies such as experience and ability can be more salient than age to a child's competence. The statutory age of consent to treatment varies considerably between countries from 12 to 19 years, illustrating how arbitrary it can be. However, formerly the child's status, as silent infant or articulate young adult, has been keenly debated around questions of an age of consent to health treatment and research. Anglo-American law recognises that 'Every

human being of *adult* years and sound mind has the right to determine what shall be done with his own body' (my emphasis) (Cardozo, 1914). Until recently, obedience rather than autonomy has been expected of children.

The emphasis is changing around the world in British Commonwealth countries influenced by English law, from attention to a stated age of consent to interest in individual ability (Gillick, [1985] 3 All ER 423). The *Gillick* ruling does not specify an age when children become competent, but defines a competent child as one who 'achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed', and has 'sufficient discretion to enable him or her to make a wise choice in his or her own interests'. The parental right to consent 'terminates' when the child achieves this competence (*Ibid*). 'Nor has our law ever treated the child as other than a person with capacities and rights recognised by law (Gillick, [1985], 2 WLR 480)'. Parents have a 'dwindling right which the courts will hesitate to enforce against the wishes of the child. It starts with a right of control and ends with little more than advice' (Hewer v. Bryant [1970] 1 QB 357, 369). In the US, doctors have long been permitted to treat 'mature minors': young people who have left home or who have drug, alcohol or sexual problems and who want to be treated without their parents' knowledge and consent (Gaylin and Macklin, 1982). During the 1970s and 1980s, some judges in Britain did recognise minors' rights and capacities. However, in the 1990s a few court cases contracted the *Gillick* ruling by refusing to recognise certain minors as competent, for example, (Re J [1991]; Re W [1992]). Although these cases involved mental health problems, and the rulings therefore have limited relevance to most young people, they have been widely influential.

For years, the government has advised that 'young people should be kept as fully informed as possible about their condition and treatment to enable them to exercise their rights' (DH, 1991), and that their wishes (Children Act, 1989, s 8) and views (UNCRC, 1989, article 12) should be heard. There should be respect for 'informed, free, express and specific consent' (DH, 1991). The government now advises professionals to encourage young people aged from about 12 years to involve their parents in deciding about their care and treatment, but not to enforce this, and to accept the consent of young people who do not want their parents to be informed and involved (ECM, 2006). In Britain, doctors are

protected against prosecution when they treat children aged under 16 years without parental consent if they claim that in their clinical judgement the child is competent to consent (Age of Legal Capacity (Scotland) Act, s 2 (4) 1991).

Legal debates about minors' consent have complex contexts. The debates are less concerned with children's rights than with adults' freedoms. These include lawyers' concerns to safeguard human autonomy and privacy rights, and judges' and parents' powers to decide for children (Bynoe, 1993:7). There are also governments' and doctors' anxieties that if judges rule that parents must always be involved in decisions about minors, including decisions about contraception and abortion, many young people will be unable to trust medical services to respect their privacy and will avoid using them. Rates of sexually transmitted disease and unwanted pregnancies are therefore likely to rise rapidly. So legal rulings such as *Gillick*, and government guidance (ECM, 2006), which appear to respect young people's decision-making rights, may be more influenced by motives to protect them and assure they can receive treatment and advice.

Inquiries into scandals about medical maltreatment of living and deceased babies and children in English hospitals (Kenney, 2001; Redfern, 2001) indicate particular public concern with consent as a means to protect children, both living and dead. Kennedy's inquiry report (2001) advised that consent should precede every clinical intervention and all 'touching'. (Technically, illegal 'assault' means unwanted touching, not necessarily violence.) The inquiries have led to a renewed and stronger emphasis in English guidance and law on consent, for example, NSF (2004), Human Tissue Act (2004). Shenoy et al. (2003:17) concluded that such emphases would require 'drastic changes' to clinical practice.

To summarise the present position on health care treatment: in English law, the people who can give valid consent to medical treatment for a child include the competent child and anyone who has parental responsibility for the child under the 1989 Children Act. Following *re R* ([1991] 4 All 177), the consent of only one of these people (child or parent) to treatment can overrule the refusal of all the others. Therefore treatment may be enforced on a resisting child if it is considered to be in the child's best interests.

## *Consent to research*

This section reviews current guidance and also earlier sources on which present standards are based or from which they developed. Modern international bioethics guidance on research began with the *Nuremberg Code* (1947:1), which opens with what may still be the best definition of consent.

‘1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or ulterior form of constraint or coercion.’

*Nuremberg* does not mention ‘informed consent’ but assumes that, when properly informed, ordinary people can make ‘enlightened decisions’ about whether to consent to research. *Nuremberg* dealt only with research on healthy adults and vetoed research on children, who were assumed to lack legal capacity. The loophole that *Nuremberg* left in not covering ‘therapeutic’ research involving medical treatment is shown by British guidance (MRC, 1964: 21-5), which was not revised until 1991. It stated that if the doctor researching a treatment is satisfied that the treatment will benefit the patient, because of the ‘willingness on the part of the subject to be guided by the judgement of the medical attendant he [the doctor] may assume the patient's consent [as he would assume consent to] established practice’ – without the person’s knowledge or consent.

By 1964, *Nuremberg*’s legal concern with the human rights of ‘healthy volunteers’ was superseded by the medically authored *Declaration of Helsinki* (WMA, 1964/2000). *Nuremberg* can be regarded as a response to unjustifiably harmful research in concentration camps during World War II. In contrast, *Helsinki* addresses the dangers of under-researched treatments. It was first published after thalidomide was reported in 1963 to have caused many fetal limb malformations when women took the medication during pregnancy, and is another example of dangers to babies and children, which have alerted public

attention and led to new ethics guidance. *Helsinki* affirmed the benefits of research and faith in physicians who are dedicated 'to help suffering humanity' and who alone are fully qualified to make accurate risk-benefit assessments. The research subjects' 'freely given informed consent' is not mentioned until clause 9, and 'responsibility for the human subject must always rest with the medically qualified person and never rest on the subject'. Physicians are trusted to research on children with parental consent (clause 11) and, by the 1983 version of *Helsinki*, the competent 'minor's consent must be obtained in addition to the consent of the minor's legal guardian.'

In the United States, there is a long tradition that the consent of parents/guardians to research must be sought 'at all ages of the child; furthermore the child's assent should be sought from the age of 7 upwards' (US 1977). 'Assent' here is non-refusal or simple agreement without the understanding, discretion and legal validity associated with consent, and the term does not appear to be used much in English law. For example, it is missing from Montgomery (1997) and Kennedy (1988). This may be because English law recognises minors' consent, but United States (US) law does not, and assent allows a partial recognition. However, the thorough multi-disciplinary guidance on research developed in the US (1977) influenced English guidance (BPA, 1980; Nicholson, 1986; MRC, 1991; RCPCH, 1992). Children have fewer rights in the US when research investigates treatment. 'On a cautious view of the law' with 'therapeutic research', the parents' consent can 'be deemed to override the refusal of assent by the child aged under 14 [although] non-therapeutic research should not be carried out if a potential child subject aged 7 to 14 years refuses assent to it' (US, 1977).

Similarly, in English guidance, the child has a higher status in decision-making as a potential research participant than as a patient. Adults must take extremely seriously the refusal or resistance of even very young children to research, which is not associated with treatment (RCPCH, 1992/2000; BMA, 2001:234), and 'the investigator should reconsider whether it would be appropriate to proceed' (RCP, 1990a) as well as working to enhance and encourage children's share in decision-making (BMA, 2001:232). 'Either those included have given consent, or consent has been given on their behalf by a parent or guardian and those included do not object or appear to object in

either words or action...When a child lacks sufficient understanding to consent, his willing cooperation should be sought' (MRC, 1991, and similarly MRC, 2004). Children should be consulted and informed in terms they can understand (BMA, 2001). 'When parental consent is obtained, the agreement of school age children to take part in research should also be requested by researchers' (RCPCH, 2000/1992). 'Research which could equally well be done on adults should never be done on children' (RCP, 1990b; CMCE, 1990). In the absence of English statute or case law on consent to research, the guidance has cautioned that: 'it would be unacceptable not to have the consent of the parents or guardian', for children aged up to 18 years even when they are deemed competent to consent, to any intervention which is not for the benefit of the child especially if it carries more than 'negligible risk', 'it could be said they were acting illegally' (RCP, 1990a). Growing concern that most clinical interventions on children are under-researched and under-tested (ABPI, 2004) has led to international efforts to expand and regulate neonatal and paediatric research. As a result, insistence on involving parents' consent during all clinical trials on minors passed into law in 2004, when the government implemented the EC Directive (EC, 2001). But the law applies only to clinical trials. There is not space here to review the varying guidance on children's consent that has been agreed by many disciplines and agencies, which conduct psychological and social healthcare research with children (see Alderson and Morrow, 2004).

### *Children's rights*

The 1989 United Nations Convention on The Rights of the Child (UNCRC, 1989) has been ratified by every country except the US and Somalia. Conventions are the most powerful treaties and the UNCRC has far more support than any other treaty. Governments undertake to implement the Convention in law, policy and practice and to report regularly to the UN about their progress in doing so. The UNCRC's 54 articles promote children's 'provision' rights to services and amenities, their rights to 'protection' from abuse or neglect, and their 'participation' or modified autonomy rights. Like all rights, these are subject to public safety, health, law, order and morals.

UNCRC rights further respect children's best interests and parents' responsibilities. Particularly relevant to consent, Articles 12 and 13 state that governments must assure:

'To the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child: the views of the child being given due weight in accordance with the age and maturity of the child...The child shall in particular be provided the opportunity to be heard in any judicial or administrative proceedings affecting the child, either directly, or through a representative or appropriate body. [There are also rights] to freedom of expression... freedom to seek, receive and impart information and ideas of all kinds...through any other media of the child's choice.'

Many practitioners and researchers create imaginative leaflets, toys and videos to inform young children about proposed interventions. *Nuremberg* and *Helsinki* and their history illustrate the importance of respecting the status of potential research participants, informing and listening to them, and working as far as possible in partnership with them. The UNCRC emphasises these approaches particularly with children. However, the level of shared involvement partly depends on perceptions of the child's competence, as reviewed in the next sections.

### **Concepts of competence**

Adult research subjects are assumed to be competent unless they obviously show serious incompetence. Researchers tend to start from a presumption of incompetence with children, a double disadvantage for children since it is hard for them to challenge the strong views of the relatively more powerful and confident adults, and it is harder to demonstrate competence than incompetence, which can fairly easily seem to be proved by one or two mistakes or misunderstandings. The following sections review debates about children's competence.



### *'Children cannot give consent'*

This is the accepted view in the US (for example, NIH, 2007). Yet although, in many countries, children cannot give legally valid consent, it does not follow that they are intellectually and morally incompetent, despite enduring beliefs about their limited reasoning and morality. Piaget's experiments during the 1920s and 1930s (Piaget & Inhelder, 1956) found that children aged under 7 years could not imagine, or reason from, the perspective of a model of mountains that would be seen by someone standing in another position from their own. Leaping from geometry to morality, Piaget inferred that children were therefore egocentric and unable to distinguish themselves from others. However, his conclusions were challenged when researchers reframed his experiment into a story of boys hiding from one and then two policemen. They found that some children aged 3 years could solve harder geometric puzzles (Donaldson, 1978) and that, far from being unaware of others' viewpoints, the children were so highly aware that they tried to please by giving the replies they thought the researchers wanted to hear. 'Children are not at any stage as egocentric as Piaget has claimed [or] so limited in ability to reason deductively...At least from age four, then, we must again acknowledge that the supposed gap between children and adults is less than many people have claimed' (Donaldson, 1978: 58-9). Ironically, Piaget appeared less able to perceive the children's viewpoints than they could perceive his.

Interpersonal relationships appear to be very important to all children. Although the youngest children cannot make decisions, even babies are already on the human spectrum of awareness, beginning to discriminate, distinguish and to invest meanings in experiences, interactions and other people's moods and behaviours (Murray & Andrews, 2000:). By 6 months, babies show surprise when effect seems to follow cause (Siegal, 1997). And yet bioethicists (for example, Miller, 2004; Grodin & Glantz, 1994) continue to ignore decades of research about young children's competence. Echoing Piaget's mountain experiment, Buchanan and Brock (1989:220) assert, for example, that younger children cannot appreciate different personal positions. 'These skills are undergoing substantial development in the 8 to 11 age

period, and are often quite well developed by 12 to 14'. Children's slow physical development is taken to signify equally slow psychological, emotional and moral growth, and highly informed young children are dismissed as 'precocious' or 'outliers'.

Childhood and youth tend to be associated with being ignorant, volatile, foolish, over-emotional, needy and helplessly dependent. Conversely, adulthood tends to be identified with being informed, stable, wise, rational, reliable and above all competent. However, at times many children can be wise and many adults can be foolish. The characteristics are more realistically understood as combined at every age instead of being age-associated. The newer childhood studies research is producing evidence of higher competencies even in young children (Hutchby & Moran Ellis, 1998), through listening to children's own views and explanations, and through in-depth research with sick or disabled children about their everyday lives and real decision-making. Adversity may increase knowledge, skills and courage when children cope with disability or illness in ways that more fortunate people may not imagine (Alderson, 1990, 1993). For example, 6 year old Samantha was willing to go through two liver transplants, but after they failed she wanted to refuse a third one. Reluctantly, her parents and doctors came to believe that her decision was right for her, given the suffering involved and the estimated two per cent chance of success (Irwin, 1996).

Children who have long-term conditions know far more than people who have acute or emergency conditions. Children as young as 2 years have been shown to know the names and purpose of their cancer drugs (Kendrick, et al., 1986), and children in cancer wards have deliberately protected their parents by not telling them how much they, the children, knew or suffered (Bluebond Langner, 1978). I interviewed 120 people aged 8 to 16 years having elective major surgery, and also their parents and 70 hospital staff, and asked them all the age when the children were or would become as competent as their parents to 'be the main decider'. On average the young people had already had four to five operations, and they had one or more serious long-term conditions. Linda (pseudonym), aged 8 years, who had spina bifida, hydrocephalus and kyphosis (curved spine), was waiting for her fifth operation. Her mother explained:

'I usually tell her everything. She wants to know exactly what is entailed. Last year her urethra ruptured and she was very upset that she wasn't warned fully about the catheters...She's maturing very quickly and she asks, "Why me? Why is my body made wrong?" [The surgeon] said, "Ten percent of these children don't come out of the theatre alive." ...She reads books a lot, she writes down her questions and asks them in the clinic, but I haven't told her about that [mortality] risk (Alderson, 1993: 127-8).

Interviewed with her mother and aunt, Linda was cheerful: 'We've been waiting for ages. I say, thank goodness I'm getting it over and done with.' I asked her whom the doctors should talk to. 'Mummy and me. And auntie should hear too, so she doesn't get worried. (She leant over to kiss her aunt.) But particularly me, so I can face up to it if I'm frightened.' After the adults left, Linda hinted to me about her controlled anxiety. 'When I get back tomorrow [after surgery] they'll be in tears for me.' Earlier her mother had told me that Linda asked why the neighbours were crying when she had said goodbye to them. Only a few examples of 'ordinary' young children are required to refute generalisations about their supposed incompetence. When they demonstrate understanding of their serious condition and potential treatment choices, it is no longer viable to speak of general incapacity below the age of 7, 10 or 14 years as many commentators still do.

In Britain, around 18% of people aged under 20 have a long term condition (NSO, 2007), and many have to 'consent' to years or a life time of a prescribed treatment regime – a strict diet, daily injections, medicines or physiotherapy. Although less dramatic and risky than consent to surgery, children's cooperation with the regime has to involve an informed commitment well beyond passive compliance. Their health is often in their own hands. Everyday evidence of children aged 3 and 4 years, with such conditions as cystic fibrosis or type 1 diabetes, shows how responsible they can be when adults are not present. For example, children with diabetes refuse sweets, which their friends enjoy, and cope in sophisticated ways with being different yet sustaining friendships (Alderson, et al., 2006). Unless they understand the reasons for painful or frustrating treatment children could be overwhelmed

with fear or anger. By age 4 or 5 years, children have mapped out their life-long understandings of self, others and relationships, time and space, art and much basic science (Gardner, 1991). These sense-making abilities suggest that, even if their consent is not requested, informing them as much as possible about the nature, purpose and likely effects of interventions can reduce fearful misunderstandings.

### *Levels of decision-making*

There are four levels in decision-making (Alderson & Montgomery, 1996:66): to be informed; to express an informed view; to have that view taken into account when decisions are made; to be the main decision maker about proposed interventions, if competent to do so and potentially subject to supervision of the courts. The highest level includes signifying the decision and taking responsibility whatever the outcome. It is often argued that children cannot and should not make major decisions, for reasons linked to the four levels listed above: they cannot understand the relevant information; they cannot evaluate information in the light of lasting personal values; they cannot know their own best interests, so that adults must act for them; and, if things go wrong, children do not yet have the courage and resolve to stand by a decision, and will need to blame other people instead of enduring risk, guilt and blame themselves. Doctors used all these arguments in the past to protect adult patients from complex and distressing information and decision-making.

Yet efforts to protect children from having to decide about healthcare research and treatment may protect adult power as much as children's interests. During the study about children's consent to surgery, a hospital chaplain said he believed that children's competence greatly depends on adults' competence to be supportive, generous, courageous and 'big enough' to respect children.

'But are you going to lay on children the weight of their future? Perhaps let them make a decision that could lead to their death? These are impossible

questions, but hospital staff have to find the answers. Am I big enough to say, “Whatever you choose will be valued, even if you decide against the tide; okay, you’ve made that decision, I’ll do all I can to support you, and we’ll go forward together”? It’s such a big step for the adult to surrender power to the child’ (Alderson, 1993:143).

The UNCRC (1989) articles 12 and 13 recognise the first three levels of children’s involvement in decision-making, of sharing information, without any age barrier. Relevant information may be acquired from children’s own embodied feelings and experiences, such as when healthy babies set the timing and pace of feeds that establish breastfeeding. Immensely detailed observations of premature babies find how subtly they express their needs in a ‘language’ that can be ‘read’ (Als, 1999:34). Their need for quiet, for dim lighting and reassuring touching and talking are used to transform some neonatal unit-wide routines (Alderson, et al., 2005, 2006).

The fourth and highest level of decision-making is to be the ‘main decider’ about proposed treatment, if the child is both able and willing to do so. Although not covered in the UNCRC, this is enshrined in English law (Gillick, [1985]) and recommended practice (RCPCH, 2000; BMA, 2001:232). Replies to my research about the age of competence to consent to surgery (see above, Alderson, 1993:143-74), ranged from one surgeon saying ‘never’ to some adults and children stating ages from 6 years upwards. Much depended on the child, the family, the condition and the beliefs of each interviewee. Most of the children wanted to share the decision-making with their doctors and parents. A minority (not age-related) either wanted others to decide for them or else to be ‘the main decider’ about proposed surgery. Nurses said that after years of working with children they respected them at younger ages. The children’s understanding appeared to depend far more on their experience than their age or ability.

### *Assessing competence*

Four standards of mental competence are commonly assessed in the person

giving consent. Are they sufficiently able to: understand the relevant information; retain the information; weigh the information in order to make a reasoned choice; and make voluntary and autonomous decisions? Two other standards are the ability to communicate the decision, and the ability 'to believe the information' (Mental Capacity Act, 2005). 'Belief' here means not being deluded, but it could be misconstrued to assess as incompetent anyone who disbelieves/disagrees with the doctors' information and wants to refuse interventions they consider to be unnecessary or even harmful. If so, that would deny any rational grounds for refusal. Yet in the US there are many reports, for example, of parents wanting but being unable to stop enforced administration of Ritalin to treat children's perceived conduct disorders (Baughman, 2006).

It is also important to assess the competencies of the practitioners/researchers who are requesting consent. Are they sufficiently able: to understand all the relevant information; to retain and explain all the issues clearly and resolve misunderstandings; to assist children and parents in their reasoned choice-making; and to respect their decisions, putting no undue pressures on them? Much depends on the training and skills of practitioners and researchers, on their understanding of how childhood incompetencies are socially constructed (James and Prout, 1997), and also on the support or opposition they receive from colleagues when they risk advocating children's views and preferences.

Assessors can rely on three models of competence (US, 1977; Brazier, 1992). Status: is the person a competent adult or a non-competent baby/young child/ elderly demented person? Outcome: does the assessor consider the person's decision is reasonable? Function: even if the assessor disagrees with the decision does the reasoning that explains and justifies it seem to be valid? The first two views tend to favour the assessors' prior fixed assumptions, whereas the third approach is most likely to involve respectful flexible consideration of the individual's competence and decisions through negotiation. Then the practitioner's/researcher's information can complement the patient's personal knowledge and values so that together they can make more informed decisions with mutual respect. Linda's surgeon, for instance, described how he would operate on a slight spinal curve if a child were very

distressed, but he would leave a more severe curve if it was safe to do so and the child did not appear to be concerned. The healthcare team may have to test and stretch their own abilities to inform, and involve, and thereby increase the competence of their patients. Along with respect for children's views and values, there needs to be realism about the limits of clinical knowledge, skill and 'factual' understanding, and of the daunting risks and uncertainties in some healthcare treatment and research.

### **Risks in healthcare research**

Consent involves evaluating risks and considering whether to undertake them. There are extra risks in research with children. They tend to be more vulnerable than adults to being damaged in the short or long term by interventions. They are liable to live with the effects for many extra years. They are generally less able to question, challenge, resist or refuse researchers' proposals. Children's actual or ascribed incompetence and dependence make them vulnerable to adults' decision-making and control. While parents' usual priority is to protect their child, they may unduly perceive the research intervention to be a protection against the greater dangers of the health problem being researched. There have been marvellous advances in the cancer treatments for children since the 1960s. Yet these partly relied on denying the need to ask for consent to healthcare research (see above, MRC, 1964). With cancer treatment trials, parents had no acknowledged rights to be informed or even to see their child; visiting might be allowed for one hour a week (Platt, 1959). The very great benefits of this research were gained at the cost of children being unable to refuse or to withdraw from painful and sometimes lethal research. Currently, children's cancer treatment is almost all provided through clinical trials so that routinely consent to treatment entails consent to research. Yet this can set child cancer patients' future collective interests over their present individual interests, considering that experimental treatments are as likely to be inferior as superior to standard treatments (Children's Oncology Group, 2005:1295). Parents may enter their child for treatment trials so gruelling that, as some adults admit, they would refuse to enter the trials themselves. Belief in redemptive childhood that

promises better, brighter futures for families and for humanity generally may also subliminally encourage adults to invest extra hope and enthusiasm in research with sick or disabled or disturbed children. In these ways, children can lose the primary protections against research risks: the freedom to give or withhold consent, to withdraw at any time, and so to resist coercion. This next section reviews some confusions about risk which can increase children's vulnerability.

### *Calculating risk*

Risk is frequently discussed as if it is wholly quantifiable, but this view notices only one dimension of risk: calculating its frequency or likelihood of occurring. If seven out of 100 people develop severe adverse reactions to a drug, the risk of 'severe side effects' is seven per cent. The word 'severe' introduces the other vital dimension of risk: its magnitude or intensity, the contested qualitative aspect of risk. Consensus on what counts as 'severe' or 'minimal' is often elusive and one person's 'severe' might be another person's 'slight'. This uncertainty about intensity in turn affects the supposedly reliable 'objective' measures of frequency when they involve categories of severity. Regular debates in medical journals record that many doctors regard collecting blood samples to be of 'minimal' risk, whereas many children fear needles as 'severely' painful and invasive.

Possibly still more uncertain are the means of assessing the risks of intrusion, humiliation, embarrassment, misreport and misrepresentation, posed when questioning children (or any group). Health research ethics tends to identify risk with the central stage of projects - data collection and direct contact with research subjects. Yet the earlier and later stages of projects, from the choice of research questions and methods, to eventual dissemination and implementation of research findings, may also pose serious and far-reaching risks and harms (Alderson and Morrow, 2004). Research reports may deliberately or inadvertently propagate more widespread harms. They may further stigmatise disadvantaged groups, such as children with mental health and behaviour problems. When researchers package ghostly childhoods from



the British 1958 and 1970 longitudinal cohorts, they may promote conclusions and recommendations to influence policies on the supposed needs of today's childhood, which do not take sufficient account of today's very different circumstances and problems. Among the micro studies of small groups of children and macro surveys of large groups, attention is seldom paid to larger economic and political pressures and effects. For example, current 'research-based' government policies are establishing schools that open for 50 hours a week and 48 weeks a year to contain children aged from early months to 14 years (ECM 2003). Research has not yet addressed the potential effects and risks of such confinement, relating to the health of children and of society.

### *'Therapeutic research'*

Further confusion arises, when calculating risk, from the blurring of risks with benefits, and research with treatment. Despite reservations about the term 'therapeutic research', an early ethics report used the term to mean 'research consisting in an activity which has also a therapeutic intention as well as a research intention towards the subjects' (US, 1977:33). The report expanded the types of permissible research on children, and described risks euphemistically as 'minimal', 'minor increase over minimal' and 'greater than minor increase over minimal' - meaning the most serious risks of injury or death. The report warned that restrictions on research might leave children as 'therapeutic orphans', suffering diseases for which no treatment could be developed, a warning recently promoted with greater international emphasis (ABPI, 2004:9).

'Non-therapeutic research' is seen as including much healthcare and all social research not associated with a clinical treatment, including research about children's views and experiences, their growth and the range of 'normality'. This work is vital if children are to be protected from being over-diagnosed and over-treated when they have physical and psychological states that are well within the 'normal' healthy range. 'Non-therapeutic research' has gradually gained ethics support, coming to be accepted as not illegal (BPA, 1980:1) and later as not necessarily 'against the child's interests', even if it is not in the 'best

interests' of the child to be enrolled in research (Nicholson, 1986:234). The concept of 'therapeutic research' can skew risk assessments when highly risky research, such as toxic drug trials, is approved as 'therapeutic', but questionnaires with children about their healthcare needs and services are rejected as 'non-therapeutic'.

Risk is a relative concept. When a new treatment is tried on a 'healthy volunteer' (this term implies that patients in research are not also volunteers) in 'non-therapeutic research' the level of risk must be very low. High risk treatments are accepted if they offer a slight hope to a dying child (US, 1977; BPA, 1980:1), although arguably a strong healthy person is better able to withstand the risk. The equation that the hoped-for benefit should always outweigh the degree of risk can permit taking the highest risks with most vulnerable children in greatest need, when extreme illness, disturbance, or fear of death force parents and practitioners to 'try anything'. The equation can misleadingly imply that harm and benefit are measurable and comparable.

In confusions between therapy and research, 'therapy' implies the promise of effective treatment that does more good than harm, although the usual purpose of research is to test these hopes. It would therefore be more scientific and ethical to replace talk of 'therapy' and 'therapeutic research' with the more neutral accurate terms 'treatment', 'test' or 'intervention', for the following reasons. Treatment and research differ in their nature, purpose, methods and knowledge base, as shown in table 1, and informed consent depends on these differences being clearly explained. To blur treatment with research can increase ethical dilemmas, when talk of 'therapeutic research' (the term is not used in *Helsinki* 2000) and of 'the child's best interests being to take part in research' imply that research can directly benefit research subjects. The treatment being tested might directly benefit them, but if research is systematic investigation then research itself cannot be 'therapeutic', unless the subsequent findings are eventually published and implemented to benefit future patients. However, parents may feel that it is unethical or impossible to refuse or to withdraw their child from a research programme labelled 'therapeutic', for fear of harming the child. Clinical staff in research teams often have little understanding of equipoise (Alderson et al., 1994), meaning honest uncertainty about the relative benefits of different

treatment arms in a trial. If the staff confuse research and experimental treatments with assured therapy they are even less able to inform potential participants accurately. Adults may believe that a child must be in a trial in order to obtain effective treatment. But if the treatment is only available within a research programme, its relative efficacy and the balance of harms and benefits will be uncertain. These uncertainties and risks have to be explained clearly if consent is to be informed. It is therefore preferable to avoid the terms 'therapeutic' or 'non-therapeutic' research.

Table 1. Differences between healthcare treatment and research

|  | Treatment   | Research  |
|--|---|---|
| Definition                             | Diagnostic, preventative, palliative or curative intervention                       | Systematic investigation  |
| Purpose, hoped for outcomes            | To improve the individual's health status now                                       | To acquire knowledge that might benefit future patient groups           |
| Methods                                | Conduct diagnostic tests, provide and advise on treatments and assess their effects | Design protocols, collect, collate and analyse data, report findings    |
| Knowledge base for treatment decisions | 'Best' option, as far as can be known, for each patient<br>'pragmatic certainty'    | Randomization or other allocation method to fit protocol.<br>Equipoise. |

### *Elusive risks*

Consent may be being stretched into performing functions that it cannot adequately cover in new forms of treatment and research. Consent is premised on a one-to-one patient-practitioner or participant-researcher dyad, whereas large treatment or research teams may be involved. This complicates the coherence, consistency and continuity of information, of confidentiality, and of agreed working methods and relationships as, for example, we observed in our neonatal study. Does consent agreed with one practitioner signify consent to the entire team? How can the whole team keep up to date with rapidly changing plans for each baby? Should all the staff have access to every child's personal information? Yet consent to treatment does

at least tend to be time and space limited: a specific event on a selected body. Even if the treatment course or its effects last a lifetime these will end with death, whereas consent to research can involve unknown and boundless potential.

In the new medical technologies, data are distributed across global space in telemedicine, and across time through 'immortal' stem cell-lines. Databanks of DNA or of children's personal details in longitudinal studies are hired out to numerous research teams, and although ethics committees may vet the ostensible purposes of each research project, no one can predict all the possible uses and outcomes. Children have fewer rights than adults. Although, for example, parents may withhold their child's data from the Icelandic genebank, if they do not, the children themselves cannot withdraw until they are 18, and they cannot withdraw their data retrospectively (Rose, 2001). Brown and Webster (2004) considered the novel institutional, legal and economic networks and markets, and the future technologies of social control, surveillance, informatics, genetics, biomedical engineering, new hybrids and warfare that databanks may serve through as yet unknown technical and social processes. Consent's supposedly direct link between the gift of research data ('data' meaning given) and the donor's intellectual and moral prospective control over the specific use of data is dispersing elusively across this timeless diffusion. Risky new and growing challenges of healthcare research affect all age groups but children are doubly vulnerable in their present dependence and their likely longer lifespan over many future decades.

### **Discussion: reflections on children's consent**

(Practitioners and researchers will be referred to as professionals.) This final section suggests that main themes in this paper relate to professionals' own reflexive understanding and also illustrate how professionals' and children's status and competencies can reflect and either mutually reinforce or undermine one another. Children's consent, as with vulnerable people of all ages such as those with learning or mental health difficulties, prisoners or

asylum seekers, can raise extra ethical dilemmas. There are the risks of protecting children to the extent of silencing and excluding them from research so that their voices are not heard or are misunderstood, versus the risks of coercing or exploiting their involvement. Research and clinical governance encourage professionals to protect themselves and to be more cautious about risk taking, and this may affect how they involve children in their work. The more professionals are constrained by time, costs, protocols and regulations, useful though these may be in safeguarding standards, the fewer options professionals may be able to offer to the children they work with.

Children's competence and autonomy mainly develop through direct social personal experience and not through age and physical growth. Some of the youngest children can be among the most informed and confident. The UNCRC (1989, article 12) endorses children's involvement in sharing information and influencing decision-making and, in theory at least, English law respects competent children as decision makers. However, professionals' care, information, support and respect for children can affect the levels of a child's competence and autonomy, which rise and fall, partly depending on the adults' beliefs about whether it is reasonable or wise to inform and involve the child in decision-making.

Professionals may simply test children's apparently limited abilities and initial level of knowledge, or alternatively professionals may negotiate with children how far they can, and might be able to, understand with extra help. The adults need to be highly informed themselves about the research or treatment, and this process can test adults' own abilities to communicate with children.

Consent involves concepts of competence, respect, dignity, informed choice and understanding, which can be harder to define and assess in their positive forms than in their negative absence in obvious incompetence, disrespect, violation, exploitation and abuse, misinformation, deceit, coercion or misunderstanding. Professionals who aim to respect children therefore tend at first to have to risk taking children's competence partly on trust. Similarly, children initially have to trust that the adults will respect and not exploit or abuse them, until they can be reassured later by experiencing high standards of healthcare or research. Children with long-term conditions are frequently

involved in treatment and research and are also likely to have experienced limits and failures of healthcare, so that their consent may be highly informed.

Respect for consent involves protecting the child's integrity of body, mind, personal information and reputation from unwanted invasion or intrusion when data are collected and later disseminated. Professionals may have to move beyond assumptions that their work is wholly benign and 'therapeutic' if they are to appreciate children's own estimations of risks, costs, 'side-effects' or inconveniences.

Properly conducted, the consent process also protects professionals from criticisms, complaints and litigation. However, all concerned increasingly need to realise and question the limitations of traditional consent to cover work conducted by large teams, future contractors, and for future unknown purposes.

Consent is a paradox, often combining Kantian notions of the autonomous wise agent who alone can make the correct personal decision, with the courage to make and stand by a best guess about uncertain futures. The protective courage, implied in Linda's cheerful tone when she spoke to her mother and her more sombre anxious tone talking to me after her mother left, was repeatedly shown by children in the surgery study. Adults make mistakes and children may be able to make wise choices besides having unique and essential embodied knowledge, which adults need to understand if the decisions they make for and with children are to be informed. Orthopaedic surgery, for example, aims to relieve pain, immobility or deformity, about which the child who lives in and is the body in question knows most.

A crucial part of consent is voluntariness. It is possible that the more professionals feel able to make informed, willing commitments to their work, the more they are able, willing, confident and, in the chaplain's words earlier, 'big enough' to share information and risks, options and commitments with children, instead of trying to impose these on children.

Basic principles for consent to healthcare and research with children need to be more clearly agreed, and analysed into their many component practical questions for professionals to address. Ways of informing and consulting with children, respecting their autonomy and their vulnerability need to be refined, to help to fulfil the longstanding guidance that 'research involving children is

important for the benefit of all children and should be supported and encouraged, and conducted in an ethical manner' (BPA, 1980:1; RCPCH, 2000:117).

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