

# Chapter 7

Concluding thoughts

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### Striking the right balance: conceptual recommendations

7.1 The terms of reference for this inquiry required the Working Party to consider the extent to which current systems for regulating clinical research with children and young people achieved the right balance between three important considerations:

- the scientific and clinical benefits that research may bring;
- the role of children and young people themselves in research decisions; and
- the proper protection of those taking part in studies.

In considering this question, we were struck repeatedly by the overriding importance of the second of these considerations: the role to be played by children, young people, and their families. However, it also became clear that this role was not limited simply to decisions relating to children's and young people's *own* potential participation in research, but rather was critical across the whole research agenda, including in the prioritisation, design, and scrutiny of studies.

### The potential value of clinical research

7.2 From early on in our considerations, it became clear that the starting point for our analysis should be the claim that “scientifically valid and ethically robust research, addressing questions of importance to the health of children and young people, should be seen as intrinsically good, and as a natural and necessary part of a healthcare system” (paragraph 1.19). Such a claim, however, demands considerable elucidation: what *are* the features of “ethically robust” research, and what systems are required to ensure that they are in place? In the language of our terms of reference, how is the proper balance between the benefits of research, the involvement of children and young people, and the protection of research participants to be assured?

### Understanding children, young people and parents as partners

7.3 We concluded that a critical feature of ethically robust research lies in the recognition of children, young people, and their parents as genuine partners in the research endeavour. In the context of their own family and social environment, children and young people have the potential from an early age to play an active role both in determining their own lives and in engaging with others, as part of their social world. Clinical research must thus always be *with* children and young people, not *on* them: children and young people are not mere passive subjects but rather active participants in a joint enterprise of research. So, instead of trying to second-guess what aspects of a particular health condition are of most concern to children and young people living with it, or what elements of a proposed study protocol might be unacceptably burdensome or distressing for them, researchers should ensure that the experiences and opinions of children, young people, and parents inform the development of their studies from the beginning. Such an approach casts a whole different light on how we understand the notion of the ‘vulnerability’ of children and young people in research, and how the potential for such vulnerability can be minimised through open and honest partnerships.

## Professional responsibilities within that partnership

- 7.4 Recognising children, young people and parents as partners in research that may affect their lives and healthcare should not, however, shift responsibility away from professionals. As we saw in Chapter 2, decisions about research participation are often taken at times of great emotional stress for families; even where this is not the case, the knowledge and professional status of researchers may still result in children and families feeling at a disadvantage, or unable to make a free choice about participation. These potential inequalities emphasise both the importance both of the professional virtues that inform researchers' practice (trustworthiness, openness and courage), and the role of providing assurance played by those responsible for the ethical scrutiny of proposed studies. The 'proper protection' of research participants remains the responsibility of professionals, albeit informed by the knowledge and experience of those most likely to be affected by the research.

## Sensitivity to context

- 7.5 An important thread of the Working Party's analysis throughout this report has been awareness of the *diversity* of childhood experience. This diversity is significant both in the heterogeneity of those understood as 'children' (from newborn babies to young people on the brink of adulthood), and in cultural understandings of how childhood is perceived: what is expected of, or regarded as acceptable for, children and young people at different stages of their development. In coming to our conclusions and recommendations, we have sought to be sensitive to this diversity, both in our identification of three paradigm cases of childhood in which distinct ethical questions about children's involvement arise, and in the extent to which our analysis and recommendations may resonate beyond the UK.
- 7.6 Our practical recommendations (notably those in Chapters 5 and 6) relating to specific aspects of research governance have been targeted primarily towards a UK audience, on the basis that they have in the main been informed by the knowledge and experiences of families and professionals within the UK. However, as we discussed in our Introduction, we were also alert to the fact that clinical research with children and young people is often international in its scope. Moreover, international guidelines and declarations (while not necessarily binding unless implemented in national legislation) play an important role in shaping understandings worldwide of what should be considered 'ethical' in research with children and young people.
- 7.7 In addition to our practical recommendations, we also made a number of *conceptual* recommendations throughout this report that we believe will help to ensure that the right balance is struck between the sometimes competing considerations summarised in paragraph 7.1. We suggest that these conceptual recommendations, if implemented flexibly and with regard to local context, should be of relevance to all those concerned with research with children and young people, both in the UK and beyond. We draw them together in Box 7.1.

### Box 7.1: Conceptual conclusions and recommendations

#### Position of children and young people

- Children and young people should be seen as people who, in the context of their own family and social environment, have the potential, from an early age, to play an active role in determining their own lives and in engaging with others (paragraph 1.25).
- Three paradigm cases identify situations in which children's or young people's potential for input into a decision about research raises distinct ethical questions:

**Case One:** children who are not able at this time to contribute their own view as to whether they should take part in research, such as babies and very young children, or children who are temporarily unable to contribute because they are so unwell or are unconscious.

**Case Two:** children who are able to form views and express wishes, but who are not yet able to make their own independent decisions about research.

**Case Three:** children and young people who potentially have the capacity and maturity to make their own decisions about taking part in a particular research study, but who are still considered minors in their domestic legal system (paragraph 4.5).

#### Role of parents

- Ethical considerations that parents should take into account when making decisions with or on behalf of their children include:

**Respect for children as individuals**, regardless of their age or capacity, expressed, for example, through consideration of children's wishes and respect for their bodily integrity, although children's wishes may not always be determinative.

**Recognition of children's developing capacity** for autonomous agency, and the supportive or educational role of parents in helping their child develop and 'practise' decision-making skills and confidence.

**Concern for children's immediate and longer-term welfare.** Longer-term welfare is concerned with children's and young people's future 'good' including, but not limited to, what is 'best' for them in terms of their physical health or personal interests. Parents also have a responsibility to seek to influence the values that their child acquires as they grow up, and to shape the adult they become (paragraph 4.10).

#### Understanding welfare

- An understanding of children's longer-term welfare should encompass the possibility of contributing to wider social goods. This could take the form of participation in properly regulated clinical research in order to contribute to the knowledge base necessary to improve healthcare for all children in the future (paragraph 4.28).
- The language of 'best interests' is often used to capture this general concern for children's welfare, but is misleading in the context of research, as research-related procedures are not, primarily, carried out for the personal benefit of participants. Parental consent to research should therefore be based on their confidence that participation in the proposed research is *compatible* with their child's immediate and longer term interests (paragraph 4.33).
- There is a morally significant difference, which may potentially justify differential treatment, between 'competent children' and adults. Children, however intellectually capable, do not have full adult powers – and hence also do not have full adult responsibilities. Parents are there, both ethically and legally, to share that responsibility until the agreed threshold of adulthood is reached (paragraph 4.47).

**Challenging vulnerability**

- Concerns about the potential vulnerability of children and young people in research should be treated as an alert, and not as an automatic brake on research: a prompt to researchers to ask themselves ‘Does this research raise particular ethical challenges and what can I do about them?’ (paragraph 4.58).
- An appropriate response by professionals to concerns about children’s potential vulnerability in research is to ensure that they work in partnership with children, young people, and parents throughout the whole research endeavour. Such a partnership approach will ensure that, whenever children and young people are invited to take part in research, the procedures to which they are being invited to consent have been developed with the input of others in a similar situation to themselves (paragraph 4.59).

**Professional virtues**

- Professional virtues that lie at the heart of professional ethical practice in research with children and young people, and encourage a reflexive approach to practice, include trustworthiness (facilitating trust), openness, and courage. These should be encouraged and nurtured (paragraph 5.8).

**Role of ethical scrutiny**

- In order for research ethics committees to be well-placed to make finely balanced decisions as to whether the burdens and risks presented by a particular study protocol can ethically be justified, it is essential for them to have access to appropriate expertise: that of professionals with specialist knowledge of children’s healthcare, and that of children and families (paragraph 5.23).
- The fundamental role of ethical review is to ensure that an invitation to participate in research would constitute a ‘fair offer’ to children, young people and their parents, where the value of the research and its likely risks, burdens and benefits have been carefully weighed up (paragraph 5.28).

**Making decisions about taking part in research**

- Where children and young people have sufficient maturity and understanding to make their own decision but are not yet treated as fully ‘adult’ by the law of their country (Case Three), consent should, wherever possible, be sought from the children and young people concerned, and from their parents (paragraph 6.5).
- Where children and young people are not yet able to make their own decision (Case Two), there is an ethical imperative to *involve* them in the decision as much as possible. Requirements to ‘seek’ or ‘obtain’ assent from children who are being invited to take part in research should be understood as a requirement to involve children (as much as they wish and are able) in the decision about participation. This involvement should be recorded in some way, but it is the *process* of involvement that is ethically significant (paragraphs 4.11 and 6.10).

**Prioritisation of research**

- Our primary ethical concern with respect to prioritisation decisions relates to the *process* by which such choices are made. The key challenge for those responsible for making decisions about which research to pursue and which studies to fund is to ensure that key stakeholders, including children, young people, parents and professionals, are appropriately involved in those decisions (paragraph 5.40).

## Making research part of everyday life

- 7.8 The aim of our analysis in this report, summarised in the conceptual conclusions and recommendations in Box 7.1, has been to clarify some of the key ethical concerns that arise in the context of clinical research with children and young people. In so doing, we have sought to remove potential barriers to research that may arise because of misplaced anxieties about what constitutes ethically acceptable practice. However, the barriers to research practice, as we outline in the background chapters of our report (see, for example, paragraphs 2.17–2.18 and 3.62–3.64) are not limited to concerns about ethical acceptability.
- 7.9 In order to reach the point where clinical research is genuinely seen as a core ‘everyday’ part of health service provision, commitment to evidence-based care will be required on the part of *all* those able to influence how care is delivered: including health professionals, health managers, and those responsible for health policy. It will also require substantial commitment on the part of policy-makers to increase knowledge of research among the general public. For children, young people, and parents to feel confident in taking part in research, they need to be able to trust that what they are being asked to do constitutes a fair offer. The task of researchers will be made much easier if the children and young people they are seeking to recruit, along with their parents, already have *some* understanding of the need for clinical research to improve healthcare, and of the many safeguards in place to ensure that what they are being invited to do is fair and worthwhile. Similarly, those who have had the opportunity to find out more about research are much more likely to take up the kinds of opportunities to influence the wider research agenda that we have advocated in this report. In the context of the UK, we suggest that the All Party Parliamentary Group on Medical Research, which has been active and engaged in the question of clinical research with children, would be well placed to initiate work on how best to achieve these aims.

### Recommendation 19

We recommend that the All Party Parliamentary Group on Medical Research should take the lead in exploring ways of increasing general public awareness of clinical research in general, and of the benefits of such research for children’s and young people’s health and healthcare.

- 7.10 During our inquiry we heard many suggestions as to how this awareness might be increased. These included inclusion in school curricula, podcasts on hospital websites, ‘ambassador’ work undertaken by young people already involved in clinical research networks, open days by research centres, wider publicity of research opportunities, and greater knowledge and enthusiasm on the part of health professionals. We are aware of some positive initiatives along these lines, including the ‘It’s ok to ask’ campaign by the National Institute for Health Research (NIHR), encouraging patients and carers of all ages to ask their doctors about research.<sup>611</sup> We thus conclude our report by highlighting the central importance of further work exploring the most effective methods of increasing knowledge and awareness, and the means of implementing them. For research to become part of the ‘core business’ of the NHS and other health services, it

<sup>611</sup> National Institute for Health Research (1 May 2013) *It’s ok to ask - the NIHR’s new patient empowerment campaign*, available at: <http://www.ct-toolkit.ac.uk/news/its-ok-to-ask-the-nihrs-new-patient-empowerment-campaign>.

is important that we see an increasingly positive attitude towards research among potential participants and health professionals, together with confidence in the ethical robustness of that research.