In the light of changes in the understanding of children's interests and in legal requirements, these guidelines were revised in 1992. The section on the interpretation of assessment of risk in the earlier document was expanded and the particular issue of whether taking blood from children should be regarded as a minimal or low risk procedure was considered in more detail. It was concluded that taking blood from a child's vein was a low risk rather than a minimal risk procedure. Professor Sir David Hull in his foreword to the revised BPA report states 'The sentence on low risk that "Many children fear needles and to them low rather than minimal risks are often incurred by injection and venepuncture" is intended to encourage research workers to recognise the distress of these children. The Department of Health's 1991 circular on local research ethics committees states in para 4.3 'Where the proposal is for non-therapeutic research . . . the child must be subject to no more than minimal risk as a result of his/her participation'. In the Medical Research Council publication, The Ethical Conduct of Research on Children, it is stated in para 8.1 that 'We recommend that children should only be included in research if in the case of non-therapeutic research, participation places a child at no more than negligible risk of harm'.

The work of Hammond and her colleagues into the many factors which influence the child's and parent's decision to donate venous blood is important in that it challenges the revised guidelines and goes against the Department of Health's 1991 circular. They provide clear evidence on the acceptability of blood sampling by venepuncture in primary schoolchildren and the effects of age of the child, parental attitudes to testing, and peer group pressure on the child's perception of the benefits of participation. They also reported no difference between the response rate to venepuncture compared with an earlier study involving the collection of fingerprick capillary blood. Anaesthetic cream was used in the recent study but while being effective in relieving pain associated with needle insertion it might have contributed to the child's anxiety. Parental presence at the time of blood sampling was also a factor which might have increased anxiety levels. Parental attitudes, presumably determined by their own levels of education and life experience, also affected the uptake and the child's attitude to blood testing. These factors together with the child's age resulted in the acceptance rate in one school being 46% and in another 91%. It could be argued that there was a potential benefit to the individual child detected to be anaemic on the basis of the blood tests. What was not discussed was the fact that measurement of cholesterol in the blood samples was performed and there is no indication that the parents were counselled as to the family implications of the detection of significant hypercholesterolaemia. On the other hand without the valid information of the sort to be derived from the study we would have no knowledge of the definition of significant hypercholesterolaemia in young British children.

Many adults who donate blood or take part in medical research have an extreme dislike of venepuncture and the anxiety that precedes the insertion of the needle. This fear and dislike of pain however slight or transient is normal and outweighed by the altruism of the participant. It would be wrong to presume that the child is incapable of altruism and as Mott and Chambers comment 'both sentimentality and insensitivity are unhelpful attitudes in responsible and medical care of children'. They also emphasised the need to know normal ranges of blood biochemistry at various ages, particularly as child reference ranges often differ substantially from those in adults. Failure to obtain clinical and biochemical measures of the influence of diet on health and disease during the early years of life can only serve to delay our understanding of the environmental factors that cause later ill health and early degenerative disease.

The present guidelines are being interpreted by some ethic committees as precluding venepuncture in children for non-therapeutic research. This view must be challenged if it threatens studies which are essential to provide 'normal' data. I hope that the BPA Ethics Advisory Committee will review their revised guidelines.

Commentary (2)

Judith Hammond and her colleagues assess the feasibility and acceptability of collecting blood by venepuncture from two groups of primary schoolchildren. They state that 'venepuncture is ethical provided that the problem under investigation is of great importance, the response rate is high, and the sample size is appropriate for the question being asked'. Embarking on trivial research is obviously wrong but information is given on which we can judge the relative importance of this project. I assume that the study was properly designed and appropriate to its objective. However, it is potentially dangerous for investigators to use the argument that it is ethical because of its scientific value. It also cannot be argued retrospectively that a study is ethical because there was a high response rate. 'A study is ethical or unethical at its inception; it does not become ethical post hoc - ends do not justify means'.

Another issue is the question of coercion or even subtle pressure on the subjects to
participate. ‘Parents were also informed that children who underwent venepuncture would be given a T-shirt bearing the study’s initials and an illustration of healthy lifestyle as a token of our appreciation of the child’s participation and cooperation in the study’. This implies that a bribe was offered in advance. For research to be ‘ethical’, a ‘token’ reward should not be part of the negotiations towards recruitment for the study and should not be contingent on the child completing participation.

The authors conclude that ‘our recommendations have to be scrutinised in the context of recent guidelines on the conduct of research in children by the Medical Research Council and British Paediatric Association’. Although the strict legality of what is usually called ‘non-therapeutic research’ remains uncertain, it is generally accepted that such research is ethical, provided that certain conditions are met. Assuming the consent of parents and the approval of an ethics committee, all such projects also involve a value judgment in deciding what is an appropriate balancing of the potential harms to the individual child participants with the potential gains for other children. In the example under discussion, the value of the information obtained must be set against the pain and distress caused by the venepuncture. In these circumstances a venepuncture seemed to be acceptable to the BPA Ethics Advisory Committee in 1980.4 In 1985, a study of 92 healthy children aged between 6 and 8 years who had a venepuncture, and were followed up by questionnaire 18 months later, revealed few negative effects, and in some cases positive effects.5 Surprisingly, in the current BPA guidelines, venepuncture is classified as ‘low’ rather than ‘minimal’ risk, and it is stated that ‘it would be unethical to submit child subjects to more than minimal risk when the procedure offers no benefit to them’. However, as the BPA President points out in an accompanying commentary, classifying venepuncture as ‘low risk’ might discourage important research that could benefit children generally. He emphasizes that every effort should be made ‘to reduce the amount of pain suffered by children by performing procedures skilfully and by considering the use of anaesthetic agents’. This recommendation was followed by Hammond et al. Perhaps the Ethics Advisory Committee might consider reclassifying venepuncture as ‘minimal risk’ provided that an anaesthetic agent is used to minimise pain.

The authors mention ‘recommendations’. What recommendations? I was unable to discover any advice that might be useful to others in carrying out similar studies. For example, it would have been useful to have the benefit of their experience in suggesting ways of overcoming the poor response rate from schools with children from deprived social backgrounds and of minimising the number of children who dissent at the time of venepuncture. It would also have been interesting to know why the third phlebotomist had such a significant failure rate. For example, assuming basic technical expertise, how important was the personality of the phlebotomist and the ability to communicate effectively with apprehensive children and parents – so important in a project of this kind?

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Commentary (3)

Parents, children and their doctors have, rightly, high expectations for safety in the practice of childhood medicine. The risk/benefit ratio for practical procedures and treatments should be known so that consent might be given. Seasoned paediatricians know that the intuitive acceptability tests which parents apply are probably set at a higher standard for their children than for themselves.

In research and development the traditional approach has been to try out the procedure or drug on adults and extend it to children if this experience is satisfactory. Practical and financial considerations probably explain why many drugs prescribed by paediatricians are not recommended by manufacturers for use in children; studies required to satisfy licensing bodies would be too demanding.

Two emerging arguments have a bearing here: first, the recognition of childhood autonomy, especially following the Children Act of 1989. This means that the child must be consulted and his or her decision must have an important influence on medical activities. The second is that tests and drugs should be evaluated in children as rigorously as happens with adults. He emphasizes that the ‘minimal risk on children’ approach should be abandoned. Both of these issues have important implications on research in children, both therapeutic and, particularly, non-therapeutic. The BPA has addressed these by publishing guidelines for the ethical conduct of medical research in children, the latest edition of which appeared in 1992. These caused alarm to many of us researchers because they estimated the risk to children of injections and venepuncture as being low (rather than minimal – the least possible) and then declared it would be unethical to submit children to more than minimal risk in non-therapeutic research. This was a change from the guidelines issued in 1980 where the calculus of risk estimate was slightly different but a negligible risk was thought to be one less than was run in everyday life – and this clearly applies to blood sampling. Many researchers now fear that research ethics committees would ban non-therapeutic research involving injections, fingerpricks, or venepuncture. As a consequence, the desirable aim of extending the range and safety of procedures...