Involving children and young people in health research – getting it right

I don't like the idea of getting poked on the arm.

I don't like injections!

I don't like the bottle either.

Helping, curing children. Helping other people.
The Nuffield Council on Bioethics is an independent body that looks at ethical issues in biology and medicine. Between 2013 and 2015 we looked into the question of how children and young people can ethically be involved in clinical (health) research. The project involved an expert working party, a group of parents and young people (our stakeholder group) who helped us throughout the project, and many other children, young people, parents, and professionals who responded to consultations, took part in workshops, and commented on what we were thinking and writing.

This magazine summarises the project’s main conclusions and recommendations for young people, parents, and anyone involved in carrying out research with children and young people. The photographs are of young people whom we’ve talked to throughout our work. The quotes and drawings we have included are also from young people and parents who have helped us in our project. We would like to thank them all.

What’s this report about?

Why carry out health research with children and young people? What’s the problem?

What’s different about research with children and young people?

Three different research situations for children and young people, and what these mean for parents

Researchers’ responsibilities

Making sure children and young people aren’t vulnerable in research, and checking that research is ethical

Inviting children and young people to take part in research

Information that’s easy to understand, good communication, and the rules on consent and assent

Making shared decisions about research

Children, young people and parents making decisions together, and how to deal with disagreement

Deciding what research happens in the first place

Who ought to decide what research takes place? How can more research with children and young people be encouraged?

Making research easier for everyone

Making research an ordinary part of healthcare, and making it better known

Resources, links and glossary

People we talked to as part of this project

Summary

Involving children and young people in health research – getting it right

In May 2015, as well as this magazine, we published:

- A detailed report: Children and clinical research: ethical issues
- An animation Health research: making the right decision for me, illustrating what our report is about for children and young people

All these, plus news updates, blogs and interviews, are on our website www.nuffieldbioethics.org/children

To order a printed copy of this magazine or our report, please contact us:
E: bioethics@nuffieldbioethics.org
T: +44 (0)20 7681 9619

You can also follow us on:

@Nuffbioethics

www.facebook.com/nuffieldbioethics

Film icon: link to a video
(click to go to a website to see the video)

Audio icon: link to a recording of an interview with a young person
(click to hear the interview)

Devices incompatible with Flash Player can access these files via our website
Health research with children and young people
This report is about how best to carry out health research – research that tries to find better ways of keeping children and young people healthy, as well as looking after them when they are ill or have a disability. There are many different kinds of research that children and young people might be asked to take part in. Some studies involve children who are healthy, and others involve children who have an illness or disability.

Why do research with children and young people?
Researchers can’t just carry out this research with adults, because children are different from adults. Their bodies respond to treatments differently because they are still growing. They may also have different opinions about what matters to them.

Does research help children and young people who take part?
Researchers usually have some evidence that what they are doing may help children or young people with a particular condition. However, they need to collect information from lots of people, so they can be sure that they are providing care in the best way. This may or may not help children or young people who take part in the research. However, it may help other children in the future. Sometimes research may show that the treatment does not work or is not necessary. This information is just as important.

Ethical questions
Because research is important, we need to find ways of making sure children and young people are given the option of taking part in it. We also need to make sure that they are protected from harm. This report looks at ethical ways of involving children and young people in research.

FOR EXAMPLE, RESEARCHERS MIGHT:
• ask children and young people about their daily lives, such as how much they exercise, what they eat, and whether they smoke
• find out how health conditions, such as asthma, affect children’s lives
• find out whether a new treatment, such as a new medicine or vaccine, works better for children and young people than existing treatments
• invite children and young people to give their opinions about health services they have used, and how they could be improved

Burdens
are things about research that people taking part might find unpleasant, or boring.

"Extra visits to the hospital or having to do diary notes because I think I’ve got a lot going on and I just wouldn’t find the time for that as well. Things like blood tests and needles – I’m not scared of them or anything – they just make me uncomfortable. I just wouldn’t want these."

Burden is about deciding what is the right thing to do. Often there isn’t an easy answer because there are good things and bad things about all the options. Our report suggests ways of thinking about how to decide. But it can’t give all the answers to every difficult question.

For more information, see Chapter 1 of the full report.

Nuffield Council on Bioethics 3

Image from our film of children and young people discussing taking part in research
What’s different about research with children and young people?

Many of the rules that researchers have to follow are the same for adults and for children. However, there are ways in which children and young people are different from adults. These include:

• The way children develop as they grow up – for example in what they can do, what they understand, and the way they feel.

• Children aren’t on their own – they are part of their families. They have parents looking after them and making decisions with them.

What do parents need to think about?

When parents make decisions with their children, or for their children, they need to take a number of things into account:

• Children are individuals, however young they are. Children’s wishes matter, even if adults don’t always agree with them.

• As they grow up, children get more confident at making decisions for themselves. They need to be able to practise making decisions – but they also need help and support from their parents.

• Parents are responsible for looking after their child’s welfare – what’s ‘good’ for them.

What do we mean by ‘welfare’?

Parents look after their children’s welfare by trying to protect them from harm. But welfare is also about having opportunities to learn and develop. For parents, this includes thinking about the kind of person their child is growing up to be, and what they think is important.

Taking part in worthwhile research might be ‘good’ for a child or young person, even if they don’t get something back for themselves or benefit from taking part.

Parents and children will need to know that everything has been done to make the research as safe as possible. They may also want to know afterwards whether the research has proved something, and is likely to help others.

Three different research situations for children, young people and parents

There are three situations where the questions about how to treat children and young people in research will be quite different.

1. Children and young people who can’t say what they think about taking part in research. This could include babies and very young children, but also older children, who are unconscious after an accident, or just too unwell to say what they think.

Parents will mainly think about their child’s welfare, and what is best for their child’s health.

2. Children and young people who can say what they think about taking part in research, but can’t yet make a decision on their own. This could include children as young as three.

Parents will gradually give more weight to their child’s wishes, and will want to support their child as they begin to take the lead in making decisions for themselves. However, parents will want to be sure that their child is not overwhelmed by choices and decisions that they aren’t yet ready to make.

3. Children and young people who are able to make their own decisions, but are not yet treated as adults by the law in their country.

Children’s and young people’s wishes will usually be the most important thing. Parents are there to support and advise, but not to ‘take over’. But even in this situation, parents still have a responsibility for their child’s welfare.

What’s different about research with children and young people – For more information, see Chapter 4 of the full report

When we talk about PARENTS in our report, we mean anyone who is doing a parent’s job – for example a guardian, or a grandparent who is responsible for a child all the time.

When we talk about CHILDREN AND YOUNG PEOPLE, we mean anyone who isn’t yet treated as an adult by the law in their country.
Researchers’ responsibilities

Researchers have responsibilities towards children and young people too. Like parents, they should treat children as individuals, think about their developing ability to make decisions, and be concerned for their welfare. As professionals, they also have extra responsibilities. They need to be:

• **TRUSTWORTHY.** Children and parents will only feel able to take part in research if they can trust researchers.

• **OPEN.** Researchers need to share information clearly and honestly with children and parents – when inviting them to take part in research, during the research itself, and afterwards. They also need to be willing to share information and work with other researchers.

• **COURAGEOUS.** Some research with children and young people is difficult to do, and it may seem easier just not to do it. But if research isn’t carried out, then children will not have the best possible healthcare.

Making sure children and young people aren’t vulnerable in research

People often think that children and young people are vulnerable in research. Sometimes worrying about children and young people being vulnerable means that research just doesn’t happen.

We think that the best way of preventing vulnerability is through researchers working in partnership with children, young people and parents. One way of doing this is for researchers to involve children, young people and parents in the design of their research from the beginning. This kind of partnership can help make sure that children and young people are not placed in situations where they may feel vulnerable.

Who makes sure that research is ethical?

In most countries, researchers are only allowed to do research involving people if they have the permission of a research ethics committee (REC). The REC is a group of people who are interested in research for different reasons, such as researchers themselves, health professionals such as doctors or nurses, or ordinary people who think that research is important.

The REC’s job is both to protect the people taking part in research, and to help research go ahead if researchers’ plans are good enough. They need to make sure that any invitation to children and young people to take part in research is a ‘fair offer’ – an invitation that children and their parents can trust. This includes looking at questions like:

• Is the research worth doing? Is it trying to find out something useful that isn’t known already?

• Are the risks and burdens as low as possible? Are they reasonable in the circumstances?

• Is the information about the study clear and easy to understand, so that children, young people and parents can make up their own minds?

To do their job, RECs need to hear from the experts such as:

• children and young people who know how the research might affect their lives and what they think might be ‘reasonable’; and

• from professionals who understand what the study is about – for example an expert in children’s mental health if the study is about mental health, or an expert in children’s infectious diseases if that’s what the study is about.

YOUNG PERSONS’ ADVISORY GROUPS (YPAGs)

The English Clinical Research Network: Children and the Scottish Children’s Research Network (ScotCRN) both have YPAGs. YPAG members comment on the design of studies, so that researchers understand how their ideas might affect children’s and young people’s everyday lives. They also help to produce information that children and young people can understand. They do this for research that is paid for by the government, and also for research by commercial companies who make money out of developing new treatments.

**WE THINK THAT:**

• Researchers should involve children, young people and parents when developing their studies.

• Groups like Young Persons’ Advisory Groups (YPAGs) are a good way of doing this.

• Commercial companies should help pay for the costs of running groups like YPAGs. For example companies could contribute to a central pot of money to help fund lots of groups.

**“You'd want them to be friendly, to be trustworthy: they wouldn't be over-familiar straightaway... you build it up, cos if you're doing visits for like six months - I don't know how long it'll be - you kind of want to build up a relationship with them.”**

**“The ideal [researcher] would appreciate that the research isn’t the most important thing in that child’s life. They have other priorities which need to come first, and they would sit the research around the individual rather than setting out all their goals and saying, ‘you have to come to hospital five times a week, and we’re going to do this, this, and this.’ They’d step back and say, well, what suits you? Will that mean you’ll miss out too much school?”**

**“I would want to know that a parent or parent group had been consulted at study design/ ethics stage so that the researchers took on board ‘the man in the street’ point of view.”**

The REC’s job is both to protect the people taking part in research, and to help research go ahead if researchers’ plans are good enough. They need to make sure that any invitation to children and young people to take part in research is a ‘fair offer’ – an invitation that children and their parents can trust. This includes looking at questions like:

• Is the research worth doing? Is it trying to find out something useful that isn’t known already?

• Are the risks and burdens as low as possible? Are they reasonable in the circumstances?

• Is the information about the study clear and easy to understand, so that children, young people and parents can make up their own minds?

To do their job, RECs need to hear from the experts such as:

• children and young people who know how the research might affect their lives and what they think might be ‘reasonable’; and

• from professionals who understand what the study is about – for example an expert in children’s mental health if the study is about mental health, or an expert in children’s infectious diseases if that’s what the study is about.

**WE THINK THAT:**

• Research ethics committees (RECs) should require researchers to involve children, young people and parents in the development of their studies, unless there are good reasons why not.

• When RECs make decisions about research involving children, at least one person on the committee should be an expert in this area of children’s healthcare. Sometimes RECs might need to invite an expert to advise them, just for this one decision.

• There should be a list of experts from different areas of children’s and young people’s healthcare who are willing to be advisors. Organisations like the National Research Ethics Service and the Royal College of Paediatrics and Child Health should take the lead in drawing up this list.

**Researchers’ responsibilities – For more information, see Chapters 4 and 5 of the full report**
Inviting children and young people to take part in research

Communication and information
Children and young people need clear information about the research before they can decide if they want to take part. Good communication and good relationships with researchers are very important.

"If they had other ways of going through the research or the process - maybe if it wasn’t just verbal, if they had, like, some visual aids maybe or clips. Things like that."

Explaining research clearly to parents
Parents need clear information too. It is important that researchers work with parents of younger children to make sure that they are happy with what their child is being told and how it is being done.

"I would decide and explain to my child in a way that would encourage them to see the benefits and take part."

Consent and assent
The law says that people can only take part in research if they have received enough information about the study, and if they have given their consent. In research with children and young people, it is usually parents or guardians who give consent.

Sometimes, children are also asked to give their assent to research - say that they agree to take part.

Consent is legal permission
In England and Wales, the law allows a young person of 16 or 17 to consent to take part in research for themselves. However, parents can also consent for their children until they are aged 18. This means that researchers can ask for consent from either the young person or their parent.

In Scotland, 16 year olds are treated as adults, and their parents can no longer make decisions for them.

Assent and consent are different
Consent gives researchers legal permission to go ahead. Assent is a way of showing that children and young people have been involved in the decision.

There is some confusion over how, in practice, children should be asked to give their assent:

• Some guidelines say that only children old enough to understand the research should be asked to give their assent.
• Some guidelines say that children should be asked for their assent from the age of three.
• Some guidelines say that children should be asked to sign an assent form to show that they agree.

Being able to know what the researchers found out
Children, young people and parents must have the option of finding out about the outcome of the research - what the researchers found out as a result of doing the research and what difference this might make.

"Personally, I like seeing what my efforts have gone and produced, and how the information I give or the time I sort of give to do whatever it is ... it’s nice to see that they’re bearing fruit, and actually having an outcome."
Making shared decisions about research

What if parents and children disagree about taking part in research?

Researchers should always try to help families come to a shared decision. However, this isn’t always possible. In most cases, if not everyone in the family agrees, then it’s best if children or young people don’t take part in the study. The law allows research to go ahead with just a parent’s consent, even if their child disagrees. However, researchers may decide not to include children in a research study if they don’t feel it’s right – for example, if a child really doesn’t want to take part, and the researcher believes that it would cause more harm than good to continue.

What if children and young people who CAN’T make their own decision?

- As soon as children are able to express views or wishes about taking part in research (which may be as young as three), they should be involved in the decision.
- Some research guidelines say that children should be asked for their assent but there is little agreement on what this means in practice. We believe that assent should mean real involvement in the decision.

Parents should usually be asked for their consent too, so that the decision is made together, as a family. One way of recording this shared decision could be for children and parents to sign a consent form together.

If the law says that a young person has the right to consent to research (16 in the UK) then, legally, only the young person’s consent is needed. However, many young people still prefer to involve their parents, or another trusted person, when they make their decision. Researchers should encourage this.

What if young people don’t want to involve their parents?

Sometimes it may be necessary to carry out research with young people without their parents being involved.

For research like this, researchers should ask the research ethics committee to agree that parents don’t need to be involved. The committee might ask the researchers to discuss their idea first with people in the local area to explain why they believe the research is important. This may help parents to feel things aren’t being done behind their backs, even if they don’t know whether or not their own child is involved.
Deciding what research happens in the first place

Who gets to decide?

It is important to think about how research studies get the money to go ahead. Who gets to choose these studies, and why? There are lots of different sources of funding, including:

- governments;
- commercial companies, both big and small, that make money out of producing medicines;
- charities that fund many different types of research; and
- charities concerned with children living with a particular health condition.

Some research funders have very clear ideas about the kinds of research they want to fund, and what they think is most important. Others depend more on ideas that researchers come up with. Some research funders involve children, young people and parents by asking them what research they think is most important.

The James Lind Alliance is a group that campaigns for a more systematic way of working out what research is most important. It sets up ‘priority setting partnerships’ (PSPs) which bring patients with a particular condition, researchers and health professionals together to agree what are the most important areas of research needed for that condition.

Waivers in the Paediatric Regulation 2006

A company may be given a waiver if they are developing a medicine for a condition that doesn’t affect children, such as lung cancer. This means they don’t have to involve children and young people in the trials. However, sometimes the way the medicine works might still be helpful for different conditions that do affect children and young people.

Encouraging research into new medicines

Governments can encourage commercial companies to do particular kinds of research by offering them extra rewards, or by making special rules. Many medicines given to children and young people have only been researched in adults. This is now changing. In Europe, the 2006 ‘Paediatric Regulation’ says that when companies carry out clinical trials of new medicines with adults, they must include children and young people in the research, unless they get a waiver to say they don’t have to.

The Regulation also encourages companies to do research on old medicines – for example making a medicine available as a syrup, instead of a tablet, so it is easier for young children to take.

As a result of the Regulation, it is now much more usual for research into new medicines to include children and young people. This means that there is much more information for doctors on how these medicines will work if children and young people need to take them.

Although the Regulation has been very successful, some changes are still needed. Rewards to encourage research on old medicines haven’t worked very well, and there are problems with the way waivers are given.

We think that:

- People who choose what research studies to give money to must make sure that children, young people and parents are properly involved in these decisions.
- Government departments of health are in a good position to take the lead when looking at what areas of children’s healthcare in their country particularly need research. They, too, must make sure they involve children, young people and parents in these decisions.

We think that:

- The rules on waivers need to be changed. If the way that the medicine works might help children and young people, then research with children and young people should go ahead.
- All companies should include children and young people in trials where this might be helpful, even if they are given a waiver and aren’t obliged to do so.
- Regulators need to find new ways of encouraging researchers to carry out research on old medicines that might be useful for children and young people.

Clinical trials of new medicines look at how well new medicines work, and whether they are better than existing treatments.

The European Medicines Agency (EMA) has started trying to involve young people in its work. The EMA is in charge of clinical trials of new medicines in Europe.
Research needs to become an ordinary part of the National Health Service (NHS) in Britain. It shouldn’t be seen as something optional or unimportant. At the moment, it’s often hard for people working in the NHS to find the time they need either to do research themselves, or get involved in research ethics committees.

**WE THINK THAT:**

- NHS managers should encourage worthwhile research in their hospitals and clinics.
- NHS managers, universities, and policy makers should make sure that members of research ethics committees have enough time in their working day to do this important job.

The general public, both adults and children, need to understand more about health research – both about how it’s carried out and why it’s important. Knowing more will make it easier for children, young people, and parents if they are ever invited to take part.

There are many ways in which this can be done – although no single easy way. For example:

- Researchers and research organisations could do more to tell people what they do, through open days, events for children and young people, and well-designed webpages.
- Schools, museums, youth clubs and other groups could offer opportunities to encourage people to learn more about research.

**WE THINK THAT:**

- The All-Party Parliamentary Group on Medical Research should take the lead in finding the best ways of increasing everyone’s knowledge about research.

**Glossary**

- **Assent:** An agreement to do something, and a way of showing that children and young people have been involved in making decisions about taking part in research.
- **Burdens:** Unpleasant or boring things about taking part in research.
- **Children and young people:** Anyone who isn’t treated as an adult in the country where they live.
- **Clinical trials:** Research to see how well new medicines work, and whether they are better than medicines that are already used to treat children and young people.
- **Consent:** A legal term for when a person agrees to do something, such as take part in research.
- **Ethics:** Ways of thinking about the right thing to do.
- **Fair offer:** An invitation to take part in health research that children and their parents can trust.
- **Parents:** Anyone who does a parent’s job. This might be a guardian or a grandparent who looks after their grandchild full time, as well as children’s mums and dads.
- **Policy-makers:** People who decide on the rules, for example about research.
- **Regulation:** The rules on how something should be done (for example, how research should be carried out with children).
- **Research ethics committee:** A group of people who are interested in research, and make decisions about whether inviting children and young people to take part in research is a ‘fair offer’.
- **Vulnerable:** Describes a person who is particularly likely to be harmed.
- **Welfare:** Things that are good for a person, such as their wellbeing or happiness. This includes having a chance to learn new things.
- **Waiver:** When a person or organisation is freed from a responsibility to do something.

**ALL-PARTY PARLIAMENTARY GROUPS**

are groups of Members of Parliament (MPs) who are interested in a particular subject, and who meet regularly with experts in that subject. They look at ways in which laws or policies might change to make things better.

**Resources and links**

The films, animation, blogs, and articles we have produced are all available on the Nuffield Council on Bioethics’ website (www.nuffieldbioethics.org/children). The websites and documents mentioned below can all be accessed via our website.

**Young persons’ groups**

The iCAN network is a growing consortium of young persons’ advisory groups, including groups in the UK, United States, Canada and France. The CRN: Children group in England has produced GenerationR magazine, showcasing how children, young people and parents can be involved in the design and delivery of research. They also provide a practical Guidance document for researchers designing patient information leaflets giving tips to researchers on presenting information clearly for children and young people.

The Young Persons’ Mental Health Advisory Group (YPMHAG) gives advice to researchers working on mental health studies.

**Resources for young people**

Other resources that may be of interest to young people include interviews with young people who have experience of taking part in research, which are available on the website YouthHealthTalk. Information about how to get involved in research, and what studies are taking place at the moment is available on the CRN: Children website.

**Other resources for researchers**

The website YoungHealthParticipation brings together a range of useful resources on involving children and young people in research.

The National Children’s Bureau has also published Guidelines for Research with Children and Young People.

**Making research easier for everyone** – For more information, see Chapter 7 of the full report

Nuffield Council on Bioethics
People we talked to as part of this project

- Young people and parents in our stakeholder group who advised on our project
- Children, young people, parents and professionals who replied to our online consultation, and commented on drafts
- Children and young people from schools in Brighton (see our Youth REC film) and in Wimbledon (see our blog)
- Young people, and community representatives in Kilifi, Kenya
- Members of Young Persons’ Advisory Groups (YPAGs) in Liverpool, London, Aberdeen and Connecticut
- Children and young people who took part in our animation workshop

The quotes in this magazine are all from children, young people and parents who have taken part in this project.

Summary

In this report, we present the following conclusions and recommendations:

**Good research is important for children and young people**
- Well-designed health research that asks important questions is essential in order to improve children’s health and healthcare.
- Research should always be carried out with children, not on children. If children and young people choose to take part in research, they should be listened to, and feel that they are actively involved.

**Different situations for children and parents**
- We describe three situations where the questions about how to treat children and young people fairly in research will be quite different:
  1. Children and young people who are unable to say what they think about taking part in research (for example, very young children, or older children and young people who are too unwell or upset at the time). Parents will usually make decisions based on what they think is best for them.
  2. Children and young people who can say what they think about taking part in research, but can’t make a decision without some help. Parents will think about their child’s wishes, as well as what they, as parents, think is best. As children get older, parents will see their job as helping them start to make their own decisions.
  3. Children and young people who can make their own decisions, but aren’t yet treated as adults in the country they live in. Children’s and young people’s wishes will usually be the most important thing to take into account. Parents are there mainly to support and advise. However, it’s still their job to think about their child’s welfare.

**Making sure children and young people aren’t vulnerable**
- People often worry that children and young people may be vulnerable in research. The best way of making sure this doesn’t happen is for researchers to involve children, young people and parents when they design their studies, and to take their opinions on board.

The job of research ethics committees
- Before researchers are allowed to go ahead with research involving people, they have to get approval from a research ethics committee. This committee should make sure that any invitation to children and young people to take part in research is a fair offer: an invitation that children and their parents can trust.

Making decisions about taking part in research
- Children, young people and parents all need clear information about a research study before they are asked to take part. Good communication and good relationships with researchers are very important.
- Wherever possible, a decision about taking part in research should be a shared decision between a child or young person and their parents. Young people who are able to make their own decisions should be asked for their own consent.
- Children who can’t yet make their own decisions about research should be as involved as they want to be. This is what we mean by ‘assent’. It’s their parents’ job to make the final decision.

Deciding what research happens in the first place
- People who choose what research studies to fund must make sure that children, young people and parents are involved in these choices.

Making research easier for everyone
- Good research needs to become an ordinary part of the National Health Service. People running health services should encourage worthwhile research in their hospitals and clinics. Children, young people and adults all need to know more about research. That way, it’s much easier for them to decide what to do if they are ever invited to take part in research.
I don't like the idea of getting pricked on the arm.

I would like to take part in this to help other people.

Helping other people

I could hurt me and there might not be any cure.

Doctors don't understand that children's conditions may change.

People have check-ups to see how they have progressed.

Having a lolly "paracetamol" makes the feelings better.