Legal conversations
Researching people who cannot consent

Marc Cornock
Is it against the law to do research on individuals without their consent? What if a person can't consent can someone else consent on their behalf?

Phil- what's your perspective on this?

Phil Bates
Well I think it depends on what kind of research we are talking about and what kind of people we are talking about. Somebody might be unable to consent to research for a whole variety of reasons, young children and also people suffering from diseases, disabilities, people with learning disabilities or Alzheimer's disease. Now many people in all of those categories may actually be able to consent to research. They may understand what's proposed. They may be able to – to participate in the decision. But in other cases somebody may not be able to make their own decision. Now that doesn't necessarily mean that we shouldn't be doing research on them. There may be good reasons to do research but we do have to be very careful. We have to make sure that the level of risk that those people are exposed to is limited. We have to make sure that the research that's done on them is not an exploitation of them.

Marc Cornock
So are we talking about a legal issue here or an ethical issue?

Phil Bates
I think it's a mixture. My interest in this area arose when I worked at the Law Commission in the early 1990's. I was doing a project on the law relating to the treatment of incapacitated adults. So we were looking at under what circumstances an incapacitated adult could be receive standard medical treatment, whether they could receive treatment that was contraceptive to prevent pregnancy or even an abortion without their consent in their own best interests. End of life care relating to cases like the Tony Bland case where the decision was being made as to whether to withdraw a feeding tube from someone at the end of their life when they couldn't participate in the decision. So most of the issues were around the treatment of incapacitated adults. But one of the issues that came up while we were doing that was if we can treat these people in their best interests, what about research? Should we be able to do research on people at all? Should we be able to do research on them only if we think that it is benefiting them in some way? Or should there be situations where we can do research which is not directly beneficial to the individual but perhaps it helps other people in a similar situation. So we had to think about all of those issues and eventually as a result of that project the Mental Capacity Act includes provisions relating to whether it's lawful to carry out research on an incapacitated adult. At the same time as those changes in the law there was a whole range of ethical guidance which helps to clarify how those kinds of decisions should be made as to whether to include an incapacitated person in a research project, what kinds of safeguards are necessary, who else should be involved in the decision. And finally in order for any research project to be approved by a Research Ethics Committee there's going to have to be some consideration not only of the lawfulness of the research but also of the ethical questions. So there is a mixture there of legal and ethical issues.

Marc Cornock
So when you say there should be some safeguards involved what kind of safeguards are you thinking of?

Phil Bates

Well one of the safeguards is going to be the role of the research ethics committee. So we have a system in this country which is quite mixed but we have National Health Service Research Ethics Committees, which relate to research on patients and NHS employees. We also have university ethics committees, which approve research being conducted in the academic setting. And we also have a range of other types of research ethics committees that deal with particular kinds of research in particular sectors. So one of the safeguards is the idea that research ethics committees should not approve research if it's too dangerous or too exploitative. Now in some areas that – that may work quite well. Some other ethics committees it's less clear how independent they are. It's less clear how much expertise they have to assess these things. And even if a research ethics committee has approved something there is always a risk that the researcher may actually go off and do something quite different. So the research ethics committee is a really important part of the safeguards but it's not necessarily a guarantee. The other kinds of safeguards we might include would be the role for somebody who knows the incapacitated person to protect their interests. In the incapacitated adult situation you might have somebody who is close to them, a carer or a relative, someone who can look out for their interests. In the other situation where you're dealing with children then you are almost always going to have a person with parental responsibility and getting the consent of the person with parental responsibility maybe an important safeguard for the interests of children. We hope that parents would not agree for their children to be subjects to research without thinking about the risks and without looking into the issues. But in some contexts we wonder whether parents have all the information. We wonder whether they perhaps are agreeing to the research because they think there is some benefit to their child from the research when in fact the benefits may be very small or none existent. And the burdens may be higher than the parent realises.

Marc Cornock
Do you think it's a controversial view you are putting forward of none therapeutic research on individuals who aren't directly going to benefit from this?

Phil Bates
Yes I do think this is controversial. There are quite a few people who say if you're dealing with somebody who can't consent then everything you do to them should either be for their direct benefit – sorry – I'll do that – can you ask the question again

Marc Cornock
Do you think that you are putting forward a controversial view that many people would say that none therapeutic research on people who can't benefit shouldn’t go ahead?

Phil Bates
Yes. I think this view is controversial. Some people would say if you're doing something to a person then either you need that persons consent and if they can't consent you shouldn’t do anything to them unless it's intended directly to benefit that person. So doing something to someone without their consent in order to improve other people’s lives is an exploitation of that individual, is an abuse of that individual, that it should be unlawful and that any one who does it is unethical and perhaps illegal. Now that’s a very strong protective view of the rights of individuals. If somebody can't consent for themselves then we may need to do things to them to benefit them. We may need to care for them, treat them. But we shouldn’t be using them in research unless they stand to directly benefit. That’s a very protective view. Now my problem with that view is that if we are trying to improve the quality of care for people who can't consent then I think we do have a responsibility to do good ethical research, to see what works and what doesn’t. Otherwise the standard of care is going to be stuck at a particular point and it may be very hard to improve things. Now we might be able to do research on people who can consent and then improve the quality of care for other people on the basis of that. So if we can do the research with people who can consent then we should. We shouldn’t be doing research on people who cannot consent unless they're the only people upon whom we could do it. But if for instance we’re trying to test whether a particular medication works on very young children, we may know it works on adults but we have no idea what dosages, what effectiveness it would have with young children. Then we may need to carry out research with those children otherwise they won't benefit from the development of that medication. The other concern I have is that if somebody is incapacitated they may still

have a view about their care. So somebody who's living in a care home, somebody who has Alzheimer's disease, they may not be able to understand what's involved in taking part in a research subject –

Someone who's living in a care home, someone who has a learning disability, someone who has Alzheimer's disease; they may not be able to understand fully what's proposed in the research project. They may not be able to give a fully valid consent to taking part in the research. But they may be able to answer questions. They may be able to tell you what it's like for them, what they like, what they don't like, how they feel about their situation. Now that research may not directly benefit that individual. They may enjoy the fact that they have had a chance to express their view. On the other hand they may find it burdensome and distressing. Now in the course of the interview perhaps if the person starts to become upset you should stop and give them some more time or not ask them any more questions but you don't go into that research thinking that you are going to benefit the incapacitated person. If it happens at all that's an incidental benefit. What you're trying to do is to find out what their life is like to give them a voice, to improve their quality of care that people receive. Now, the level of risk and burden for that person may be very small. Now it seems to me that if we can carry out research which improves the situation of incapacitated people or children in general and we can do that in a way that doesn't harm the individual, then I think there is a good argument for doing the research. Even if we don't have consent and even if it doesn't benefit them directly

Marc Cornock
How can we protect the individual who can't consent whether it's a child or an incapacitated adult from harm? What about the rogue researcher who may say they are going to do one form of research and actually the research takes a different form all together.

Phil Bates
Well I think rogues are always going to be a problem. The rogue GP, the rogue social worker, the rogue academic, could always do a lot of damage. To some extent we need robust systems of supervision by colleagues. We need reporting systems so that if adverse events occur we get some sense that something is going wrong here. So we can't necessarily have a system that prevents any possible form of maltreatment or abuse. But it seems to me that people who are going through the proposal of putting forward an idea to a research ethics committee explaining what they are going to do, having information forms that are given to relatives perhaps, having the data being scrutinised by academic colleagues and others, in that situation the risk of abuse is probably much less than someone who is just going off and doing bad things who isn't doing it in the context of research. So I think we should be aware of that risk but I don't think we should have such a nervous attitude that we say because there is that risk of abuse we should stop all research which potentially benefits individuals.

I think we should definitely be looking out for risk of harm, both when the research is proposed, when it's being looked at by the ethics committee and by the researcher when they're carrying it out. If you start doing research believing that it's harmless believing that the risks involved a very small but actually during the course of the research it becomes obvious that it's distressing or it's causing problems for people then that's a reason for stopping. So you need ethically responsible researchers. The fact that you've got approval from an ethics committee doesn't take away the responsibility to carry out the research itself in an ethical way and also a legal way. But shutting down all research and saying we are not going to do research on children because they can't consent and we can't accept parental consent. Shutting down research on incapacitated adults because they can't consent and it's not in their interest and nobody else should be allowed to consent. I think that would be just too restrictive and in the end it would hurt children. It would hurt incapacitated adults.

Marc Cornock
So do you think the current system provides adequate protection, you agree these individuals need?

Phil Bates

I think there are always going to be ways that the system can be improved. You're always looking for a balance between protection and also the benefits of research. So there are probably ways the system could be improved in both directions. There are ways in which the system needs to be more effective in protecting people. There are also ways in which research needs to be facilitated, good quality ethical research needs to be encouraged. So for5 instance at the moment we have a system which is very mixed. We have the National Health Service Research Ethics Committees, which are the only committees that can approve research on incapacitated adults. Now it seems to me that's potentially too restrictive. There might be good academic university research involving people with learning disabilities; involving people with Alzheimer's disease for example where it should be possible for – for –

There may be research involving people with learning disabilities, people with Alzheimer's disease, that research could be ethical, it could be of benefit to the community and it seems to me that open – sorry – I keep saying Open University ethics committee – I don't mean the ----

If you're doing research with people with Alzheimer's disease, people with learning difficulties, if you're asking them questions, if you're trying to look at the care that they're receiving, observing them in a care home for example it seems to me that you shouldn't necessarily have to go to a National Health Service Research Ethics Committee for that. It might be that in a university ethics committee would be an effective safeguard. It depends on the level of risk obviously. Now if you're exposing the person to some kind of invasive procedure, if you're giving them a medication then I think it's completely different. You obviously need much more effective safeguards and then the National Health Service Research Ethics Committees are going to be to be the way to go. And in fact for clinical trials we have European law. We have a clinical trials directive that requires extra safeguards if we are doing drug trials, either on children or incapacitated adults. So we need to have a mixture of safeguards. We need safeguards for the kind of research that is being done by academics which involves asking questions or observing. We need a different system to protect people from the risks involved in experimental treatment or drug trials. So we want to have a system which protects people from risks but which is not so restrictive that it prevents good ethical research from being done.

Marc Cornock
Thanks Phil.