Wellcome Trust Lecture 5 Questions
http://dcnapp1.dcn.ed.ac.uk/neurotube/player/player.asp?vidID=aop82137

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Q: radiographers are generally trained and would see their roll as acquiring imaging examinations. Now some of them will undergo specialist training to interrogate those examinations in specific areas. And so, for instance, there are circumstances where routine reporting of CT brains by Radiographers is generally accepted. But there have been a number of studies where Radiographers have been asked to identify abnormalities on images where their performance has been really very poor, because that is not what they are trained to do. Similarly the Society of Radiographers may well be very unhappy seeing more of that unless it's a formal extended role. So how does that tie with your recommended approach of giving this task to a Radiographer?

A: To be clear, this is what UK Biobank was proposing to happen in the context of that particular project. This is not some sort of catch all approach for very much the reasons you suggest. Given that UK Biobank are thinking that they want to do MRI scanning, they want to do whole body images, they want to involve radiographers at that earlier stage then it would be set up and they would be appropriately trained in order to carry out this protocol as defined. It wasn't a suggestion that should apply across the board.

Q: To go back to your slide on duties of care. To what degree are those informed by a subject's expectation? Because we have heard that, regardless of more of less what you say to a subject at the point of consent, there appears to be an implicit expectation for some form of diagnostic review of their imaging.

A: It's a really good question. The tendency of the courts is to move more towards this fetishisation of consent, this idea that if somebody has certain expectations then there is an expectation, in turn that they should actually be met. I don't think that would be the determinative but I think it would be a relevant factor, and it would also ultimately be for the court to decide what is reasonable in the circumstance. So to turn it on it's head and go back to you, there are various things, if you are not going down the route of feedback, there are various options available to you as to how you would disabuse somebody of the notion that there was going to be feedback, and arguably if you had made robust attempts to do that somebody coming in none the less with an expectation, the court would probably look at that and say, that's not a realistic expectation in the circumstances because you did all that was reasonable to make clear what the circumstances were.

Q: Comment regarding previous question: I don't doubt that the Biobank Ethics and Governance Council guidelines are extremely informative and extremely useful, but I do worry about the naming of particular professional qualifications as being the appropriate way to ensure that obligations by researchers are discharged. I think it is important that participants know who will be looking at their data and what they will be doing with it, but I think it's a real danger to say that everything will be inspected by a Radiologist, Neuro-radiologist or Radiographer because the particular context in which the research is done, and the particular reason for which the research is done determines who will be looking at that data and for what purpose. I think a duty of care always exists and the participant needs to know, to have some

transparent information and labelling it with professional categories will not apply to every context and we need to be very wary about using these professional names.

A: I completely agree and just to reiterate, this is simply an example of what was put forward by UK Biobank to the Ethics and Governance Council. We understand this particular set up might already be changing by UK Biobank, but just in terms of the matter of public record you will see, if you look at our minutes, we have had this discussion in the context of what was proposed. That's the real challenge for a body like the Ethics and Governance Council because we can only respond to what is being proposed by the Scientists. But you are absolutely right that we should not take from this particular terminology and set up that there would be equivalent duty of care that would apply across the board to other professionals.

Q: I agree about the fetishisation idea, but what interests me the most is establishing the duty of care between the researcher and the participant in particular. If you are just looking at just the researcher and how you might go about establishing that duty of care, it seems to me as though the issue of consent, and the discussion that the researcher and the participant have at the outset will play a much bigger role in establishing the nature of the duty of care as apposed to the clinical context where you might think there are other things that go under duty.

A: That's right. I think we can not remove consent from these considerations altogether. What I was just trying to suggest was, I don't think either that we should be imagining that consent is somehow determinative of the extent of any duty you might have. In other words even if you got somebody to sign up to saying there was absolutely no feedback here, "Do you understand? Yep I signed on the dotted line", it may be still further down the line, for a court to turn round and say "but your duty which is imposed from above, it's not about what you agree, your duty may have required you to act in a certain manner if there was something which was clearly serious and treatable etc". So consent has a role but it is not determinative.

Q: Comment – as to make the 2 categories Doctor/Researcher, participant. I am a doctor and a Researcher. There is an issue there for me which is complicated in that the participant has an expectation because I am a medical doctor and known to be rather than a Researcher.

Q: Biobank is of course involved in lots of human tissues and other things. Can you just, to put things in context, tell me what happens if I give my blood, or I have my DNA analysed and one of the principle investigators is sitting at the bench and he sees my DNA go past, and he sees a profile which indicates that I will get renal cancer in the next 5 years. What does he do? What's his duty of care?

A: Our understanding is that that should not actually happen in the way in which UK Biobank is actually set up, because it's about the group producing a resource, and its the aggregate resource itself which would be valuable in research terms and the security provisions are set up in such a way for the protection and privacy of the participants so that you would not actually hopefully have that situation.

Q: How does Biobank stop that situation ever arising?

A: Well arguably there is only a very limited number of individuals who would have access and they would not have routine access because its about

constructing a resource which is then sitting there to be used for research purposes.

Q: Inaudible

A: Why would you find it ethically questionable?

Q: Inaudible

A: This is one of the reasons UK Biobank came back to the Ethics and Governance Council and said is the no feedback policy at all, actually attainable across the board.

Q: I'm just curious as to what the final outcome of this process is meant to be, I know there is going to be a draft statement, but we people use the term guidelines and I was interested about the comments earlier, about who reports on these and things being so fluffy that basically they encompass any practice that happens in the UK. My understanding of guidelines is that it's meant to bring everyone up to the minimal standard of care that is appropriate, because most centres are probably doing fine, so it is the bottom/minimal standard. And I have to say I think the one size fits all type thing, probably isn't' appropriate. To have a PhD student producing, interpreting imaging and making a decision about whether that person has a serious abnormality I actually don't believe, I don't think that's right. So I think the guideline does have to bring the baseline up a bit. And just to say that sitting back (like options b's and c's) probably isn't appropriate at a global level, and you have to bite the bullet and say there is a minimal standard and hopefully there will be some conclusions later about that.

A: I would agree, that's why I would suggest that that (pointing at the screen) would be the way forward this afternoon.