Trust and consent in longitudinal research roundtable event

Monday 25 September 2023 between 10am-1pm

NHS Health Research Authority (HRA), 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ or Microsoft Teams meeting.

The Health Research Authority in partnership with Genomics England and Our Future Health organised a roundtable discussion focused on the subjects of mental capacity, consent, and ethical considerations within longitudinal research. The session was chaired by Vivienne Parry, OBE, science writer, broadcaster, and head of engagement at Genomics England. Participants included public contributors, legal professionals, individuals from academic institutions, the NHS, patient representative groups and charities, organisations responsible for health data management and regulatory bodies.

Executive summary

- attendees discussed the need for a balanced approach to these complex issues that respects participants' autonomy, avoids paternalism, while ensuring ethical and legal compliance
- the Mental Capacity Act 2005 (MCA) was examined, and concerns raised about the original intention of the Act regarding people who lose mental capacity after they have consented to participate in research. These concerns pertain to the Act's effectiveness in addressing capacity related issues within ongoing longitudinal research studies
- it was acknowledged by attendees that there is ambiguity in the law in certain situations relating to loss of mental capacity and longitudinal research.
- consideration was given to the possibility of revisiting consent forms and raising the prospect of potential mental capacity loss with participants at the beginning of a study
- attendees were told current HRA guidance underlines there is no legal expectation placed on researchers and research institutions to periodically check in with participants to monitor capacity
- consideration was given to the types of research being undertaken in these circumstances and how this might affect different approaches to deal with loss of mental capacity and consent in longitudinal research
- the potential benefits of continuing research with participants data in later stages of illness (when loss of capacity may be likely to occur) were emphasised during discussions
- discussions also touched on the legal provisions and variations across the devolved nations in the UK

Potential next steps

- there was agreement amongst attendees that more evidence could be generated to guide the way forward on these issues, including engagement work involving stakeholders and the wider public
- a potential opportunity to liaise with the Ministry of Justice and its work to update the MCA's Code of Practice was also raised.

Roundtable in-depth discussions

An overview of the type of work Genomics England and Our Future Health conduct and existing challenges was presented

- Genomics England and Our Future Health are regulated as research tissue banks/biobanks. They collect samples, such as blood
- Genomics England does not have a direct clinical relationship with participants; that relationship is in the NHS
- Genomics England collects ongoing clinical data from routine care such as biometrics and hold the data in a secure research environment
- Genomics England does whole genome sequencing of participants' data
- Genomics England's participants tend to be people who have a rare condition or various types of cancer. Some of them might have neurodevelopmental conditions, so capacity issues can arise
- Our Future Health is operating at a large scale with the aim of recruiting 5 million adult participants from across the UK
- Participants complete a questionnaire and give a blood sample from which some participant genetic data is generated
- Our Future Health will be linking health records
- A significant proportion of Our Future Health's participants will lose capacity because this involves long-term follow up and data collection. Respective issues for those participants' ongoing involvement in Our Future Health's research programme will arise when that capacity is lost
- Whilst Our Future Health has a direct relationship with its participants, it is not a clinical relationship, so direct assessments of capacity would not be possible

Question 1: What responsibility should those managing longitudinal health research have to check if their participants have mental capacity?

Attendees began by highlighting points that focused on how the law is construed, and how its provisions should be acted on in the context of a loss of mental capacity

- the Mental Capacity Act 2005 (MCA) is not well drafted for this issue but there is no change of the Mental Capacity Act on the horizon
- the MCA is construed in present terms / if the person cannot currently consent. Hansard (the official report of Parliamentary debates) is specific about the scenario where, if a person loses mental capacity, there has to be a move into safeguards provided in research
- fundamental problem: when the MCA was drafted the problem was thought about only in the context of pre-existing studies, not longitudinal studies that will run into the future. Hansard indicates that the understanding that if researchers know that a participant will lose mental capacity, they will put in place procedures for people who do / do not have mental capacity
- one legal concern that was raised is that you cannot rely on a presumption of mental capacity blindly: courts have made it clear that if there are good reasons for concern, and legitimate reasons to doubt, you have to consider mental capacity

Attendees then moved onto focus on the question of responsibilities.

- there was consideration that from reading the law and guidance on this issue there is should be a spectrum of considerations
- there was a presumption of respect for an autonomous individual in this situation. Taking the view that if someone has signed up for a longitudinal study, we should respect their choice to participate in research, including in situations when their capacity might fluctuate
- there was agreement that relying on hospital data for confirmation of loss of mental capacity was not good, especially as the quality of the data such as outpatient neurology is poor with huge variation in accuracy. There was also agreement that just because someone is diagnosed with early onset dementia or Huntington's disease it does not necessarily equate to a loss of capacity
- it was suggested that it might be intrusive to keep checking in with people on their capacity status and would go against the spirit of the MCA
- there was a brief discussion on the different legal approaches to capacity and continuing consent in research across the UK
- there was an acknowledgement that Scotland's REC treats consent as surviving loss of mental capacity
- in Northern Ireland consent taken prior to loss of capacity remains legally valid after loss of capacity provided the research protocol has not changed significantly

Question 2: what should those who manage longitudinal data do if they become aware that a participant might have lost capacity, but they don't know for sure?

Attendees reflected on current challenges in managing scenario's where research participants might have lost capacity.

- there was agreement that it is challenging to place responsibility on the NHS to flag information, and that the information that could be returned would be patchy, as there is not a standardised way of doing so
- It was highlighted that clinicians would be able to give an opinion on mental capacity but would not be able to specify if the loss of mental capacity is temporary or permanent. This would still be a burden on the NHS and there are not face-to-face opportunities in longitudinal studies to facilitate this kind of review of capacity
- it was also emphasised that the quality of NHS Hospital Episode Statistics is poor, with huge variation in accuracy, the consistency of codes used, and diagnosis of acquired brain injury, Huntington's Disease, or dementia
- a challenge for Genomics England is that participants could lose mental capacity for a reason that is *not* associated with the condition for which they entered the resource. Section 31 of the MCA states that research has to be related to the cause of loss of mental capacity. This could mean that, in the case of rare diseases for example, research that could lead to a diagnosis would not be possible. In real terms this means that they may not get a diagnosis which would be against the purpose of the resource and the participant's expectations

Attendees then moved onto focus on the question of responsibilities.

- responsibility could rest with the biobanks, but the issue is wider, more and more researchers want to do all sorts of studies over 20-30 year follow ups.
- Genomics England emphasised the challenges they face in not knowing the mental capacity of participants because the healthcare data they collect is not processed in a way that can identify if a participant has lost mental capacity
- it was noted that for the Genomics England's research environment, no identifiable data are used, however where Genomics England link data to the NHS it is identifiable
- it was acknowledged that there are multiple users interested in using data held in secure research environments and so there is a responsibility to act and respond to an established lack of mental capacity or to legitimate reasons to be concerned about a loss of mental capacity
- It was suggested the researchers who access the data Genomics England hold do not know who the participants are. Those third-party researchers would not have responsibilities towards participants
- attendees were told in the common law, there are cases where there has been bodily invasion following a loss of mental capacity, and that the law is clear that

consent given before mental capacity is lost cannot endure the loss of mental capacity in such cases. However, it is less clear whether consent could endure the loss of mental capacity in the context of ongoing collection of data for research. Intrusive research is clearly defined in the MCA, but it might be different in the common law

Question 3: what should be taken into account when considering whether to remove or keep people in longitudinal research where we're sure that they've lost mental capacity?

Attendees provided a range of views in response to this question, including:

- it is essential to consider the views of the participant when they had mental capacity
- it is important to keep people in research when that is what they want, but it is also important to protect people and remove them when necessary
- it is valuable to reflect on the types of research and existing data gaps involved when considering these issues
- consideration should be given to the importance of new discoveries for certain conditions; and whether the research is based on conditions that cause a loss of mental capacity
- when the MCA was drafted, it was taken for granted that it was intended to cover only in-person research, rather than the forms of remote research that have since emerged since
- often people who are participating in research are doing so for altruistic reasons: loss of mental capacity would not necessarily change that
- excluding participants who lose capacity could hinder research on conditions that cause capacity loss, particularly in the advanced stages of illness
- we should consider that the National Data Guardian has explored people's reasonable expectations with respect to the ongoing use of their data
- that it might be appropriate to be supportive and facilitative for research participants who have lost or fluctuating capacity, rather than excluding them