Ethical, Legal, Social Issues (ELSI)
Work Package 12

Aims

Using empirical research with participants and researchers to examine the ethical, social and practical issues in the development and implementation of Dementia Platform UK. Additionally, to explore and advise on the issues of importance when re-contacting cohort participants for experimental medicine studies.

Overview of findings

Work with cohort researchers and participants demonstrated the complex interactions and relationships involved in establishing platforms for data science and experimental medicine (EM) for dementias research in the UK. The study was the first in the UK to solicit participants' views on their willingness to be re-contacted for further research studies.

What is important

(a) For researchers:

- When proposing the use of data from multi-cohorts, researchers need to be aware that all cohorts have different data sharing policies related to their governance structure. Advice may need to be sought from local REC bodies, associated HEIs as well as the local cohort management;
- There was concern that participant re-consent could cause attrition, may lead to the loss or withdrawal of data with increased administrative burden and costs. Consent should only be renewed if there was a strong research imperative or ethical risk, with clear social and scientific benefit,
- There was no consensus amongst researchers regarding the ethical limits of acceptable data sharing with industry and commercial research partners;
- Data considered sensitive varied from cohort to cohort and would need to be negotiated with reference to a well —designed study incorporating a clear purpose and a focus on data security;
- There was a highly cautious approach to re-contact for EM purposes from cohorts. There was concern that the parent cohort may be disadvantaged by recruitment and hence a plea for early sight of EM proposals to allow assessment of whether the scientific benefits outweighed issues of study burden and negative participant experience or reaction;
- It was vital that any study that aimed to identify people or groups of people based on existing data must have clear procedures for preventing, limiting and managing risk disclosure. Such procedures must be transparent and discussed with both cohort researchers and research participants;
- The federated DPUK data access and EM proposals have been designed to allow cohorts to continue to use their own highly developed governance structures, including controls, in tandem with DPUK access processes and
- Collaborative work relied on trust, understanding the motivations of external groups and confidence in scientific rigor. No cohort was willing to allow undifferentiated access to its full data sets or their participants. Full open- access was considered neither practical, nor ethically or scientifically desirable.

(b) For patients:

- Patients valued their data and were keen to share existing cohort data for further health research and wider social benefits. They also wished to receive feedback (using the cohort newsletter or website) about how the aggregate cohort data was used in research;
- Need to better understand the benefits of acquiring healthy research participant data for dementia research alongside data from those with a condition or family history of dementia;
- Breaches in data security would have a long-term detrimental effect on cohorts. There was a strong desire to ensure data was not used for targeted marketing or commercial use;
- Value the opportunity to be part of a parent cohort and trust it to manage data requests in the best interests of participants, and according to current informed consent. There is less trust and confidence in unfamiliar public or private research organisations, particularly those whose primary motivations were perceived to be profit;
- Patients were mindful of balancing existing obligations and commitments with taking part in new research; the research design and corresponding participant time were important;
- Participants would be willing to be re-contacted for the following reasons (i)confidence and commitment to the parent cohort, health research and regional/community identity; (ii) appreciation of the benefits and advantages of research for society and (iii) the perceived positive benefits of research participation for the individual and their extended family;
- There was the expectation that secondary research studies would be undertaken in a similar manner to the parent cohort research and if there were any differences there was the need to manage this at an early stage (e.g. in the availability of feedback);
- The regular physical and cognitive tests involved in research were viewed as a plus to general health care provision. There was also the belief that taking part in the research may enable patients to receive additional, or fast-tracked, diagnosis or treatment, for cognitive issues;
- Participants drew on a range of experience and evidence, including the comments of others, to decide how willingly they would tolerate a particular study type or test. There was also assessment of whether burden or a short period of discomfort would outweigh any potential scientific, medical or social benefit.