



Ethical, Legal and Social Issues in DPUK Work Package 12

Objective(s):	Using empirical research focused on participants and researchers to examine the ethical, social and practical issues in the development and implementation of DPUK. Additionally, to explore and advise on the important issues when re-contacting cohort participants for experimental medicine (EM) studies.
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Overview Summary:	Through qualitative research with cohort researchers, this work demonstrated the complex interactions involved in establishing platforms for data science and experimental medicine for dementias research in the UK. Through work with cohort participants, this study was the first in the UK to solicit participants' views on re-contact for further research studies.
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Executive Summary:	<p>Dementias Platform UK (DPUK) marks a new phase in the development of data science and experimental medicine for UK dementias research. Drawing on relationships with pre-existing studies and participant populations, DPUK has the potential to impact on researcher practices and participant experiences of dementias science. The report from this workpackage examined the ethical, social and practical issues related to the development of a cross-cohort data platform and the potential re-contact of participants from existing cohort populations. Based on empirical research with researchers and participants, the work provided recommendations on key ethical, social and practical areas.</p> <p>The report provided recommendations in the following areas:</p> <ul style="list-style-type: none">• Ethical practices in the development of a cross-cohort data-sharing platform;• Re-contacting cohort participants for experimental medicine studies;• Participants' social and ethical concerns around data-sharing and linkage;• Social and ethical issues around re-contacting cohort participants for experimental medicine studies.
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Summary of Outputs:	(As per Researchfish categories)
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Publications	Published:
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	<p>Milne, R., Brayne, C. We need to think about data governance for dementia research in a digital era. <i>Alz Res Therapy</i> 12, 17 (2020). https://doi.org/10.1186/s13195-020-0584-y</p> <p><u>In preparation</u></p> <p>Atkinson, S., Badger, S., Milne, R, Brayne, C. & DPUK 'Recruiting from Existing Cohorts in the Dementias Platform UK: Research Participant Perspectives.'</p> <p>Atkinson, S., Badger, S., Milne, R., Brayne, C. & DPUK. 'Data Relations: Views on data sharing in the changing landscape of UK dementias research' Submitted to <i>Sociology of Health & Illness</i></p>
Collaborations & partnerships	
Further Funding	Milne, R. "An empirical ethics study of the introduction of AI techniques to the assessment of cognitive decline" Wellcome Trust Seed Award in Social Science and Humanities, (£88,968 , started Nov 2019)
Next destinations	Badger, S. Patient Advocacy Specialist, illumina Cambridge Ltd Atkinson, S. Research Associate, Department of Sociology, University of Exeter
Engagement Activities	<p>External presentations of findings:</p> <p>Atkinson, S., Badger, S. Milne, R. Brayne C. & DPUK 'Relations in biomedical research participation: Building a cross-cohort platform in the context of a national health system'. Paper Presentation, <i>13th Conference of the European Sociological Association, Athens, Greece.</i> Audience: Sociology of health, public health, bioethics of public engagement and recruitment.</p> <p>Atkinson, S., Badger, S. Milne, R. Brayne C. & DPUK. 'Research Participants perspectives on recruitment from existing cohorts in dementia research'. Poster Presentation, <i>Alzheimer Association International conference, London, UK.</i> Audience: Public health, bioethics of public engagement and recruitment.</p> <p>Atkinson, S., Badger, S. Milne, R. Brayne C. & DPUK. "I'd be OK getting the letter, I still would need to discuss it first": Ethical considerations for recruitment from existing studies to dementias research. Poster Presentation, <i>Alzheimer's Society Annual Conference, London, UK.</i> Audience: Public health, bioethics of public engagement and recruitment.</p> <p>Atkinson, S. 'Personal to whom? Careers, custodianship and control in biomedical big-data'. Paper Presentation, <i>BSA Medical</i></p>

	<p><i>Sociology Group Annual Conference 2016, Aston University, Birmingham, UK.</i></p> <p>Audience: Sociology of health, social studies of science and technology and social studies of bioinformatics.</p> <p>Atkinson, S. 'Health or illness, person or patient: Blurring the lines in the development of pre-symptomatic biomarkers for dementia'. Invited Symposium Paper, <i>Navigating Impasses in Bioethics: Rethinking Ill/Health 2015</i>, Von Hugel Institute, St Edmund's College, University of Cambridge, Cambridge, UK.</p> <p>Audience: Public health, bioethics of public engagement and recruitment</p>
Influence of policy, practice, patients & the public	<p>Detailed report-“ Ethical, Legal and Social Issues in DPUK” available on DPUK website: https://www.dementiasplatform.uk/publications/ethical-legal-and-social-issues-in-dpuk-full-report</p>
Research tools & methods	
Research Databases & Models	
Intellectual property & licencing	
Medical products, interventions & clinical trials	
Artistic & creative products	
Software & technical products	
Spin outs	
Awards & recognition	
Other outputs & knowledge/future steps	<p>More general engagement- Interviews</p> <p>Brayne C - Interview: a life-course approach to prevent dementia https://apps.who.int/iris/handle/10665/272247 WHO Bulletin</p> <p>Interview with Carol Brayne</p>
Use of facilities & resources	
Most successful outcome and what it means for future dementia research:	
<p>The work highlighted that cohorts remain highly cautious when it comes to re-contact of their participants for new EM studies. There is concern that if cohort members agree to participate in EM studies they may be less willing to undertake further work within the cohort and this could have a negative impact on the parent cohort. This finding has directly influenced the development of the DPUK Clinical Studies Register (work package 18) where new participants sign-up to participate in EM studies within a governance structure which has the necessary ethical approvals</p>	
Lessons learned:	<ul style="list-style-type: none"> • DPUK's guidance on EM studies should prevent over-burdening of cohorts and address participants' motivations to participate. This guidance must also make it clear there are no obligations for cohort participants to take part in further studies and that withdrawing from a study is possible at any time;

	<ul style="list-style-type: none">• The DPUK web-site should have better visibility of policies/agreed protocols and practices related to data security, including a description of sanctions for data misuse;• Communication/ public engagement activities should be undertaken to increase trust around the role of industrial partners plus highlight the security controls governing the work of public or industry researchers;• Further public and research engagement activities would be helpful to highlight (i) the role of healthy participants in data studies and (ii) the current limitations of pre- symptomatic biomarker studies for dementia research.
Other:	