



ROADMAP

The involvement of the EWGPWD in the ethics work of ROADMAP

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- RWE is the evidence derived from the analysis and/or synthesis of real-world data (RWD) collected outside of randomised trials.
- RWD may be primary research data, collected in contexts that reflect clinical practice, or secondary research data derived from routine clinical data itself.
- Using RWE raises ethical, legal, and social issues (ELSI).
- The secondary use of data can also raise concerns among people.

- As part of ROADMAP's extensive stakeholder engagement work to ensure patient interests and concerns are accounted for in an ELSI framework for a RWE platform for AD, WP8 carried out a literature review of research into the attitudes of patients and the public to the secondary use of data and conducted two focus groups.
- The presentation today focuses on the approach and some of the key issues from the focus groups conducted with people with dementia and their supporters to understand patient and carer attitudes towards the ethical, legal and social implications of a real world data platform for Alzheimer's disease.

ROADMAP The EWGPWD

AE set up the EWGPWD in 2012. Composed of people with dementia, the 2016-2018 group had 12 members. To ensure that AE's projects and activities, duly reflect the priorities and views of people with dementia. They meet 3-4 times a year. They are involved in EU projects.



- The focus groups were conducted during one of the regular meetings of the group in Brussels in December 2017.
- All members who attended the meeting were invited to participate.
- Although usually the supporter only attends the meeting to provide support to the person with dementia, in this occasion, they were invited to participate in their own right.
- Research ethics approval was granted by the University of Oxford Social Sciences and Humanities Interdivisional Research Ethics Committee (IDREC).

- Members of the EWGPWD were familiar with the ROADMAP project as they had participated in a consultation on outcomes with WP2.
- They were provided with information about the focus group in advance of the consultation event and again on the day, so that they could decide whether to participate. This included information sheets and consent form.
- Each EWGPWD member was free and able to decide not to participate in the proposed focus group.

- The whole session lasted half a day.
- First, a brainstorming exercise was used to explore their understandings of health data and data sharing.
- Then, the group was split. Focus group discussions made up of
 - one group of EWGPWD members (facilitated by AE)
 - a second group of the supporters (facilitated by UO and AE)
- In total, 11 people with dementia and 10 carers participated

- Within each group vignettes describing different data sharing scenarios provided a basis for detailed discussion.
- Members of the EWGPWD and their supporters were asked to reflect and give their views about
 - what kinds of data should be used for research,
 - who it should be shared with,
 - what measures should be in place to make such sharing acceptable.

Jayne Goodrick, supporter.

My personal experience of the consultation.



- Focus groups were audio recorded and fully transcribed.
- Transcripts were anonymised by replacing participant names with pseudonyms that preserve participants' genders
- Each member of the EWGPWD comes from a different European country, so references to participants' home country was disguised as northern, eastern European etc. References to native languages were replaced by 'non-English language'.
- The membership of the EWGPWD is small and public, so anonymity cannot be guaranteed however these measures make it difficult to associate quotes with particular individuals and make the risk of reidentification low.

- Transcripts were analysed thematically following Braun and Clarke (2006)
- Themes were derived inductively to ensure they were closely linked to the data.
- Transcripts were coded independently by all authors using NVivo qualitative analysis software.
- Focus groups conducted with EWGPWD members and with supporters were treated separately for the purpose of generating codes and themes.

- Several issues were discussed in both groups and similar issues were flagged.
- In today's presentation I will only focus on two issues of particular relevance due to their impact for ROADMAP:
 - Trust
 - Greater engagement

1. Trust as a necessary condition for progress.

Michael: I know there are obvious reasons to not trust the system. But I have to, when we sit here talking, I have to believe that the system is operating correctly. Otherwise there wouldn't be any discussion at all around these tables.

Facilitator: Hmm. So you have to be in faith?

Michael: You have to have that faith in the system.

James: There's a lot to trust involved, yeah.

Sandra: I agree with that.” (EWGPWD members)

2. Greater engagement about the research of people with dementia and supporters as this could enable participants to deal better with uncertainties about risks of sharing data.

“You see, you gave your permission, you were involved, and they haven’t had the courtesy to say, ‘Look, this is what we’ve produced’. So, it’s very bad form.” (Susan, EWGPWD supporters).

Based on the focus groups discussions, three consortium-level activities that could validate and improve ROADMAP's approach to participant engagement were recommended:

- (1) Audit ROADMAP's compliance with reporting and feedback requirements to ROADMAP data providers.
- (2) Collect from ROADMAP data providers their best practices for engaging and informing participants about secondary research.
- (3) Ensure these are adopted in all ROADMAP analyses.

- A session to discuss the results and recommendations with members of the EWGPWD and their supporters was carried out in June 2018.
- Additionally, the EWGPWD will have opportunity to provide feedback and comments on subsequent publications to ensure that their contribution is properly acknowledged.
- The findings from the focus groups will be integrated into an ethical framework that will guide data integration practices in ROADMAP and provide recommendations for an EU-wide real-world evidence platform for AD.
- Findings from the focus groups have been submitted for publication in a peer-reviewed social science journal.



- Why is it important to involve people with dementia and their supporters in these discussions?
- What are the key take home messages for researchers?

Thank you!



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