Building a practical strategy and framework for diverse and inclusive involvement of patients and carers in Real World Data & Evidence Generation (RWDEG)

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Introduction

Involving patients and carers in RWDEG strategy is essential for the pharmaceutical industry to conduct true patient centric research.[1] Over the past decade, clinical trial researchers have become increasingly aware of how important it is to not only include measures of patient reported outcomes but also involve patients in the design and planning of trials, with work having been done to understand behavioural drivers and barriers for involvement.[2]

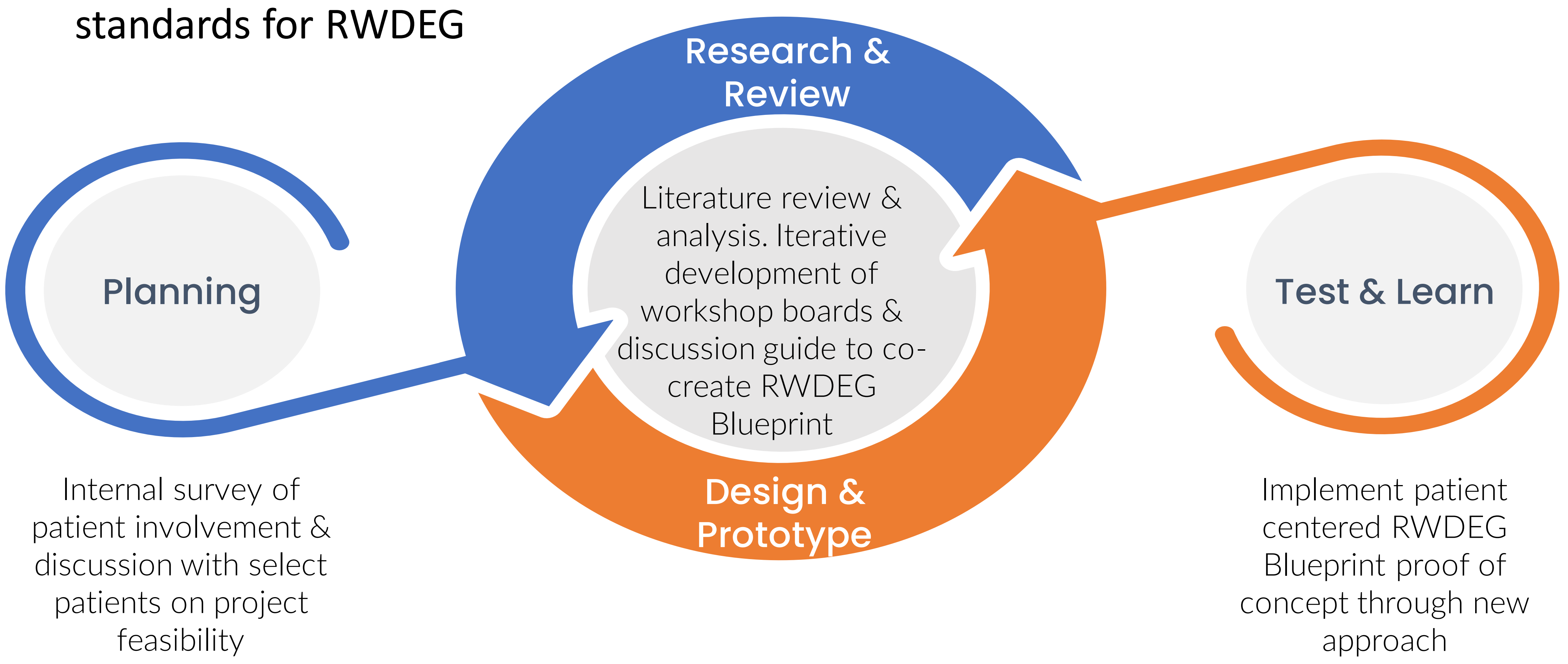
Patient and carer involvement (PI) in designing and executing real world research is in a much more nascent phase. Making sure the patients and carers involved in RWDEG are representative of the wider population and includes people that are harder to reach, experience health inequality or have lower health literacy is essential in making sure data and the evidence generated from it aligns with what is important to all patients and their carers.

The main objective of this ongoing project is to develop a pragmatic framework that will demonstrate how best to involve patients and include their insights and preferences throughout the RWDEG cycle

Methods

A multistage iterative approach that is continuously informed and updated based on insights received from patients and carers is being used to develop the framework (Figure 1). It includes:

- Conducting a mapping review to gather insights on how industry is involving patients and carers in RWDEG
- Recruiting individuals from diverse backgrounds and behaviour personas for participation in a series of focus groups and co-creation workshops
- Designing workshop boards and developing discussion guides to facilitate co-creation workshops
- Developing short introductory videos about RWDEG to assess user acceptability and experience
- Gathering participant perspectives and current awareness of RWDEG
- Ideating on how to centralise repositories of information, tools and communication to share existing materials, case studies and resources across a range of platforms for patients and carers
- Generating pragmatic strategies to inform and fully include patients and carers in initiatives to establish standards for RWDEG



Planning

Internal survey of patient involvement & discussion with select patients on project feasibility

Research & Review

Literature review & analysis. Iterative development of workshop boards & discussion guide to co-create RWDEG Blueprint

Design & Prototype

Test & Learn

Implement patient centered RWDEG Blueprint proof of concept through new approach

Figure 1: Approach to developing framework

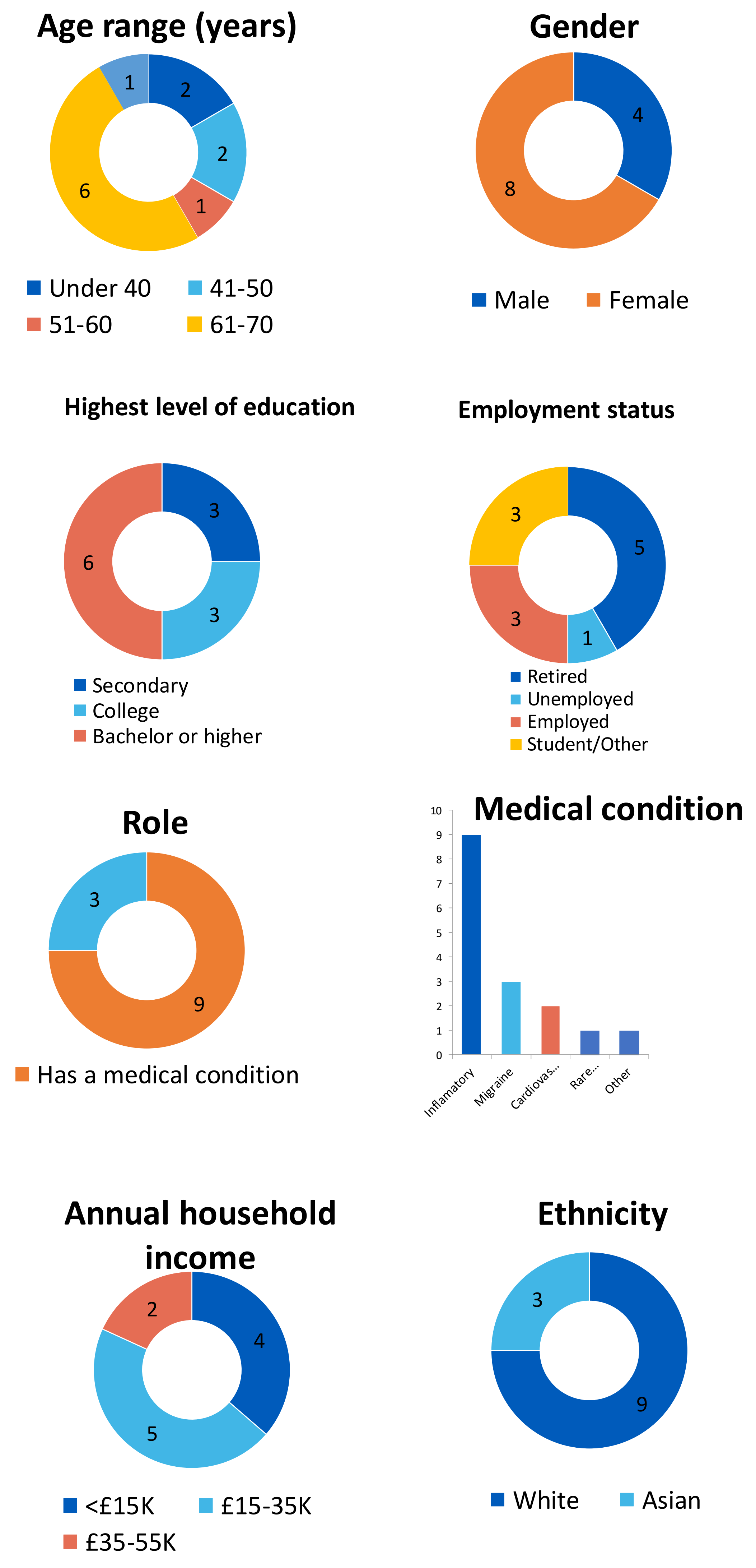


Figure 2- Participant demographics

Results

Twelve individuals residing in the United Kingdom from diverse backgrounds have been recruited into the study (figure 2). The group have the following persona types: Courageous Fighter (n=3), Naïve Optimist (n=2), Overwhelmed Worrier (n=2), Deflated Resigner (n=3). Two were mixed Naïve Optimist/Overwhelmed Worrier types.

Initial feedback from patients uncovered several themes about their views and understanding of real world data and evidence in their own words. These will be refined as they continue to provide us with more feedback

Any data that is gathered outside the controlled environment of the clinical trial. - anything out of this

Difficult for some people to engage with trials because people feel nothing will come of them, especially if you've had a problem so long. These people are hidden voices.

Diversity

Long term monitoring of those on medication - can see long-term effects on people

Clinical trials often done on a small group of people - need different diversities, cultures included in trials

captures wide ranging nature of real world data

Some people with disabilities may be hidden too

list of who is currently included - to suggest who should be included but currently is not

collecting - continue to monitor people taking medication in the long term - see any ill/better effects. we can contribute to this as people taking medication

Conclusion

This work is still in progress but we anticipate being able to develop materials and approaches that will challenge existing assumptions and approaches on how to involve patients and carers in RWDEG. The findings will be communicated across the life science, policy and research communities

References

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2. Sacristan JA, Aguaron A, Avendano-Sola C et al. Patient involvement in clinical research: why, when and how. Patient Prefer Adherence.2016;10:631-40

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