

Considerations for Successful Implementation of Patient-Reported Outcomes in Real-World Evidence Generation: Interviews with Stakeholders

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INTRODUCTION

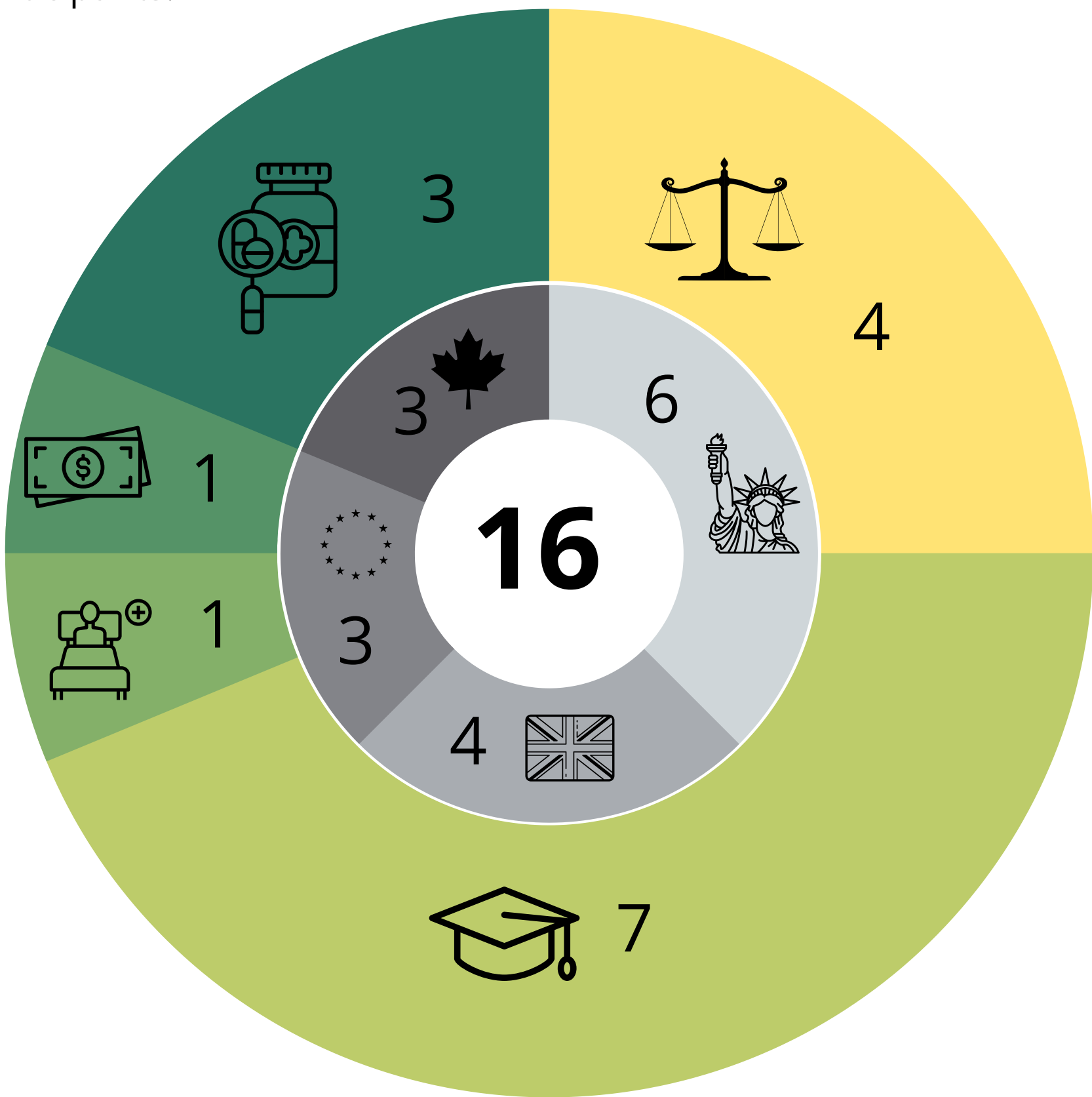
- Real-world evidence (RWE) plays an increasingly important role within global regulatory and reimbursement processes, as proven by several recently published RWE frameworks and guidelines [1].
- RWE generation can be enhanced by collecting and using patient-reported outcomes (PROs). They could provide valuable information on the long-term effectiveness, safety, and tolerability of health interventions from the patient perspective.
- PROs utilisation among phase IV clinical trials remains lower than in earlier phases of clinical research [2].
- Methods for collecting and using PRO data in the real-world setting are currently underdeveloped. There is a lack of international guidance specific to RWE generation in the context of use for regulatory decision-making, reimbursement, and health policy [3].

AIM

This study explores stakeholders’ perspectives on the current and future use of PROs in the RWE generation.

METHODS

- 16 one-to-one, online, semi-structured interviews were conducted with international stakeholders.
- Participants:



Graph 1. Study participants

- Interviews were transcribed verbatim and analysed thematically with QSR NVivo 20 based on the Consolidated Framework for Implementation Research (CFIR) [4]. Both inductive and deductive coding was used to identify the main themes in the data gathered.

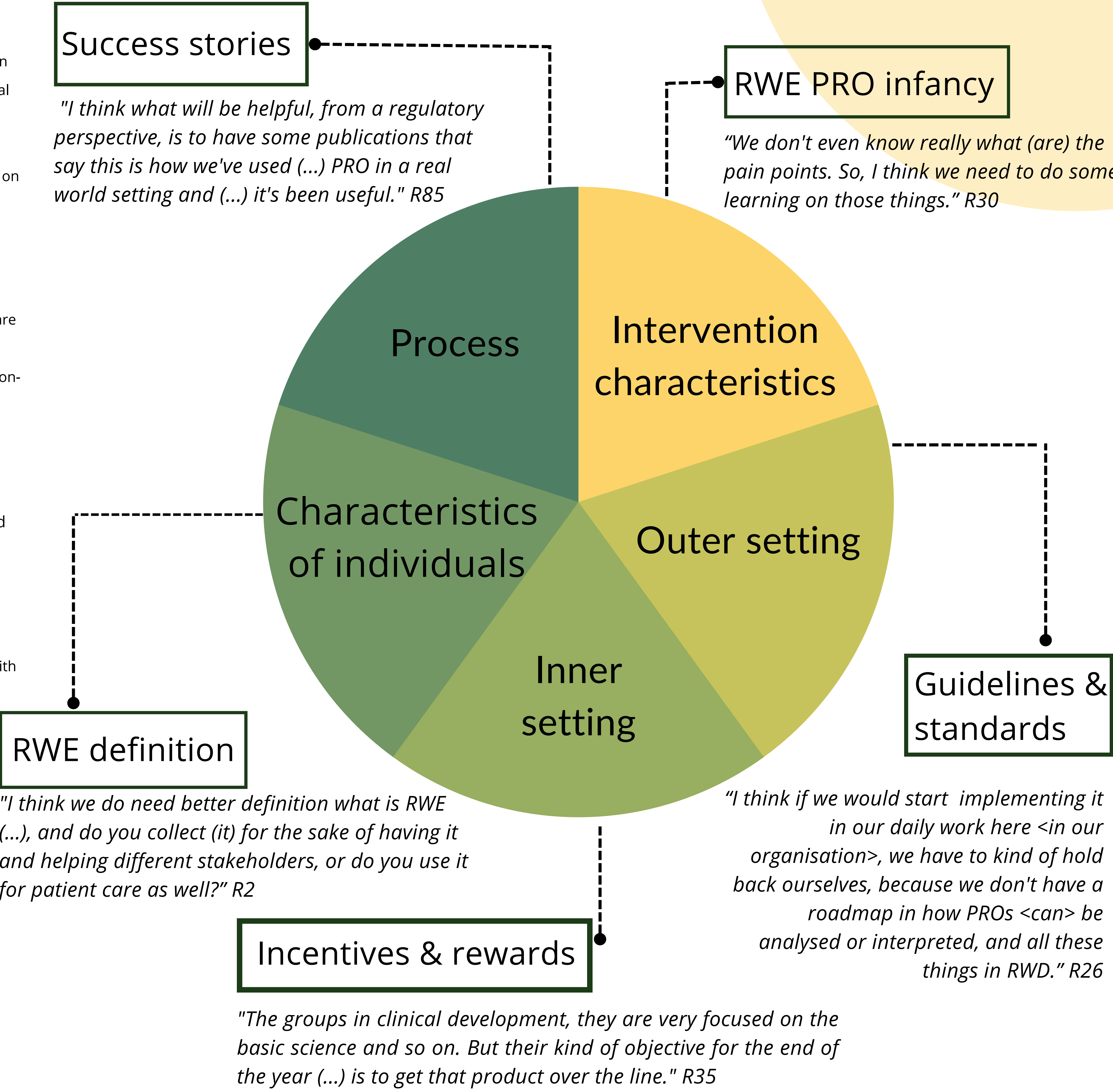
CONCLUSION

The use of PROs in RWE generation is in its infancy. Setting standards for PRO data collection, analysis, and use in the real-world would maximise its benefits. The needs of various stakeholder groups (including patients, health care professionals, regulators, payers, and industry) should be considered when developing future guidelines.

FUNDING STATEMENT

This analysis was conducted as part of the research project funded by an unrestricted educational research grant from GSK. KM is the holder of the GSK PhD grant. TK is an employee and shareholder of GSK Ltd. MJC & OLA – NIHR, UK Research and Innovation (UKRI), NIHR BRC, NIHR ARC West Midlands, GSK, Gilead MJC & CM – NIHR Surgical Reconstruction and Microbiology Research Centre MJC, CM & OLA – NIHR Birmingham-Oxford Blood and Transplant Research Unit (BTRU) in Precision Transplant and Cellular Therapeutics, Innovate UK (part of UKRI) OLA – The Health Foundation, Sarcoma UK MJC- UKSPINE, European Regional Development Fund – Demand Hub and HDRUK, University of Birmingham and UHB NHS Foundation Trust; Macmillan Cancer Support, UCB Pharma, personal fees from Astellas, Aparito Ltd, CIS Oncology, Takeda, Merck, Daiichi Sankyo, Glaukos, GSK and the Patient-Centered Outcomes Research Institute (PCORI), Catapult UK CM - personal fees from Aparito OLA - personal fees from Gilead Sciences Ltd, GlaxoSmithKline (GSK), Viiv Healthcare, Catapult UK, and Merck

Graph 2. Key findings



RESULTS

- The thematic analysis helped identify several themes in participants’ responses. Preliminary results, providing a high-level summary of important considerations, are presented in **Graph 2**.
- The most frequently mentioned barriers that hamper the full implementation of PROs in RWE generation can be categorised in two groups:

Methodological – lack of agreement about the standard for data collection and analysis

Operational – related to setting up the infrastructure needed to collect PRO data in routine practice, changes to the current workflows and availability of resources

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