The Book of Good Practices

Methodology article

Background

In 2016 PFMD started to bring together experts representing various stakeholders, with the objective of advancing the work needed for the co-creation of a coherent, scalable and actionable "meta-framework" for patient engagement (PE). The framework is aimed to be relevant and usable across all phases of medicines lifecycle, and support diverse stakeholders to implement more meaningful PE measures and practices.

The process started with landscape mapping, literature review and analysis of existing frameworks and toolkits, to learn from current efforts and avoid duplication of work. After the preliminary mapping exercise multi-stakeholder Working Groups (WGs) were established, a plan of action developed and specific Task forces convened to co-create an action plan to deliver the framework.

Co-creating a robust and coherent framework for PE requires collective effort and commitment. Therefore, more than 100 international experts joined forces, representing patients and patient organisations, industry (including clinical research organisations and biotech), independent experts (with backgrounds from academia, research and industry), Health Technology Assessment (HTA) and regulatory bodies.

To support practical implementation of the framework, another objective was to create a Book of Good Practices that would showcase initiatives with a good quality and level of PE that exemplify the 7 PE *Quality Criteria* presented in the co-created *PE Quality Guidance*[1] framework.

The creation of the Book of Good Practices was identified as a priority due to:
- a lack of common agreement about what represents "good practice" in PE
- a high demand and need to have access to examples demonstrating quality and impact of PE efforts
- a need for examples offering practical guidance and providing a benchmark of "what good looks like" for newcomers to PE

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[1] The PE Quality Guidance is a practical tool to facilitate planning, developing and assessing the quality of PE activities and projects throughout the research, development and lifecycle of medicines. More info of the co-creation of the PEQG from Deane, K. et al. (2019) *BMJ Innovations.* Available at:
https://innovations.bmj.com/content/early/2019/03/01/bmjinnov-2018-000317.abstract

The first edition of the Book of Good Practices was released in 2018, with 8 representative case studies. The second edition of the Book of Good Practices will be released in 2019.

The BoGP initial initiative selection methodology

The selection process was conducted in 4 stages (Fig. 1) that comprised: 1) identification of initiatives via SYNaPsE database, call for suggestions and WG nominations, 2) first-pass screening and shortlisting based on completeness of the information provided by initiative owners, 3) initial review based on the PE Quality Criteria as defined in the PE Quality Guidance, and 4) further review to identify and reach consensus on cases for inclusion in the Book of Good Practices conducted by the Core Team (external stakeholders who had actively participated in co-creation of the PE Quality Guidance).
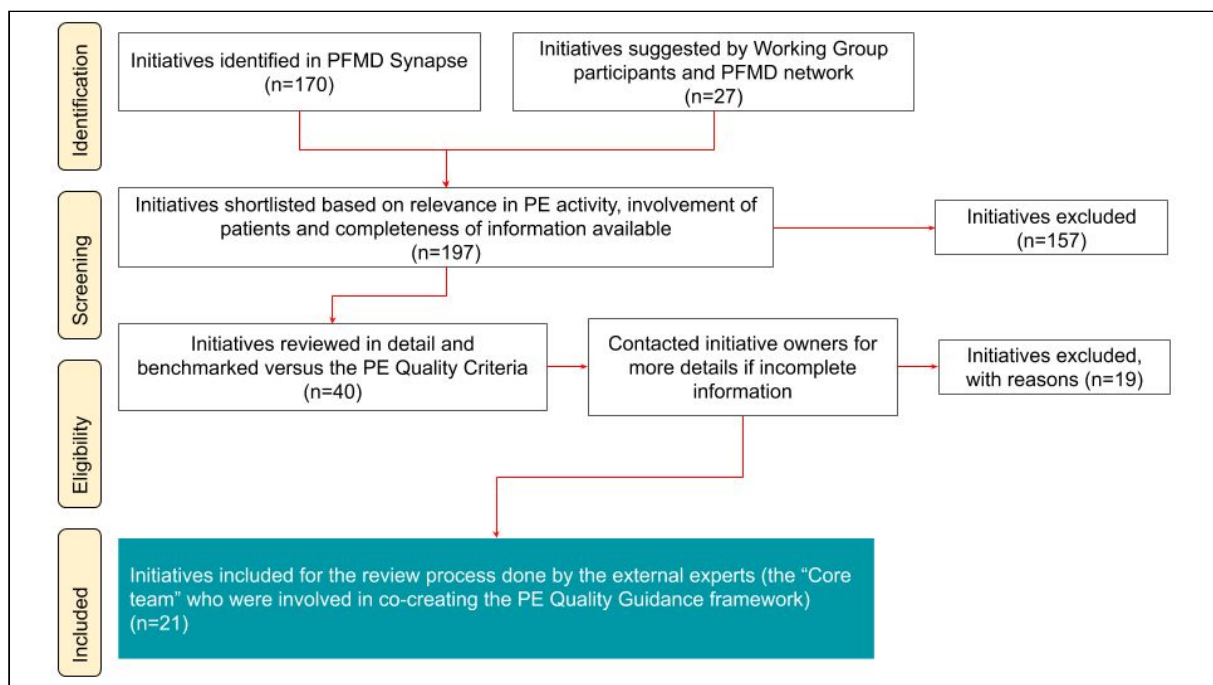

Figure 1. Selection methodology for PE initiatives to be included in the Book of Good Practices review process

Step 1 - IDENTIFICATION
The first step was to identify a collection of initiatives, which was done in two ways:
- via SYNAPSE: an in-depth screening was performed in two waves (Jan 2017 – Sept 2017) and examples were identified by the PFMD team;
- via the global PFMD network: participants in the PFMD working groups as well as PFMD members shared their cases in the workshops throughout Europe and North America, and via email.

Initiatives were taken into consideration if they had reported to be doing PE (i.e. with patients, and not merely providing guidance to others about PE). This selection resulted in a total of 197 initiatives.

Step 2 - SCREENING
The 197 initiatives were screened and shortlisted with the following set of criteria. The initiatives were to represent or include

- activities specific to PE work in the development phases of medicines
- multiple stakeholders being involved (with at least one being a patient, patient advocate or patient organisation representative)
- an adequate description of the work that had been done (including a brief description of methodology, outcomes and impact).

From a total of 197 initiatives, 40 were shortlisted for in-depth review in Step 3 and Step 4.

STEP 3 and STEP 4 - ELIGIBILITY and INCLUSION
The PFMD team reviewed the 40 initiatives to determine if further information was needed from the initiative owners. Initiative owners were also notified and their permission was asked in order to proceed to include their initiative in the review process.

Nineteen initiatives were excluded in this step for several reasons: 1) some initiative owners could not deliver the requested additional information within the agreed timelines for development and finalisation of the Book of Good Practices, 2) the relevant people were no longer within the organisation to provide additional information, 3) due to existing commitments, some initiative owners were unable to devote time to contribute to the process and withdrew their participation.

As a result, 21 initiatives were finalised and anonymised by PFMD for the Core Team of external contributors to start the review process of the Book of Good Practices. The finalisation process included asking initiative owners to transfer their initiatives in the PEQG template (if not already submitted in this format) and the PFMD team anonymising the initiatives for review. The Core Team of 9 reviewers had been involved in the co-creation of the PE Quality Guidance and had a good understanding of the PE Quality Criteria.

Initiative evaluation and selection process - by the external review group (Core Team)
The methodology for reviewing initiatives was proposed by the PFMD team and further refined and validated with the Core Team reviewers (Fig. 2). The process consisted of two rounds of review; the first round was an overall evaluation of the initiative and how well it addressed or demonstrated

each of the 7 PE Quality Criteria. Comments and questions from reviewers allowed initiative owners to provide responses that helped reviewers to get a fuller picture of the initiative. Five initiatives were excluded after the first evaluation round due to inadequate information for Core Team reviewers to continue to the second round.

The second round of evaluation involved scoring the initiatives based on how well they exemplify each PE Quality Criteria. As there was no globally agreed threshold of what constitutes 'a good practice' in PE and patient involvement (and specifically within the PE Quality Criteria) to allow for more granular scoring, a decision was made with reviewers to use a simplified version of scoring (Yes/No). This meant that reviewers analysed each initiative, following the 7 Quality Criteria and gave a YES - vote for each if they considered them fulfilled, or a NO - vote if they did not. Each YES - vote counted as 1 point, totalling to a maximum of 63 points for each initiative (a maximum of 9 points, 1 from each of 9 Core Team reviewers, for each of the 7 Quality Criteria).
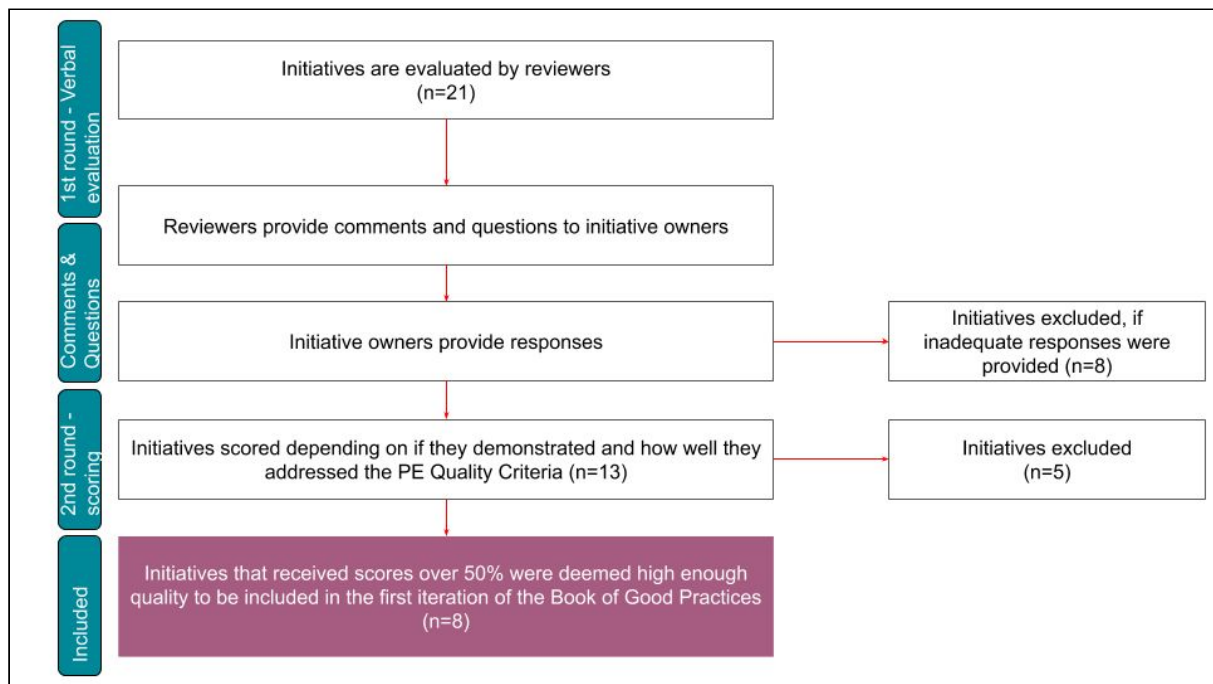

Figure 2. The Book of Good Practices review process

Initiatives selected for the Book of Good Practices

Initiatives that scored over 50% on average were included in the first edition of the Book of Good Practices and those PE Quality Criteria that received over 5 points in each initiative were highlighted as exemplary activities.

A decision was also made within the PFMD team together with the Core Team reviewers, that the initiatives would be kept anonymised until the second edition of the Book of Good Practices was released in order to prevent potential bias. This also allowed PFMD together with external contributors to reassess and refine the scoring methodology for the second edition.

The 8 good practices that exemplify one or more of the 7 PE Quality Criteria can be found in the PFMD SYNaPsE platform[2], and from the resources at pfmd.org.

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[2] Access the first edition of the Book of Good Practices here:
https://involvement-mapping.patientfocusedmedicine.org/book-of-good-practices