PATIENT FOCUSED
MEDICINES DEVELOPMENT

Patient Engagement Quality Guidance

What is it?

A tool that contains seven quality measures to assess projects to involve patients. We call this Patient Engagement Quality Guidance (PEQG). You can also use it to capture the quality of the PE project and the benefit it brings to the stakeholders involved.

How was this tool developed?

It was created by a large community of stakeholders, including patients and others with experience in the medicines-development process, using a development and feedback process.

Who is it for?

Any stakeholder (for example, patient advocate, clinical investigator, researcher, or sponsor) can use it to plan or assess the quality and effect of a PE project.

Why use this tool?

To increase the quality of your (organisation's) PE activities. You can use it as a planning tool before starting a PE project, as an assessment tool at the end of a project, or as a gap-analysis tool to compare projects within an organisation.

When should it be used?

You can use it for a PE project that takes place at any point along the research and medicines-development continuum, lifecycle of medicines, or care continuum and can be applied to health and social research.

Click here to access the editable version of the PEQG to add your comments and feedback.

PEQG version 2.0 - officially released on 15.5.2018 and in piloting phase.

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Patient Engagement Quality Guidance

A practical guide to planning, developing and assessing the quality of patient engagement (PE) activities and projects throughout the development and lifecycle of medicines.

The Patient Engagement Quality Guidance (PEQG) has been co-developed with different stakeholders through an iterative process, building on existing PE knowledge. For the background on the project and more details, please visit our website.

Contents

Glossary

NHC	National Health Council (US)
NIHR	National Institute of Health Research (UK)
PCORI	Patient-Centered Outcomes Research Institute (US)
PE	Patient engagement
PFMD	Patient-Focused Medicines Development initiative
PPIE	public and patient involvement and engagement
PRO	patient-reported outcome
SEM	Stakeholder Expectations Matrix
Stakeholder	all parties, organisations or individuals relevant to medicines research and development and care continuum; for example, patients, patient advocates, patient organisations, healthcare providers, healthcare companies and medicine and healthcare researchers, payers and regulators, health technology assessment bodies, etc.
WP(s)	working groups
TF(s)	task force(s)

Terminology and definitions used in this document

There is no widely-accepted definition or consistent language to describe patients' involvement and engagement in the research and medicines-development continuum and care journey. In this document, the term 'patient engagement' refers to the active and meaningful involvement of patients and carers in developing medicines. The following definitions should help to explain what we mean.

Patient – "those (people) having or at risk of having the medical condition(s) whether or not they currently receive medicines or vaccines to prevent or treat a disease" as well as "the family and those caring for those with the medical condition(s)," patient advocates, and patient groups. (National Health Council, 2017)

"**Patient engagement**, in drug development and product review, means **involving patients as active participants** in these processes. Simply enrolling and following patients as passive research subjects in a clinical trial does not rise to the level of patient engagement. Instead, patients should be treated "as valued and valuable partners whose input, advice, and guidance is sought and implemented" throughout these processes." National Health Council, (2017)

"INVOLVE defines **public involvement in research** as research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them." INVOLVE, (2017)

"By "**engagement in research**," we refer to the **meaningful involvement of patients**, caregivers, clinicians, and other healthcare stakeholders throughout the research process—from topic selection through design and conduct of research to dissemination of results." PCORI (2015)

"**Patient engagement occurs when patients meaningfully and actively collaborate** in the governance, priority setting, and conduct of research, as well as in summarizing, distributing, sharing, and applying its resulting knowledge (i.e., the process referred to as "knowledge translation"). It is of vital importance as "engaging patients in health care research makes [investments in] research more accountable and transparent, provides new insights that could lead to innovative discoveries, and ensures that research is relevant to patients' concerns. **The international experience with engaging citizens and patients in research has shown that involving them early in the design of studies, ideally as early as at the planning stage, leads to better results."**" Canadian Institutes of Health Research, CIHR (2014)

Purpose of the Patient Engagement Quality Guidance Tool

The PE Quality Guidance is a practical guide to help all stakeholders[1] improve the quality of their PE activities. This tool can be used in:

1. Planning and development;
2. Quality and impact assessments; and
3. Gap analysis.

Once a project is completed, the tool can be used to measure the level and quality of PE activities within an organisation, and to compare different PE projects and their impact.

The guidance introduces seven PE Quality Criteria to assess PE practices. These have been consolidated from published PE frameworks and co-developed further by PFMD Contributors[2]. The Quality Criteria describe the core elements that a good PE practice should consider including in its processes.

It is encouraged that you use all Quality Criteria for your project, although it might not be feasible to implement every Quality Criteria in any given project, as not all criteria might be relevant to all projects. The tool is intended as a practical guide to help you plan, reflect and put in place the most appropriate level of PE for your project and organization.

How the tool is structured

There are two versions or scenarios of the PE Quality Guidance Tool - scenario 1 will help you in planning a patient engagement project, and scenario 2 will help you assess your ongoing or completed project. In each scenario, the tool will provide you with things to consider and key questions to address.

The tool incorporates the following four components (Figure 1).

1. The basic description of the project – what you are aiming to achieve
2. The quality of PE in the project – how you will achieve these aims
3. Your assessment of results and outcomes
4. The lessons you have learned from completed projects

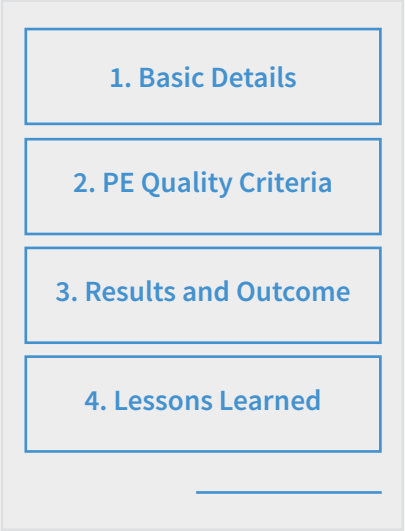

Figure 1. PE Quality Guidance Tool

Section 1 covers the basic details of the PE project. Here you can define what you are aiming to achieve and the key stakeholder groups with whom you will work, or are working.

Section 2 deals with the quality of PE – it explores how you propose to use PE and assesses whether your project has considered the seven PE Quality Criteria **(Figure 2)** in terms of both operations and core values.

Section 3 covers the results and outcomes of your PE project. At the planning stage, you will be guided to consider expected outcomes and impact, as well as the benefits you expect it to bring to processes and the medicines development lifecycle, and to the stakeholders taking part. You can use these planning points at the evaluation stage once you have completed the project. For ongoing or completed projects, you will be asked to think about the actual (and measurable) impact the project has had in the medicines development continuum, and the benefits it has brought to stakeholders.

Section 4 gives you an opportunity to capture the lessons learned in the project. This section will help you identify opportunities for future improvement and will help others in your organisation learn more about your project and gain from your experiences.

[1] All stakeholders relevant to medicines research and development and care continuum; for example, patients, patient advocates, patient organisations, healthcare providers, healthcare companies and medicine and healthcare researchers, payers and regulators, health technology assessment bodies, etc.

[2] This is a group of 76 participants to the PFMD workshops during 2016 and 2017 that we have named "PFMD Contributors". However, there are many more collaborators who have contributed to reviewing and commenting the work in progress and ultimately the outcome. For more information, see Appendix 1 and please visit our website at http://patientfocusedmedicine.org/framework-building-methodology/.

The seven Patient Engagement Quality Criteria

The PE Quality Guidance proposes seven PE Quality Criteria which have been co-created based on existing patient engagement frameworks published[3] and in the PFMD co-creation work stream that brought together various stakeholders. These criteria describe the core values that a good PE practice should consider having included in its processes.

1. Shared purpose
2. Respect and accessibility
3. Representativeness of stakeholders
4. Roles and responsibilities
5. Capacity and capability for engagement
6. Transparency in communication and documentation
7. Continuity and sustainability

The 7 Quality Criteria (QC) provide an agreed set of principles to improve consistency in PE practices, help you ensure the quality of PE in existing and future projects, and enable showcasing the results and impact of projects in a systematic way.

We suggest the 7 QC to be considered in this particular order. The relevance of each Quality Criteria may differ from project to project but it is considered important to review and apply all criteria for all projects.

Figure 2. Overview of the PE Quality Criteria

[3] The pre-existing frameworks analysis done by PFMD in Autumn of 2016 included literature review and the following six frameworks. Please check sources in detail at the end of the document.
(1) CTTI Recommendations (2015), which sets out what PE could be in different phases in the medicines and research development and lifecycle with detailed guidance for 1) all stakeholders generally, 2) research sponsors - industry and academic institutions, and 3) patient groups on what should be done to make sure there is meaningful patient engagement.
(2) The M-CERSI Conceptual Framework (2015) presents a set of instructions (created based on the pre-existing frameworks produced by NHC (2015), CTTI (2015) and Perfetto et al. (2015) that helps stakeholders to assess the level of meaningful PE.
(3) The NHC Framework (2015) which is based on the multi-stakeholder communication aimed at creating agreement and steps to take for meaningful PE and overcoming barriers.
(4) The PCORI Engagement Rubric (2014), geared towards research, this framework shows how patient input can be included in the research process (planning, carrying out and passing on the results of the study) and presents six PCORI principles to keep to.
(5) Perfetto et al.'s Framework for understanding the pace of evidence adoption (2013) includes five elements that may affect how the stakeholders use clinical trial evidence in decision-making. This framework (tested by applying it to three case studies) sheds light on when there is enough evidence to make a decision.
(6) FasterCures Patient-Perspective Value Framework (March, 2016) aims to find gaps in assessing the value of treatment options through patients' perspective. The resulting PPVF (released in November 2016) aims to provide guidance in assessing healthcare options from a patient's viewpoint (representing five broad domains equally important for patient decision-making).

This co-created guidance is work-in-progress and will be updated to its next version by **Q2 of 2018**.
Please contact PFMD team for any questions you have regarding this work.

How to use the PE Quality Guidance

The PE Quality Guidance aims to create common quality criteria for PE projects and activity. The tool's usability has been tested in PFMD workshops by assessing ongoing and completed projects (during 2017). We propose the guidance is used as a practical planning tool for future PE projects and as a gap-analysis tool.

These criteria were created to help you keep in mind the importance of including PE in the medicines-development continuum and care journey. They also provide a commonly agreed set of basic principles that help standardise the levels of PE, assess the quality of PE in any existing projects, and showcase the results and effect in a standardised way.

How to use the PE Quality Guidance

1. Use it as a planning tool
If you are starting a new project, you can use the PE Quality Guidance to assess the level of PE included in the project, and to get inspiration for new ways to involve patients. You can use the PE Quality Criteria to help you identify and set the PE goals you want to reach. Each criterion has a description that will help you fill in the tool.

Use section 3 of the tool, 'Outcomes, impact and measurements', to help you identify – and communicate – the benefits of increasing the level of PE in a project (in the research and medicines-development continuum).

2. Use it as an assessment tool for ongoing or completed PE projects
If you have an ongoing or completed PE project, use the guidance to assess the level and the quality of PE in the project. You can also use it to compare different projects and gather what you have learned in a more planned way that will allow you to analyse your projects more accurately and consistently.

- **Use it for gap analysis**
  Use the PE Quality Guidance to identify what works well and areas that can be improved, and to help you plan future PE projects. Fill in the guidance tool as best as you can – it will highlight any missed opportunities for PE. You can then analyse the effect of those missed opportunities and what could still be gained with some improvements.

Access the PE Quality Guidance Tool here

There are two possible scenarios described below, please use the appropriate template.

Scenario 1: Preparing or planning a project

Click below to access the template for Scenario 1.

SCENARIO 1

Scenario 2: Assessing an existing project (ongoing or finalised)

Click below to access the template for Scenario 2.

SCENARIO 2

Annex 1 - Background to the PE Quality Guidance

The PE Quality Guidance came from the Patient Focused Medicines Development (PFMD) Board's discussions and from their multi-stakeholder working groups (WGs) organised in 2016. In the context of a specific PFMD project called "Co-Creation of PE meta-framework", the working groups decided that there is a need to create guidance for PE across the lifecycle of medicines that would be valuable and relevant for various stakeholder groups. Since the initial meetings in November 2016, the multi-stakeholder WGs (and since then, their operational task forces (TFs) have met and further tackled the need to create specific criteria or a set of principles that could be used to define "good patient engagement practice".

[The Co-Creation of Patient Engagement Meta-Framework is a project that aims to create practical PE guidance and a toolkit on how and when to do patient engagement at any phase of the medicines-development lifecycle and care journey. This meta-framework is created by all stakeholders for all stakeholders. By using meta, we mean overarching and broad.]

Method for building the meta- framework

The PFMD framework building methodology puts an emphasis on two main aspects – the principle of co-creation (which highlights collaboration and sharing) and including all stakeholders and their points of view to make sure the outcomes represent those views. PFMD is building the framework step-by-step, and checks the outcomes of each step with the stakeholders involved.

The step-by-step approach allows us to look at the complexity of PE across the medicine-development continuum.

The four main steps in the framework process are:

1) mapping and connecting the PE landscape;
2) co-creation workshops to identify preliminary criteria for good PE practices;
3) developing the straw-man meta-framework for testing; and
4) creating the final PE meta-framework and toolkits, that take into account the lessons learned in the testing phase.

Framework building methodology - the step-by-step approach

The final PE meta-framework will be a wide-ranging package that includes guidance, templates, toolkits, learning and experiences from existing PE projects through case studies and practical, real examples. The package will potentially also include training and support for all those who are carrying out a PE project, or those looking for ways to make their existing framework more targeted and meaningful. The PFMD PE Meta-framework will be updated regularly to deal with any changes in patient engagement. The following step-by-step strategy has been created to reach the planned outcome.

Step 1 – Mapping and connecting existing patient engagement to learn from existing resources and published material (completed with active ongoing review)

The first step involves categorising PE landscape through the SYNaPsE (SYNergising Patient Engagement) Mapping and Networking Tool. The PE initiatives entered in SYNaPsE are analysed and shortlisted based on the maturity of the methodology and categorised according to their stage within the medicines lifecycle, geography, type and level of PE.

Together with the insights provided by reviewing relevant information, analysis of existing PE frameworks, and the Stakeholder Expectations Matrix, these initiatives form a starting point for building the PE meta-framework. (The Stakeholder Expectation Matrix is a PFMD project (started in 2016) that aims to clarify what stakeholders expect of PE and each other. In phase 1, 59 in-depth, semi-structured interviews were carried out from all seven stakeholder groups. The outcomes and views from this work will be further checked using a survey done in 2017. Interim reports will be published on the PFMD website.)

Step 2 – Co-creating a plan (completed)

PFMD members identified stakeholder representatives to be invited to the framework building working groups (WGs). These working groups had to define what the meta-framework would cover, to identify gaps in the outputs from Step 1 (mapping and connecting), and to create a prioritised action plan to move forward. Operational task forces from the groups were formed to continue developing and delivering prioritised action. The preliminary criteria to assess PE practices created are based on the outputs from the task forces and previous analyses, and will be checked as described below.

> **1. Collecting evidence:** The task forces collect and analyse existing PE practices using the preliminary criteria as a guide, which will be checked and built on with each round of collection and analysis. Including real examples of PE with measurable outcomes will help show how effective PE practices are, provide evidence of a positive effect, and make sure the PE meta-framework is working. Ultimately, these examples will offer guidance and measures of success for those who want to develop and put into practice new projects or initiatives.
>
> **2. Checking the outcomes** will be done at each step and by different stakeholders. Feedback is collected from contributors, including PFMD members, and members of the working groups and task forces as well as those who took part in the workshops. Outputs are reviewed after each round of feedback and adapted accordingly.

Step 3 - Developing the "strawman meta-framework" (ongoing)

This step is to do with creating the first version of the meta-framework that is ready to test. It includes general guidance, detailed instructions and a toolkit to put in place a range of PE practices in the different stages of research and development of the medicines lifecycle. The test period will be carefully documented for further analysis in the next step.

Step 4 - Creating the PE meta-framework (depending on the outcomes from the previous step)

After the test period, we will analyse all feedback, user experience and learning to identify improvements needed so we can create a practical and useful PE meta-framework with a toolkit for all stakeholders. The scope of this step will be explained further as the previous step ends.

Figures 3 and 4 show the complete framework-building process and the current status of the project (May, 2018).

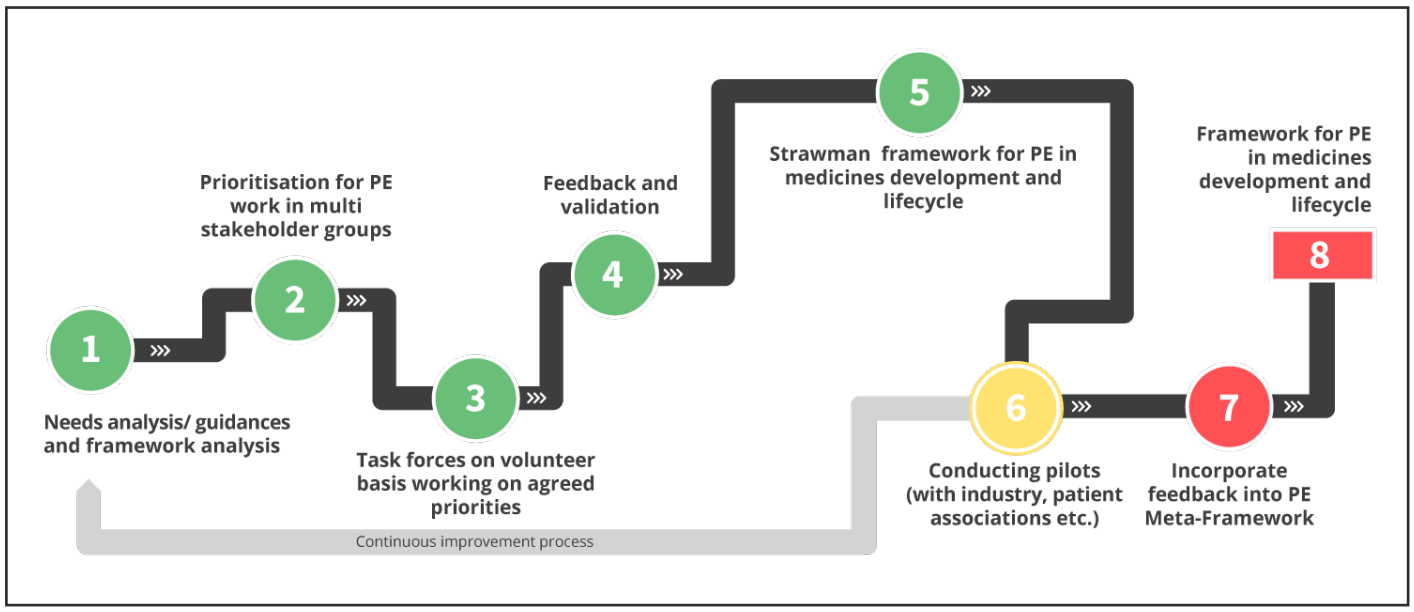

Figure 3. Roadmap to the PE meta-framework (May, 2018)

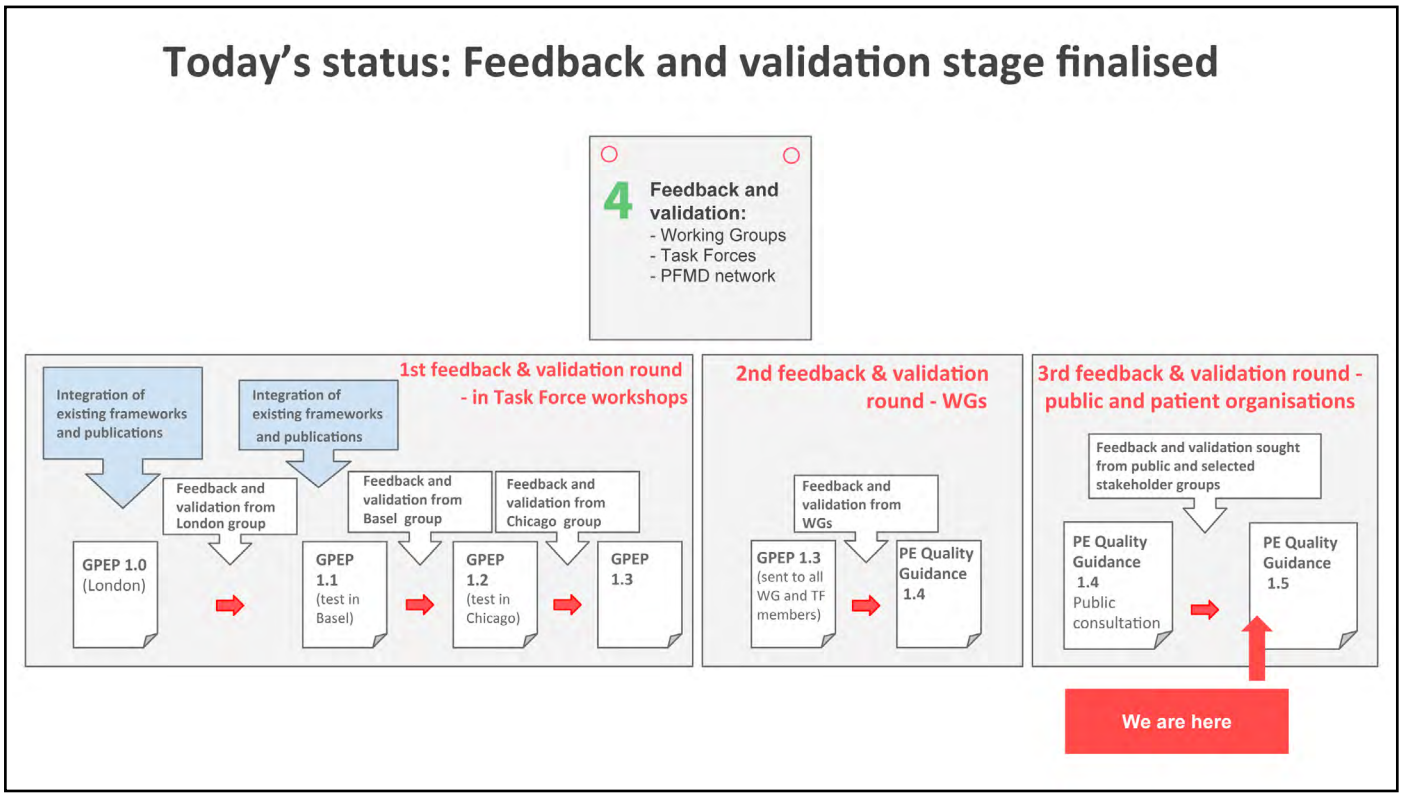

Figure 4. Status today (May, 2018)

Acknowledgements

We would like to acknowledge the PFMD Contributors' Network for their valuable contributions to co-creating this guidance which aims to facilitate more systematic and consistent patient engagement.

We also thank and acknowledge the many who have provided valuable feedback in focus groups, meetings and conferences, through their organisations and during public consultation.

Thanks also to PFMD members for their support of the project, investment of time and resources, and commitment to development of a collaborative platform for PE advances through co-creation. Special thanks to the Core team for editing, reviewing and maintaining momentum to deliver the guidance and its dissemination.

This diverse feedback and contribution has shaped the Patient Engagement Quality Guidance.

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