Plain language summaries of publications:
practical ‘How to’ guidance for multi-stakeholder co-creation

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Abstract

Objective

Patient involvement and engagement (PE) in the development of plain language summaries (PLS) is generally restricted to later stages of PLS development. Our objective was to develop practical, ‘How to’ guidance to ensure patient involvement at the earliest stage of PLS co-creation.

Research design and methods

PLS guidance was co-created by a multi-stakeholder Patient Focused Medicines Development (PFMD) Working Group (WG5) applying an iterative process. WG5 workshops (July–December 2019), identified key steps in PLS development and practical considerations for PE within each step.

These were assessed against published PE Quality Criteria[1] for relevance, comprehensiveness, and applicability. Existing PLS tools were evaluated; WG5 members involved in complementary initiatives[2,3] ensured alignment of methodology, knowledge sharing and prevented duplication.

Results

We developed actionable guidance to facilitate a structured process for PE in PLS co-creation (summarized in Table 1).

Conclusions

Practical ‘how to’ guidance for early PE in PLS development has been co-created. Pilot and validation across different source publications and audience profiles is ongoing.

References

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Scan code to pilot the Patient Engagement Quality Guidance

Table 1: Stepwise approach for PE in PLS

Step	Considerations
STEP 1: Scope and prioritization	**Where does your PLS apply?**
	▪ Consider whether the target journal or congress accepts or mandates PLS
	▪ Consider where the source publication fits in the medicines’ development continuum (R&D [early phase], preclinical, phase I–III, regulatory, post-approval), and how this may impact priority/need for PLS
	▪ Consider whether patients were involved in the study design or conduct, or as authors or contributors on the publication
	▪ Consider the type of source material for the PLS (not necessarily restricted to classical publications and could include e.g., newsletters, Annual Reports, Investor Presentations) and how this may impact priority/need for PLS
	▪ Consider resources required for PLS co-creation through to dissemination
STEP 2: Audience(s) for PLS	**Who is the PLS relevant for? Who are the audiences?**
	▪ Consider all audiences in medicines development (e.g., patient organisations, patients (lay/expert), carers, healthcare professionals [specialists/clinical investigators/primary or secondary care]) and the relevance of the PLS to each audience • Consider wider audiences (e.g. media, investors, analysts)
	▪ Consider demographics of the audience population (e.g., age, gender, language, culture, diversity, geography, disease/condition factors) • What are the priorities and needs for the respective audiences? (E.g., how do they learn, what are the expectations, what impact could the disease/condition have that is relevant to the PLS, what is the cultural environment, is this a hard to reach population, will translation be needed?)
	▪ Apply relevant PE Quality Criteria[1] across identified audiences (e.g. criterion 3, representativeness of stakeholders)
STEP 3A: Key actors for PLS co-creation	**Given the identified audience(s), who should be involved in co-creation of the PLS?**
	▪ Consider the different stakeholders who should be represented in the PLS co-creation team (e.g. patient organisations [disease specific vs general], carers, healthcare professionals and others from identified audiences)
	▪ Consider how to identify and include diverse patients (e.g. link to patient pool/list/platform)
	▪ Consider the different roles of patient co-creators (e.g. as a co-author vs. reviewer) and skills required in each role • As a co-author (e.g. may require writing skills and/or support from experienced writer, past or present involvement in clinical trials or research may be desirable) • As a reviewer (e.g. may not necessarily have been involved in trials, may require “expert” patients and/or lay patients depending on the content of the source publication, and the content [e.g. reading level] of the PLS, as this can vary depending on the target audience)
	▪ Consider individuals/organisations who can impact dissemination (e.g. editors, scientific writers, health bloggers/podcasters)
	▪ Consider creating a timeline to manage resources and expectations (e.g. could be described in the introduction or “guiding principles” of the PLS co-creation project)
	▪ Apply relevant PE Quality Criteria[1] across the PLS co-creation project (e.g. criterion 1, shared purpose; criterion 4, roles and responsibilities; criterion 5, capacity and capability for engagement)
STEP 3B: PLS tool selection	**Given the identified audience(s), what is/are the most appropriate PLS tool/tools?**
	▪ Assess existing tools and their applicability to current PLS co-creation
	▪ Consider the focus of the PLS (e.g. clinical trial, systematic review, paediatric-specific information)
	▪ Consider any journal or congress requirements
	▪ Consider the format of the PLS (e.g. video, audio podcast, leaflet, animation, infographic)
	▪ Consider the channel(s) of communication based on the audience (e.g. social media and website for PLS disseminated by patient organizations, printed) • Consider any constraints on proactive communication depending on source of PLS (e.g. industry regulations)
STEP 4: Dissemination of PLS	**Given the identified audience(s), what is/are the most appropriate channels for dissemination?**
	▪ Consider where the intended audience(s) routinely accesses information and news (e.g. journals, congresses, patient organizations, professional associations, disease databases/libraries, health institutions, industry websites)
	▪ Consider how co-creators and identified audience(s) can also act as ‘dissemination champions’
Step 5: Evaluation	**How will the impact of the PLS be measured?**
	▪ Consider what metrics are most relevant/important to capture (e.g. qualitative/quantitative feedback from PLS users, from those involved in PLS co-creation, demonstration of benefit/value of PLS [e.g. increase in access to co-created PLS/publication, Net Promoter Score])
	▪ Consider the audience/format and dissemination route for metrics and evaluation

Methodological approach to development of PLS ‘How to’ guidance
The context and the bigger picture

1 PFMD established in 2015 to integrate the patient voice across the medicines development lifecycle

An independent, global coalition of health stakeholders (currently **34 organization members**)

A rational stepwise approach to co-create a standardised meta-framework for meaningful PE,[4,5] and actionable tools for PE implementation in real-world settings

2 Working Groups (WGs) established for co-creation efforts

7 multi-stakeholder WGs, with more than **75 experts** across over **50 stakeholder organisations**

3 Research and outreach to understand, map and connect global PE efforts and communities[6]

Co-creation of PE Quality Guidance, with **7 PE Quality Criteria**[1] and complementary Book of Good Practices

Ongoing mapping of PE initiatives in SYNaPsE – currently over **430 initiatives**, **640 organizations** and **1,850 people in the network**

4 Public consultation to identify priority PE activities for WG focus

WG identification and validation of over **150** specific PE activities across the medicines development lifecycle

Representative public consultation to further validate and prioritize activities and to identify new activities not listed – **133 responses** from over **9 stakeholder groups** and **26 countries**

5 Improved patient information identified as a priority across all phases of medicine’s lifecycle

Feedback from the consultation highlighted a need to improve communication as a common theme in all phases

Discovery and preclinical phase	Clinical phase	Regulatory phase	Post-approval phase
Improve information for patients	Develop plain language patient material, channels and tools	Provide access to comprehensive information (eg, regulatory clinical trial results lay summaries, product medical information, improved packaging/labelling)	Disseminate study results to patients (eg, PLS of publications) and give feedback on patient experience in studies via multiple channels

6 PE Quality Guidance translated to actionable ‘How to’ modules for priority PE activities

Prioritized PE activities were targeted in the first phase of co-creation of ‘How to’ modules, with different WGs focusing on different priority PE activities

7 WG contributors are invited based on their experience/expertise in the ‘How to’ module focus area

Translating the overarching PE Quality Guidance into specific ‘How to’ guidance for a specific PE activity requires experiential knowledge of that activity and of PE

Each ‘How to’ module is being developed by those with the experience to make a meaningful contribution

Continuous recruitment of contributors is ongoing to achieve the optimal balance between diversity and experience

8 WG5 contributors have experience in PLS elaboration and PE

WG5 focused on development of a ‘How to’ module that provides guidance to ensure PE at the earliest stage of PLS co-creation

The module outlines **a 5-step approach** (Table 1) with PE Quality Guidance and associated PE Quality Criteria implemented for each step

9 ‘How to’ modules are piloted, validated and refined through an iterative approach

Each drafted ‘How to’ module will be tested and validated in pilot projects with feedback from each pilot used to refine (and re-test) the module

How to’ modules will also be validated during public consultation meetings and reviewed as needed to ensure they remain relevant and up-to-date in an evolving PE landscape

Development of ‘How to’ modules for other priority PE activities is ongoing

10 ‘How to’ modules are 1 element within a holistic meta-framework for PE

Each finalised ‘How to’ module will be incorporated into PFMD’s actionable toolkit – the Patient Engagement Management Suite – which is a hub of co-created tools, resources and practices to help stakeholders implement systematic, effective and meaningful PE

Scan code to access the Patient Engagement Management Suite