

Methods and Considerations for the Development, Content Validity Testing, and Evaluation of Patient Education Tools (PETs)

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1. OBJECTIVE

> Patient education tools (PETs) are designed to aid patient understanding of their health condition.¹ PETs can also facilitate communication with clinicians and improve condition management.

> PETs are useful when patients are faced with a large amount of complex information, e.g. when provided with information about a potential treatment.

> Patients may experience difficulty comprehending information provided in such situations, which may be related to health literacy levels² or complexity of the information. Patient involvement in the development of PETs can help to ensure patient comprehension.

> It is important to utilise best-practice methods for the development, content validation, and evaluation of PETs in order to develop a well-understood, reliable and effective PET. The suggested development and validation process for a robust PET is presented, along with considerations for study design.

2. METHODS

> PETs can be developed through a process involving: 1) a review of evidence, 2) qualitative research with patients and clinicians and 3) a comparative study to evaluate the PET against the standard information provided.

> It is assumed that the format of the PET and standard information is produced in a written format for the purpose of analysis.

3. RESULTS

Study Design

> Figure 1 summarises the recommended approach for PET development:

Stage 1: Review of evidence

• Review of published literature/evidence relating to purpose of PET, standard information, and existing PETs in similar conditions.

Stage 2: Exploratory qualitative interviews with patients and clinicians

> Qualitative semi-structured interviews with clinical experts in the field of interest and representative patients to understand current information provided and areas for improvement.

> Qualitative analysis to identify key themes.

Stage 3: PET development

> Development of a PET based on evidence review findings and feedback from interviews regarding suggestions for the PET.

> Development of standard information comparator tool based on interview findings relating to current standard of care.

Stage 4: Confirmatory qualitative interviews with patient and clinicians

> Qualitative semi-structured interviews with clinical experts to present the draft PET and confirm clinical accuracy of the content.

> Qualitative semi-structured interviews with patients to assess comprehension and relevance of the tool.

Stage 5: Comparative study

> Outcomes achieved following patient review of the PET can be compared to those achieved following review of the standard information using appropriate statistical analysis and study design.

Figure 1. Recommended approach for PET development and validation

Considerations

> Considerations for each stage of the study are presented below:

Stage 1

> Review evidence relating to the **purpose of the PET** (e.g. treatment option for condition) to inform content and ensure clinical accuracy.

> Review evidence regarding **standard information** provided to patients to inform comparator tool and areas for improvement.

> **Review existing PETs** in a related condition/therapy area to provide insight into the content/format of the PET.

Stage 2

> Ensure **qualitative research** is designed to provide insight into: current patient experience, information that patients want to receive, and preferred presentation.

> Patients should be **representative** of the target population for the PET.

> Clinician input ensures PETs contain **appropriate and accurate information**.

> Ensure clinicians are consulted regarding **administration of the PET** and consider if this is designed for use during appointments or at home.

Stage 3

> Development of **comparator tool** displaying standard information is important to explore outcomes of the PET.

> Information in the PET should be presented **using language and formatting** that facilitates patient understanding.

> Consider use of **graphics and images** to display the information clearly and provide appropriate sources of **further information**.

> Consider the **amount of information** provided.

Stage 4

> Conduct further qualitative research with patients and clinicians to **validate PET content**, by ensuring **comprehension and relevance** in the intended population, and **confirming clinical accuracy**.

> Consider inclusion of patients with a **range of educational levels** to confirming comprehension.

> Discuss **feasibility and usability** of the PET.

Stage 5

> The outcomes achieved following patient review of the PET can be assessed by considering **how patients knowledge of their disease** changes after review of the PET versus standard information. A **total knowledge score** can be developed including knowledge of disease pathology, treatment options, treatment side effects, etc.

> The principles of a **simple cross-over study design** (A/B, B/A)³ are recommended, where the concepts of interest (e.g. patient knowledge of treatment, confidence in discussing condition with clinician, preference between the PET and standard information, etc.) are assessed at baseline, then after viewing each source of information (PET or standard information).

> **Statistical analysis** of comparative study data can compare mean scores for the PET and standard information for the concepts of interest.

> **Statistical models** can assess changes in a concept of interest prior to, and following, review of the PET or standard information (Figure 2).

Change from Baseline in Knowledge score (%)

PET

Tool

SI

54%

31%

Difference LS means 23% (95% CI 14%, 33% p<0.001)

Figure 2. A summary of the change in knowledge score after review of the PET or standard information with summaries of the difference in the knowledge score between each group.

4. CONCLUSION

> Evidence-based PETs are valuable tools to aid patient-clinician communication and improve aspects such as patient knowledge of their condition and patient confidence in discussing treatment options.

> Best-practice methods for the design and validation of PETs may help the PET to achieve better outcomes than the standard information.

Patient-Centered Outcomes

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