PCR260

Are Patients' Perspectives Implemented in Clinical Trial Designs? A Literature Review and Semi-Structured Interviews to Explore Current Practices, Barriers, and Improvement Opportunities

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Introduction

Patient experience data (PED)

- Patient-reported outcomes
- Patient-reported experiences
- Patient preferences
- Patient input

PED **increasingly recognised** by stakeholders as an important source of information that should be considered when making decisions

Challenges hamper the systematic implementation of PED in decision-making, including in clinical trials

Objectives

This study aims to investigate current practices, barriers, and improvement opportunities regarding the implementation of **patients' perspectives into clinical trial designs**.

Methods

Literature review

Literature review with systematic search string in
- PubMed
- Embase

for reviews and guidelines on PED implementation in clinical trial design

Grey literature review of key regulatory and stakeholder guidance documents

Qualitative interviews

Purposive sampling

Semi-structured interviews with key stakeholders, including physicians from Belgian hospitals (n=10)

Ad verbatim transcription

Thematic framework analysis

Results*

** Based on preliminary insights*

BARRIERS

- Lack of guidelines and standardized methodologies
- Subjectivity of patient-reported outcome (PRO) data
- Cost and time constraints for collecting PED
- Patient burden and survey fatigue
- Representativeness of patient sample
- Lack of scientific knowledge of patients when giving input

OPPORTUNITIES

- Development of disease-specific guidelines and PRO measures, and creation of core outcome sets
- Validation of patient-informed and patient-relevant endpoints
- Methodological guidance on patient-reported experience (PRE) measures and patient preferences (PP)
- Increased use of direct patient input

FACILITATION OF MORE EFFECTIVE PED IMPLEMENTATION THROUGHOUT THE DRUG LIFE CYCLE

Pre-clinical drug development	Clinical drug development	Market access and reimbursement	Clinical practice
Define unmet needs to guide research agenda	Understand impact of disease and its treatment on patients	Indicate trade-offs to inform benefit-risk assessment	Inform the development of guidelines and standards
Define research questions	Inform trial study protocol, including design, recruitment and feasibility	Help resource allocation by considering patients' needs and preferences	Inform appropriate use of secondary data
	Help develop clear and concise study materials		Help report back study results to patients
	Inform relevant endpoints		

Abbreviations

PED: Patient Experience Data, PRO: Patient Reported Outcome, PRE: Patient Reported Experience, PP: Patient Preferences

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Abstract of poster

Conclusion

- Development of standards and disease-specific best practices
- Stimulate early involvement of patients in clinical trial designs
- Multi-stakeholder collaboration

Tailor decision-making to meet patients' needs and preferences for a more patient-centred healthcare system