



The PREFER Recommendations in brief

Why, when and how to assess and use patient preferences in medical product decision-making

This document presents the take-home messages from the PREFER Recommendations, explaining when and why results from patient preference studies can inform decision-making. We will describe how the PREFER framework should be used, how to involve key stakeholders, how to pick a method for your research questions, explore how participants' psychological characteristics may offer important insights into preference heterogeneity, and how educational materials can support patients' understanding.

The full report provides recommendations for when and how it is best to perform preference studies and include patient preferences in decision making during the medical product life cycle. It is the result of a five-year effort from public and private partners. Patient stakeholders have been involved at every level of the project, co-creating a set of recommendations that can support the development of guidelines for structured patient input into decision-making for the pharmaceutical industry, regulatory authorities, health technology assessment bodies and reimbursement agencies!

Who is this for?

This is a set of recommendations for everyone with a stake in the decisions that are made along the medical product life-cycle: we invite anyone and everyone who is or will become a patient. All those making decisions from drug discovery to post marketing of medicines. The researchers that drive innovation, the companies that develop medicines, the authorities that approve them, and those that decide what becomes available to patients in different countries and health care systems: the health technology assessors, reimbursement agencies and payers. Everyone interested in patient engagement. Along with the entire preference research community!

We expect our recommendations to...

- stimulate the design and execution of more patient preference studies that are relevant for medical product decision-making
- stimulate the publication of results from patient preference studies
- increase collaboration and interaction between study sponsors, academia, patients, and decision-makers through conceptualisation of research questions, conducting patient preference studies and using patient preference information in decision-making
- be taken as an invitation for future work on research questions that have been identified by PREFER but could not be addressed in the project.

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Introduction

Patient preferences are regarded as important in decision-making about medical treatments, and patient preference studies can make use of robust, scientific, and structured methodologies.

The PREFER recommendations address gaps in awareness, and provide guidance, on how to conduct, assess and incorporate the outcomes of patient preference studies in decision-making throughout the medical product life cycle, specifically in product development decisions, regulatory decision-making, marketing authorisation, and HTA or reimbursement decision-making.

The PREFER recommendations provide a comprehensive framework, from ideation to communication of results, that includes comprehensive details on how to design a preference study and apply its results relative to existing frameworks and guidance documents. The recommendations also uniquely emphasise the need to engage all stakeholders throughout the preference study process, and incorporate learnings on using educational materials and psychological assessments.

The value of patient preferences

Patient preferences are useful for informing preference-sensitive decisions during multiple phases of the medical product life cycle.

The results of a single patient preference study can inform decisions of multiple stakeholders, such as industry, regulators, HTA bodies and payers.

Patient preference data is intended to inform decision-making as supplementary information to other evidence generated by clinical data.

Two especially valuable use cases are where patient preference studies inform:

- the choice of patient-relevant endpoints by showing which characteristics of a medical product or disease are most important to patients (qualitative assessment), and how much they matter (quantitative assessment)
- the acceptability to patients of trade-offs between the various medical product characteristics.

Working with key stakeholders

When working with patients, it is important to empower patients as research partners in preference studies to increase the relevance, appropriateness, feasibility, and acceptability of the preference study design, as well as its conduct and the interpretation of findings. Patients should be involved as study team members or advisors throughout the entire process, from study planning through to the communication of results.

When working with regulators and HTA bodies, Early consultation with the relevant regulator and/or HTA body is needed to ensure a patient

preference study adds value and delivers results that can be integrated in the decision-making process.

Awareness of the needs and expectations of regulators and HTA bodies – including any differences between these groups – is necessary so that the sponsor of the patient preference study can design a single study that is fit for purpose.

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The PREFER framework

The proposed framework for patient preference studies is intended for use by study sponsors to facilitate stakeholder review and discussion about objectives, design, conduct, analysis, and interpretation of patient preference studies.

The framework complements other published best practices and checklists relating to patient preference studies.

Methods identification & points to consider for methods selection

Patient preference information can be obtained through many different preference exploration (qualitative) or elicitation (quantitative) methods.

Choosing the most appropriate method is a crucial step, and multiple factors should be considered, which can be grouped into three categories: methodological, participant and feasibility.

Some of the most prominent factors that influence

the choice of method include the study purpose and objectives, the preference-sensitive situation, the cognitive burden for the patient, stakeholder acceptance, and available budget and time.

Our recommendations provide detailed descriptions of the five most promising methods and points to consider for method selection.

Using psychological constructs to understand preference heterogeneity

Investigating participants' psychological characteristics may offer important insights into why preference heterogeneity exists within a study population and/or the factors that influence the formation of patient preferences.

The measurement of psychological constructs in patient preference studies should be evidence-based and/or based on theoretical considerations

concerning the strength of their associations with patient preferences and decision-making processes.

In particular, investigators should consider including at least one construct associated with cognitive abilities, such as health literacy and numeracy, given the importance of patient comprehension in preference research.

Addressing educational needs among preference study participants

Patient educational materials should be customised to the target population, choice task, and study context by using a systematic and evidence-based approach.

Educational materials should be planned, developed, and tested in collaboration with patient research partners and participants early in the study to ensure suitability and effectiveness.

The format and content of educational materials should be selected and adapted based on the specific educational needs of the participants.

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Future areas of research

PREFER was able to provide a foundation for when and how to run patient preference studies. However, there are still questions that require additional experience or additional examination, beyond this project.

Future research should involve collaboration between all stakeholders – including guidance from scientific societies, regulators and HTA bodies – to build on our results to increase the use and understanding of patient preference studies.

Cite as: The PREFER consortium. (2022). [The PREFER Recommendations in brief](#). Zenodo. DOI: 10.5281/zenodo.6470918

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The PREFER consortium. (2022). [PREFER Recommendations: Why, when and how to assess and use patient preferences in medical product decision-making](#). Zenodo. DOI: 10.5281/zenodo.6470922

Visit the PREFER project website: www.imi-prefer.eu

Find our deliverables on Zenodo: www.zenodo.org/communities/prefer/

About PREFER

The PREFER project has looked at how and when it is best to perform and include patient preferences in decision making during the medical product life cycle. We include patient stakeholders at every level of the project. The end-result is a set of recommendations to support development of guidelines for industry, Regulatory Authorities and HTA bodies.



The Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle (PREFER) project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 115966. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

This brief and its contents reflects the PREFER project's view and not the view of IMI, the European Union or EFPIA.

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