



DEVELOPMENT AND APPLICATION OF A NOVEL SYSTEMATIC METHOD TO IDENTIFY PATIENTS' UNMET NEEDS: A PILOT STUDY IN INFLAMMATORY BOWEL DISEASE

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BACKGROUND

Research priorities need to be aligned to patients' unmet needs (PUNs), as such that drug research and development can become patient-centered. However, a lack of rigid methods to reveal PUNs complicates targeted research and stakeholder alignment.

OBJECTIVES

- To identify current methods used to reveal PUNs
- To evaluate the applicability of current methods in practice
- To develop and validate a novel method to systematically determine PUNs

METHODS

- 1 Orienting **literature review** on methods for PUN identification
- 2 The development of a **literature-based, systematic method to identify PUNs**
- 3 A **pilot test** of the novel method in inflammatory bowel disease
- 4 The **evaluation and validation** of the results of the pilot via **multi-stakeholder discussions**

CONCLUSION

- We propose a new method to identify PUNs. This method was validated in inflammatory bowel disease.
- Further revision and subsequent validation of the proposed method in other disease areas is needed.
- Identification of PUNs via this new method can enable priority setting by relevant stakeholders such as health technology assessment bodies, payers, and pharmaceutical industry.

CONTACT INFORMATION



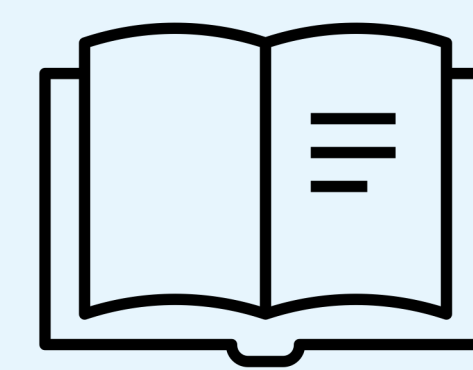
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RESULTS

NOVEL 4-STEP METHODOLOGY

STEP 1



Scoping literature review of patient-centered research

- Patient preference studies
- Quality of life studies
-

➔ Determine patients' medical needs in disease area



STEP 2

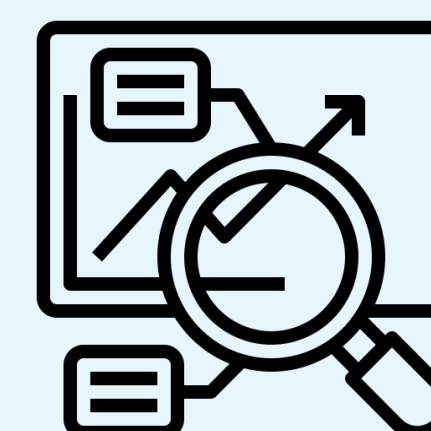


Listing of available medical therapies authorised by the responsible authority

➔ Overview of advantages/disadvantages available therapies



STEP 3

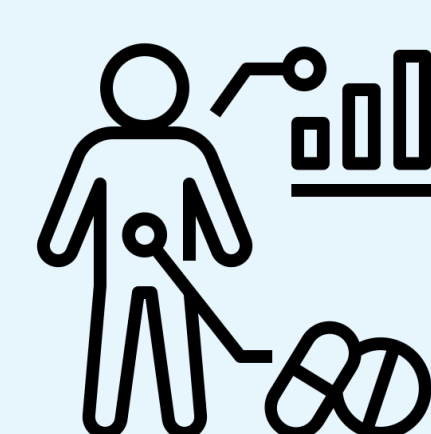


Compare patients' medical needs (Step 1) and available therapies (Step 2)

➔ Identification of PUNs



STEP 4



Review of ongoing phase III clinical trials

➔ Assess whether treatments in development target outcomes that relate to the identified PUNs (Step 3)

CASE STUDY INFLAMMATORY BOWEL DISEASE

STEP 1: Identification of 31 publications

STEP 2: List of 48 medical therapies currently available for inflammatory bowel disease

STEP 3: Identification of fatigue as PUN

STEP 4: 1/24 identified phase III IBD clinical trials explicitly include fatigue as clinical trial endpoint



Discussions with inflammatory bowel disease specialists, patients, and patient representatives confirmed the obtained results