

NEED RESEARCH TOOLBOX: INSTRUMENTS AND TOOLS FOR EXAMINING UNMET HEALTH-RELATED PATIENT AND SOCIETAL NEEDS



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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
EN	English
EU	European Union
FR	French
LUSS	Ligues des Usagers des Services de Santé
NEED	Needs Examination, Evaluation, and Dissemination
NL	Dutch
VPP	Vlaams Patiëntenplatform



■ SCIENTIFIC REPORT

1 INTRODUCTION

In late 2022, the NEED (Needs Examination, Evaluation and Dissemination) initiative was launched with the objective of developing and testing an innovative, evidence-based method to identify unmet health-related needs in order to support the transition to a more needs-driven healthcare policy and innovation system. By early 2024, the initiative had produced its first results, which were shared during Belgium's presidency of the Council of the European Union. One key outcome was the NEED assessment framework, which provides criteria and indicators to assess unmet health-related needs for both patients and society.¹

In April 2025, an updated version of the NEED framework, "*the NEED Assessment Framework 2025*," was published, supported by EU expert consensus.² Simultaneously, a core version of the framework, incorporating the minimal criteria on which evidence is required for a meaningful health-related unmet needs assessment, was published.²

To gather the data required for evaluating the criteria and indicators outlined in the NEED framework, a range of data collection methods is proposed.² The choice of method depends on the specific indicator, with detailed guidance provided in the NEED protocol.³ Both primary and secondary data sources are utilised, including systematic literature reviews, patient (or proxy) surveys, patient (or proxy) interviews, database analyses, and expert consultations.

The current report provides a toolbox of data collection instruments tailored to each method, supporting the effective application of the NEED protocol.³ These tools were developed with the primary aim of facilitating the implementation of NEED research projects through the application of the NEED protocol.³ However, they may also be of interest to researchers conducting studies on unmet needs or patient-centered care independently of a NEED research and serve as a methodological foundation for other research endeavors.

The definitions of the various concepts related to unmet needs, as well as the rationale and scope of the NEED approach, can be found in the KCE report 377¹ and in the KCE report 401².

2 AIMS

The aims of this report are to provide:

- **A standardised search strategy to conduct a systematic literature review for all indicators of the NEED framework, depending on the estimates required.** This can speed up the preparatory stage of systematic literature reviews and ensure consistency across different health conditions (see chapter 3 and supplementary material tool 1);
- **A generic patient questionnaire** to collect data via a survey addressed to patients (or their proxies when patients cannot participate themselves). This enables the measurement of patient needs indicators, as well as productivity losses (a societal needs indicator), and highlights the unmet needs that survey participants report as the most important (see chapter 4, and supplementary material tool 2);
- **A generic patient interview guide** to collect qualitative data related to patient needs indicators (see chapter 5, and supplementary material tool 3);
- **A generic patient interview guide for proxy respondents** to collect qualitative data related to patient needs indicators through their proxies in cases where patients are unable to participate themselves (see chapter 6, and supplementary material tool 4);



- A **declaration of conflict of interest form** to be completed by NEED contributors to ensure transparency, integrity, and trust in NEED studies (see chapter 7, and supplementary material tool 5);
- A **generic expert questionnaire** to collect input from clinical experts (e.g. specialist physicians) on the availability and on the effectiveness of treatment, on the implementation of primary prevention strategies, on diagnostic timing, and on research gaps (see chapter 7, and supplementary material tool 6);
- A **checklist for non-healthcare costs** to indicate which non-healthcare cost types are relevant for the condition under assessment or not (see chapter 8, and supplementary material tool 7);
- A **generic R code** for statistical analysis of data collected through the patient survey (see chapter 9, and supplementary material tool 8).

3 STANDARDISED SEARCH STRATEGY FOR SYSTEMATIC LITERATURE REVIEW

3.1 Method

Before initiating a NEED research project, it is valuable to review the existing literature to identify evidence related to the unmet health-related needs associated with the condition under consideration. This can help determine which criteria and indicators already have sufficient data available, potentially eliminating the need for additional primary data collection or secondary data analysis.

Furthermore, for certain indicators included in the NEED framework, the recommended data source is existing scientific literature. This is particularly relevant when primary data collection is not feasible within the context of a NEED project (e.g., assessing the environmental impact of the standard of care) or when literature-based estimates are required to inform specific indicators (e.g., transmissibility, preventability).

A standardised generic search strategy was developed in collaboration with a librarian trained in developing literature search strategies to facilitate and standardise systematic literature reviews to be used for different health conditions. The principle is to combine the generic search strategy with condition-specific search terms, using the Boolean operator 'and'. The generic strategy targeted three main concepts related to (i) patient (need) criteria, (ii) societal (need), and (iii) future criteria. In Medline, both MeSH and non-MeSH terms were included to ensure comprehensive coverage. The final search strategy was implemented in Ovid.

Each criterion and indicator within the NEED assessment framework was translated into a set of search terms consisting of both textwords (free-text keywords) and MeSH terms. Textwords capture language variations and common terminology, while MeSH terms unify the indexed concepts and promote consistency across different articles. Once the relevant keywords were identified, they were combined using appropriate Boolean operators.



3.2 Results

A set of generic strategies for searching scientific (and grey) literature was developed to ensure consistency across the health conditions studied. For each indicator of the NEED framework, textwords and MeSH terms were identified. For each dimension (Patient, Societal, Future), two generic standardised search strategies corresponding to different levels of specificity are proposed:

- **Moderately Specific Strategy:** combines textwords, primarily limited to titles and author keywords, and MeSH terms corresponding to each indicator that defines the dimension. This approach captures a broad range of literature while maintaining a certain level of focus.
- **Highly Specific Strategy:** combines textwords, primarily limited to titles and author keywords, along with the 'Major Topic' designation of MeSH terms corresponding to each indicator that defines the dimension. This strategy effectively narrows the search to the most relevant articles and minimises irrelevant results, which is particularly advantageous when the volume of literature related to a health condition is extensive.

The results obtained through the proposed search strategies can be refined in several ways to improve relevance and manageability. For example, the scope may be narrowed by focusing on reviews of reviews, applying a publication date limit (e.g., 2015 to the present), or restricting the search to specific languages.

Moreover, specific needs-related terms were identified, and two corresponding strategies (moderately specific, highly specific) were proposed. Combining these terms with the dimension-specific strategies further focuses the search on reported unmet needs. These terms should be integrated into the strategy for each dimension, except in cases where the existing literature on the health condition is too limited, as their use may unduly narrow the scope of the research.

This allows for the independent use of each dimension's strategies or the use of the final comprehensive search strategy combining all dimensions and needs-related terms ("Full standardised research").

These generic strategies can be readily adapted and merged with any health condition-specific search terms, facilitating efficient and reproducible systematic literature reviews. An example is provided in the NEED protocol.³

Table 1 – Ovid Links to run the standardised research strategy

Searches	Ovid Links
Patient (needs) criteria	https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=2qKO96HIGNy01gQMi6GcZHeqZqaptVzbz7htl6G7ct7rGcfvq22bEqxF5vDuuXkPB
Societal (needs) criteria	https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=3rQdPTDQe4hLmfBO5N65gS3EhZ13gAUrcvCDGMTkiWfUcv1gExXW8UjN2qptZXMxa
Future (needs) criteria	https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=33wmK9nFMk34opSNW94nLeR6bUTkXix5Ze3aSkqr5C5ibdgJQ7XXzeodvOTNiKeLL
Terms related to needs	https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=2Ae2ASy7Y74zAw6qcrNmDtLiZLxkoltSiCr55FpxrBdv6j8uLSZffqvmP4Bubc4j
Full standardised search	https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=4umlX5AxfPtner9HKICqgY6rMDVjANau5rP6L306VHzgdmD5QNIpmXUgl4ar79pl

These generic strategies are available via Ovid (see Table 1) and the complete list of search terms is provided in the supplementary material, tool 1.



4 THE GENERIC PATIENT QUESTIONNAIRE

4.1 Method

A first version of the generic adult patient questionnaire was published in 2022 as part of a KCE project preceding the NEED initiative, which laid the foundations for a framework to study unmet patient needs and which piloted this approach with patients suffering from long Covid.⁴ The initial questionnaire was validated by a Delphi panel made up of patient representatives from umbrella patient organisations and sickness funds. The full methodological details of the development of the first version of this questionnaire can be found in the KCE report 348.⁴ It underwent a first revision based on the first version of the NEED assessment framework¹ and was applied to two case studies (Crohn's disease⁵ and malignant melanoma⁶). Based on these experiences and integrating the changes of the NEED assessment framework 2025 that resulted from the Delphi study², the generic questionnaire was further refined.

Additional and modified items were, as much as possible, based on items from existing (validated) questionnaires, such as BELHEALTH, PaRIS, the Patient Assessment of Chronic Illness Care, the Primary Care Assessment Tool, the National Cancer Patient Experience Survey, the Work Productivity and Activity Impairment Questionnaire, the Zarit Burden interview, and the Caregiver Burden Inventory.

This final version was reviewed by three KCE researchers external to the NEED team, a communication expert, and representatives from the French-speaking and Dutch-speaking Belgian Umbrella Patient Organisations (LUSS and VPP, respectively). Their feedback was discussed internally and integrated into this updated version.

Additionally, the questionnaire was reviewed by patient representatives and patient associations in the context of a separate KCE study on the needs of patients with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). This feedback led to small additional adaptations.

The questionnaire was first developed in French, and translated into Dutch and English (German version is in development). Ultimately, the current versions of the generic questionnaire in its third revision were implemented in LimeSurvey (version 6).

4.2 Results

While most of the items of the generic questionnaire apply to any health condition under study, some items require adaptation. The necessary adaptation, along with the procedure, is outlined in the NEED protocol.³

This questionnaire is intended for adult patients and their proxies. A version adapted for minors or for parents of children is currently under development.

The total number of items is 55 (plus 7 items in case informal caregivers answer the questionnaire), which includes filter questions and questions which may be skipped, depending on previous answers. The questions are organised around seven themes and presented in Table 2.



Table 2 – Themes, Codes and Items included in the patient questionnaire

Theme	Code	Items / Details
Descriptive background information	D	Gender, age, place of residence, level of education, housing situation*, country of birth, employment status (before and after onset of disease), financial situation, specific diagnosis*, time since diagnosis, associated health conditions*, other health conditions*, hospitalisation for health condition*
Health	H	General health-related quality of life before diagnosis and today (EQ-5D-5L), self-reported health status before onset and today (VAS), received treatments*, side-effects* and their burden, burden of treatment aside from side-effects, symptoms* and their burden, impact on sleep, concentration, mood, and self-esteem, perceived stigma, impact on sexual life, impact on reproductive life*
Healthcare	HC	Time between first appointment and diagnosis, organisation, coordination, continuity of care, received information, involvement in decision-making, forgone care
Social impact	S	Impact on education, reduction of working time, productivity loss, financial impact, impact on relationships, foregone social support
Priority needs	P	Unmet needs to be addressed as a priority
General	G	Additional unmet needs
Impact on caregivers	CG	Impact on informal caregiver's physical and psychological health, impact on informal caregiver's social life, informal caregiving time burden

**Items or response options that may need to be adapted to the health condition under study*

The generic questionnaire (in FR, NL and EN) is available in an Excel sheet (see supplementary material, tool 2 a) and in Limesurvey:

- <https://survey.kce.be/index.php/632819?newtest=Y&lang=fr> (FR)
- <https://survey.kce.be/index.php/632819?newtest=Y&lang=nl> (NL)
- <https://survey.kce.be/index.php/632819?newtest=Y&lang=en> (EN)

The structure of the generic questionnaire is available in LimeSurvey format (compatible with version 6 or higher; see supplementary material, Tool 2b, .lss file), making it easy to import into the LimeSurvey platform for the development of disease-specific questionnaires. The Excel sheet also contains an explanation of the questionnaire structure to facilitate its integration into a different online survey platform.



5 THE GENERIC PATIENT INTERVIEW GUIDE

5.1 Method

We adapted the interview guide developed in the context of KCE Report 348⁴ using insights gained from the case studies on Crohn's disease⁵, malignant melanoma⁶ and psychotic disorder (publication expected March 2026).

The interview topics are structured around the domains and criteria of the NEED framework². The specific questions should be tailored to the health condition under study and adjusted based on the respondent's answers to the survey questionnaire.

5.2 Result

The interview guide consists of a first section that provides general guidance for the interview, and a second section that contains the themes and questions to be addressed during the interview.

5.2.1 Guidance for the interview

Interviewer guidance is provided at the beginning of the guide in two sections: the first outlines procedures for the initial call (objectives, confidentiality, duration, and scheduling), while the second details interview conduct, including guide structure, questionnaire-based preparation, and key introductory information.

5.2.2 Interview's themes

The generic patient interview guide is presented in the form of a table, including the questions, follow-up prompts, and the objective(s) of each question.

The interview begins with a brief ice-breaker before moving on to themes drawn from the NEED framework. Selected sections of the generic interview guide are adapted to each health condition, based on the relevant literature review and the main concerns highlighted in the online survey.

This interview guide is intended for adult patients; it can be conducted either with the adult patient alone or with the patient accompanied by a proxy respondent. A paediatric version is in development.

The themes included in the interview guide are presented in Table 3.

Table 3 – Themes included in the patient interview guide

Theme	Sub-themes / Details
Health	- Impact on psychological and physical health* - Symptoms* - Daily life functioning, including sexual and reproductive life - Interaction with other health problems*
Healthcare	- Patient journey leading up to diagnosis* - Experience with treatment* (received, refusal, administration) - Therapeutic needs: information needs, forgone care, accessibility, care network - Perception of quality of care: coordination, continuity, financial burden - Perception of the relationships with care providers - Administrative burden
Social impact	- Impact of the disease on social activities, relationships, work, education, and finance
Support identified	- Identification of formal and informal support networks: received and forgone support
Solutions	- Identification of potential solutions to address unmet needs in healthcare themes
Priority needs	- Unmet needs expressed across the interview to be addressed as a priority

*sub-themes that may need to be adapted to the health condition



The generic patient interview guide is presented in supplementary material, tool 3 and is available in Dutch, French and English.

6 THE GENERIC PROXY INTERVIEW GUIDE

6.1 Method

The proxy interview guide is an adaptation of the generic patient interview guide, designed to assess the same patient unmet needs indicators through responses provided by a proxy respondent (see Table 4 for definitions of proxy). The adaptation involved retaining the original content of the questions while modifying their phrasing to address the proxy rather than the patient directly. Additionally, if the proxy respondent is also the patient's informal caregiver, a section with specific questions is included at the end of the interview. These questions aim to capture the impact of the patients' health condition on the caregivers' health, time and social life and the caregivers' support needs.

The proxy interview guide has been reviewed for face validity by two representatives of informal caregiver organisations. The following criteria were asked to assess face validity: the clarity of item wording (i.e., whether the formulations were understandable and unambiguous), the representativeness of the questions (i.e., whether the content adequately reflected the intended objectives), the relevance of the items (particularly for the proxy-specific section), and the completeness of the content (i.e., whether any important elements were missing according to the participants). Feedbacks were solicited in written form, with the option of a verbal follow-up if deemed necessary.

Table 4 – Definitions of proxy respondent and proxy informal caregiver

Proxy respondent: someone who provides information on behalf of the patient. In order to participate, the proxy must meet three criteria: be an adult with a close relationship with the patient (e.g., family member, volunteer, neighbour); spend significant time with him/her; and be familiar with the patient's situation, experiences, and preferences (adapted from⁷ and⁸). Close people with a recognised legal status as a 'carer' are considered proxies, provided they meet the above criteria. In the NEED project, formal caregivers, i.e. caregivers that are paid to provide care services (e.g., healthcare professionals), are not eligible to act as a proxy.

Proxy informal caregiver: someone who provides continuous or regular help and support to the patient without financial compensation. This support may include personal care (e.g., dressing/undressing, assistance with toileting), mobility support (help with moving around), household tasks (e.g., meal preparation, cleaning), practical assistance (e.g., health monitoring, accompanying the patient to medical or other appointments), emotional or psychological support (spending time with the patient to provide emotional comfort), and help with administrative tasks (e.g., managing finances) (adapted from⁹). A filter question at the start of this interview serves to determine whether the person meets the criteria for being considered an informal caregiver.

6.2 Result

The interview guide consists of a first section providing general guidance for the interview, and a second section containing the themes and questions to be addressed during the interview.

6.2.1 Guidance for the interview

Guidance for interviewers is provided at the beginning of the guide and structured in two parts. The first part focuses on the initial call, outlining the study's objectives, confidentiality, interview duration, criteria for selecting a proxy, and confirmation of the appointment. The second part provides instructions for conducting the interview, including definitions (e.g., proxy, informal caregiver), an overview of the guide's structure, preparation based on questionnaire responses, and advice on adapting terminology and phrasing to the proxy's perspective.

6.2.2 Interview's themes and questions

The generic interview guide for proxy respondents builds upon the generic patient interview guide (see chapter 5), aimed at assessing the unmet needs of patients. It is presented in the form of a table, including the questions, follow-up prompts, and the objective(s) of each question.

To initiate the interview and provide context, a set of ice-breaker questions is asked before moving to the questions related to the framework's indicators. These questions from the generic patient interview guide were rephrased from a proxy perspective, meaning that the proxy is asked to respond as they believe the patient would^{10, 11}. Here is an example of the question framed with the proxy-patient perspective: *"How do you think your loved one would describe their relationship with the caregivers they see for [the disease]?"*

In case the patient's perspective cannot be reported by the proxy because the proxy has no knowledge of it, the proxy informs the interviewer and chooses not to answer. For some questions concerning healthcare or the patient's support needs, when the patient's perspective cannot be provided but the proxy's own viewpoint may be relevant, the interviewer may invite the proxy to share their personal opinion.

In addition to the themes covered in the adult patient interview guide, a section specifically for the informal caregiver was added at the end of the interview. This latter section covers the following themes:

- Impact on informal caregivers' health
- Impact on the informal caregivers' time
- Impact on the informal caregivers' social life
- Informal caregivers' support and information needs

Feedbacks on the face validity were received from the representatives of informal caregiver organisations, and a meeting was held with one of them. Based on this input, one interview question was revised to better capture the broad impact of the patient's illness on the informal caregiver's life, and another was added to specify the frequency of help provided by the caregiver. Additional changes concerned terminology and the refinement of examples in follow-up questions. All revisions were incorporated into the final version of the proxy interview guide.

The generic proxy interview guide is presented in supplementary material, tool 4. It is available in French, English, and Dutch language versions.



7 THE DECLARATION OF INTEREST FORM

7.1 Method

The conflict of interest declaration form was adapted from the KCE template for meetings with external participants (e.g. expert meetings, stakeholder meetings, work meetings). Several modifications were made to align it with the NEED project context. For example, the form's scope was adjusted and terminology refined to reflect the realities of a NEED study (e.g. "KCE management" was replaced by "NEED team"). The revised form was then subject to internal review.

7.2 Result

The document collects basic participant information (name, title, organisation, project's health focus) and asks respondents to disclose any financial, professional, or other interests over the past two years that could influence, or appear to influence, the study outcomes (e.g. shareholdings, consultancy, research roles, speaking fees, roles in stakeholder groups, etc).

The declaration of conflict of interest form is presented in supplementary material, tool 5. It is available in English.

8 THE GENERIC EXPERT QUESTIONNAIRE

8.1 Method

A questionnaire was developed to collect information from clinical experts (in most cases, this will concern physicians specialised in the disease) on five indicators, as foreseen in the NEED protocol: implementation of primary prevention strategies, treatment effectiveness, treatment availability and research gaps. The questionnaire was reviewed by all clinical experts (medical doctors) of the Belgian Health Care Knowledge Centre (KCE), and their feedback was used to refine some of the items.

8.2 Result

The expert questionnaire is targeted at specialists of the disease under study, and is to be completed online via Limesurvey. It consists of five parts that measure:

- Implementation of primary prevention strategies
- Appropriateness of diagnostic timing
- Effectiveness of treatment
- Availability of treatment
- Research gaps

In the questionnaire, experts are asked to rate five indicators on a Likert scale (e.g., from *treatment not effective* to *treatment highly effective*). They are instructed to base their ratings as much as possible on scientific evidence and are encouraged to provide additional details or justifications in open comment boxes.

The questionnaire is designed for use across different health conditions, with only minimal adaptations required; namely, the name of the disease and the country. An option of *not applicable* or *I don't know* is always available.

The generic expert questionnaire is available in English as a Word document (supplementary material, tool 6) and in Limesurvey:

- <https://survey.kce.be/index.php/695183?lang=en> (EN)

The structure of the generic questionnaire is additionally available in LimeSurvey format (compatible with version 6 or higher; see supplementary material, Tool 6b, .lss file), allowing a direct import into the LimeSurvey platform. The Word document also contains information on the structure (skips, conditions) to facilitate its integration into a different online survey platform.

Prior to the distribution of the questionnaire, selected experts should be asked to complete a declaration of interest form (see Supplementary tool 5 in the NEED toolbox), and those with a significant conflict of interest should be excluded.

9 THE CHECKLIST FOR NON-HEALTHCARE COSTS

9.1 Method

A checklist was created, which allows the researchers to indicate whether non-healthcare cost groups are relevant for either the majority or a minority of patients with the condition under assessment or not. The checklist comprises a list of possible non-healthcare cost types. This list was developed by the NEED team and subsequently reviewed by representatives of two umbrella patient organisations.

9.2 Result

The list of possible non-healthcare cost groups is imputed in Excel along with the possible value inputs, either applicable to most or a minority of patients:

- Applicable: “One-off costs”, for costs that occur only once;
- Applicable: “Recurring costs - short term (<1 year)”, for costs that are repeated regularly but are expected to last less than a year;
- Applicable: “Recurring costs – long term (>1 year)”, for costs that are repeated regularly and are expected to extend beyond one year;
- “Not applicable”, when the cost category does not apply to the condition under assessment.

The checklist is provided in the supplementary material as an Excel file, under Tool 7.



10 THE R CODE FOR ANALYSING THE RESULTS OF THE PATIENT SURVEY

10.1 Method

The project's quantitative analysis code was developed in R (version 4.2) and published in GitHub.

Publishing the project's analysis code on GitHub (<https://github.com/sciensanogit/NEED>) enhances adaptability, scalability, and repeatability, which are critical for rigorous (public) health research. Open-source code enables other researchers to adapt methods to new contexts and data, facilitates scalable collaboration and version control, and allows independent teams to reproduce findings, ensuring scientific integrity.¹² In the context of NEED research, GitHub enables scalable and transparent workflows that strengthen the scientific and societal impact of the project.

In short, the workflow consists of the following elements:

1. Patient data extraction from the survey;
2. Data management;
3. Integration of the indicators into the NEED database.

In the first step, the workflow will extract data from the survey. Following the data extraction, a script will handle the data management, including data cleaning, quality assessment and estimation of the indicators following the definitions of the NEED framework. In a last step, the estimated indicators are integrated and combined with other data sources (e.g. expert opinion, literature review) into the NEED database.

10.2 Result

The generic R-code can be consulted at <https://github.com/sciensanogit/NEED>. It is also available as complementary material, tool 8.

11 DISCUSSION

This report introduces eight essential tools developed to assess unmet needs among both patients and society. These tools play a central role in enabling the effective implementation of the NEED protocol.³

Certain caveats and limitations of the tools should be taken into consideration.

First of all, the tools were designed in a "generic" manner, meaning they can be applied across a broad range of health conditions, thereby enabling, among other things, the comparison of unmet needs across different conditions. However, this generic approach has certain limitations: the tools may not fully capture disease-specific features, such as the stage of illness or other particular clinical characteristics. While the content validity of the questionnaire has been investigated, other psychometric properties, such as the test-retest, remain to be examined.

So far, the tools were designed to collect data for adult patient populations only. Corresponding tools to collect data for paediatric populations are currently under development and will be published on the NEED website when available.

The patient survey offers unique insights into the unmet needs from a patient perspective. To ensure that the measured insights are accurate, the sample's representativity of the patient population is paramount. To achieve this, the characteristics of the patient population must first be defined (e.g. in terms of age distribution, gender, socioeconomic characteristics, disease severity, inpatient vs outpatient status, geographic distribution) so that recruitment efforts can be guided accordingly.

Another crucial aspect influencing data accuracy is the response rate to all questions. Given the length of the questionnaire, allowing participants to save their responses and return later can help improve completion rates.

The patient questionnaire was designed to collect data in Belgium, although its design considered potential application in other European countries. Minor adaptations related to country-specific administrative or healthcare aspects may be required before use in other European contexts.

The expert questionnaire was primarily developed with input from Belgian clinical experts; however, the topics it covers and formulations are intended to be applicable across all European countries. Some of the indicators measured through this tool (e.g. treatment effectiveness) provide pivotal information on health-related unmet needs, and their accuracy hinges on a careful selection of relevant experts, the extent to which these experts can provide supporting evidence, and a rapid literature review to validate their responses.

All tools are published in their current version in these complementary materials (tools 1-8), as well as on [the NEED website](#). It is important to note that these tools might evolve through continued use, with their content or format being refined over time. The latest versions will be made available online. Future translations into other languages will also follow and will be available on the NEED website.

12 CONCLUSION

This report presents a suite of eight essential tools designed to support the systematic assessment of unmet health-related needs in accordance with the NEED protocol.³ Developed primarily for adult populations in Belgium, the tools include instruments for literature review, patient and proxy surveys and interviews, declaration of interest collection, expert consultation, cost assessment, and data analysis. While they are generic in design to allow application across a broad range of health conditions, they provide a structured and adaptable approach for capturing both patient- and society-level needs. These tools serve as a foundation for ongoing research, can be refined over time, and offer potential applicability in other European contexts, supporting the broader goal of a needs-driven healthcare policy and innovation system.



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