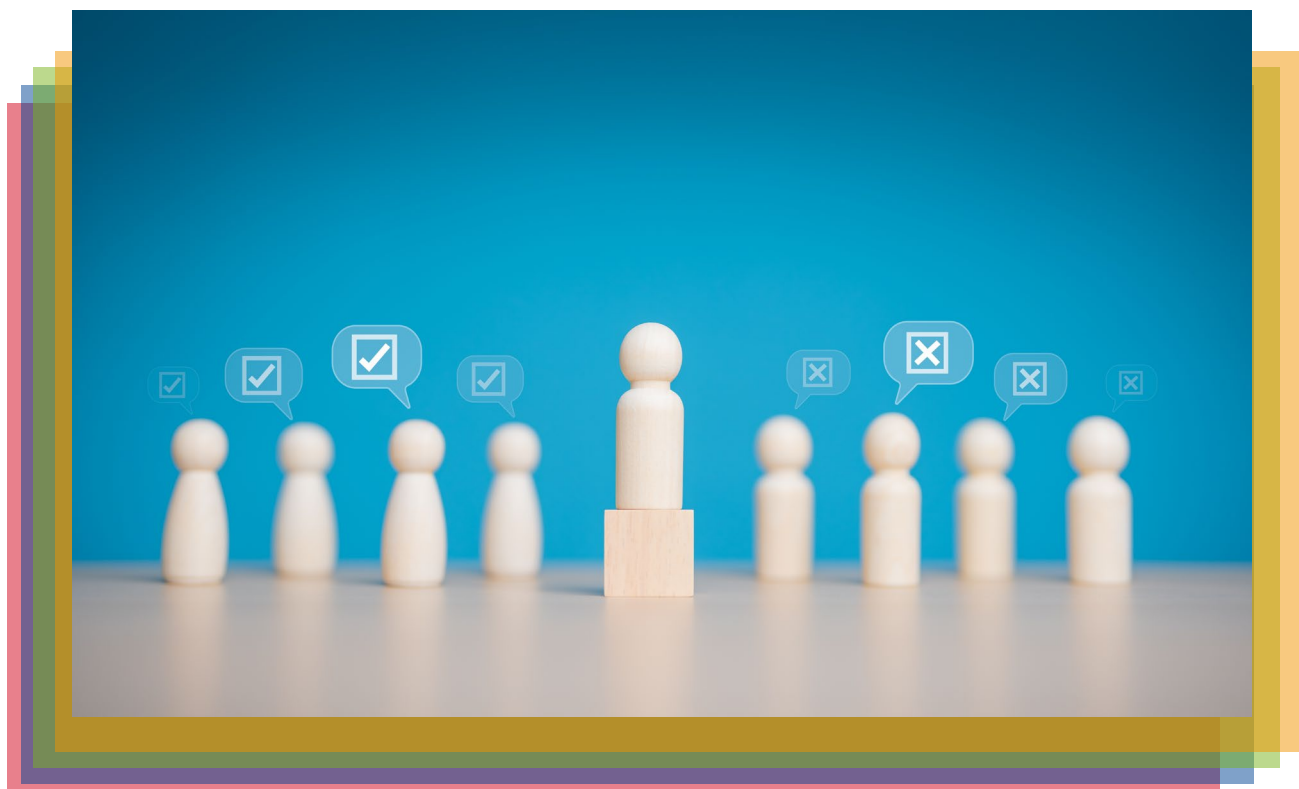


KCE REPORT 401

NEED REPORT

NEED ASSESSMENT FRAMEWORK 2025: EU EXPERT CONSENSUS AND CORE VERSION



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Title:	Need assessment framework 2025: EU expert consensus and core version.
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Acknowledgements:	We would like to thank all experts who participated to the Delphi survey and the members of the NEED steering committee. We thank Caroline Obyn (KCE), Celia Primus-de Jong (KCE), Laura Van den Borre (Sciensano), and Jinane Ghattas (Sciensano) for pretesting the Delphi survey.
Reported interests KCE members:	KCE is a federal institution funded by INAMI/RIZIV, by the Federal Public Service of Health, Food chain Safety and Environment, and by the Federal Public Service of Social Security. KCE's mission is to advise policymakers on decisions relating to health care and health insurance on the basis of scientific and objective research. It is expected to identify and shed light on the best possible solutions, in the context of an accessible, high-quality health care system with due regard for growing demand and budgetary constraints. KCE has no interest in companies (commercial or non-commercial, i.e. hospitals and universities), associations (e.g. professional associations, unions), individuals or organisations (e.g. lobby groups) that could be positively or negatively affected (financially or in any other way) by the implementation of the recommendations. All experts involved in the writing of the report or the peer-review process completed a declaration of interest form. Information on potential conflicts of interest is published in the colophon of this report. All members of the KCE Expert Team make yearly declarations of interest and further details of these are available upon request.
Reported interests:	None declared
Layout:	Ine Verhulst, Joyce Grijseels
Financial support	The NEED project is financially supported by Belspo, under grant number RT/23/NEED

Disclaimer:	• The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content. • Subsequently, a (final) version was submitted to the validators. The validation of the report results from a consensus or a voting process between the validators. The validators did not co-author the scientific report and did not necessarily all three agree with its content. • Finally, this report has been approved by common assent by the Executive Board.
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Publication date: 15th May 2025

Project number: 2023-80-09

Domain: Needs Examination, Evaluation and Dissemination (NEED)

MeSH: Unmet needs, needs assessment, prioritisation

NLM Classification: W84.3

Language: English

Format: Adobe® PDF™ (A4)

Legal depot: D/2025/10.273/09

ISSN: 2466-6459

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How to refer to this document?

Claerman R, Kohn L, Schönborn C, Obyn C, De Pauw R, Cleemput I, Maertens de Noordhout C. NEED Brussels: Belgian Health Care Knowledge Centre (KCE). 2025. KCE Reports 401. D/2025/10.273/09.

This document is available on the website of the Belgian Health Care Knowledge Centre.

<https://doi.org/10.57598/R401C>



■ TABLE OF CONTENTS

1	INTRODUCTION	3
2	AIMS	4
3	METHODS	5
3.1	MODIFIED DELPHI STUDY	6
3.1.1	Participants	6
3.1.2	Data Collection	6
3.2	INTERNAL DISCUSSIONS	7
4	RESULTS	7
4.1	INTERNATIONAL CONSENSUS ON THE NEED ASSESSMENT FRAMEWORK.....	8
4.1.1	Participants	8
4.1.2	Round 1 and 2 results	9
4.1.3	Modifications to criteria and indicators through the Delphi process	15
4.2	THE NEED ASSESSMENT FRAMEWORK 2025	15
4.3	THE CORE NEED ASSESSMENT FRAMEWORK.....	16
5	DISCUSSION.....	17
6	CONCLUSION.....	19
APPENDIX 1.	QUESTIONNAIRE FOR THE FIRST ROUND OF THE DELPHI STUDY	22
APPENDIX 2.	THE NEED ASSESSMENT FRAMEWORK 2025	45
APPENDIX 3.	THE NEED CORE FRAMEWORK.....	56

LIST OF FIGURES

Figure 1 – Delphi study process.....	10
Figure 2 – Overview of rounds 1 and 2 results for non-consensual criteria after round 1	10
Figure 3 – Expert opinion on the criteria to be included in the core framework.....	17

LIST OF TABLES

Table 1 – Key results	8
Table 2 – Characteristics of participants	8
Table 3 – Results of the second Delphi round	11
Table 4 – The NEED assessment framework 2025.....	45
Table 5 – The definitions of the indicators included in the NEED assessment framework 2025 ...	52
Table 6 – The NEED core framework	57



LIST OF ABBREVIATION

ABBREVIATION	DEFINITION
BeBOD	Belgian Burden of Disease
EU	European Union
EMA	European Medicines Agency
FAMHP	Federal Agency for Medicines and Health Products
HC	Health condition
HRQoL	Health-related quality of life
HTA	Health Technology Assessment
LE	Life expectancy
NEED	Needs Examination, Evaluation, and Dissemination
P&R	Pricing and reimbursement
QoL	Quality of life
R&D	Research and development
SoC	Standard of care
YLDs	Years lived with disability
YLLs	Years of life lost



■ SCIENTIFIC REPORT

1 INTRODUCTION

Context

The current health innovation ecosystem remains largely supply-driven, with private research and development (R&D) investments directed toward areas that promise the highest financial return on investment, rather than the most critical societal and patient needs. This has led to gaps in addressing urgent health issues, such as mental health, antimicrobial resistance, and neglected diseases.

Moreover, decision making in healthcare policy tends to be reactive, with decisions often made based on requests from health technology developers, such as pharmaceutical companies, instead of being guided by pre-defined and prioritised health needs. As a result, several unmet health-related needs remain unmet. Public resources can be used to fill these gaps through research funding or temporary reimbursement schemes. However, the evidence on where the unmet needs actually are is often missing. To transition towards a more needs-driven healthcare system, it is crucial to establish an evidence-based process for identifying and prioritising unmet health needs. This approach should aim to address the needs that are often overlooked, ensuring that innovation and policy decisions are better aligned with the most pressing health challenges, improving the overall effectiveness and equity of the healthcare system.

The NEED project

At the end of 2022, the [NEED](#) (Needs Examination, Evaluation and Dissemination) initiative was launched with the objective of developing and testing an innovative, evidence-based methodology to identify unmet health-related needs in order to support the transition to a more needs-driven healthcare policy and innovation system.

Early 2024, the first results of the NEED project were published and presented during the Belgian presidency of the Council of the European Union (EU). This included, among other things, the NEED assessment framework¹ which defines criteria and indicators to evaluate unmet health-related needs of patients and society. The framework was then applied to two health conditions: Crohn's disease and malignant melanoma^{2,3}, for which the results were incorporated into the online publicly accessible [NEED database](#).⁴ In addition, the project evaluated the NEED framework's applicability to rare diseases, taking into account specific considerations when assessing unmet needs in the context of rare diseases.⁵

In December 2024, the NEED team published a report describing a method for identifying and selecting health conditions with potentially high unmet health-related needs to be studied with this framework.⁶ Such selection is necessary if resources to perform in-depth research on the unmet needs are limited and choices have to be made regarding which diseases to study first.

The current report outlines the process of revising and refining the NEED assessment framework, which included assessing the extent of expert consensus on the framework at the European level through a Delphi process. While the previous version of the framework¹ was primarily reviewed by Belgian experts, the objective of NEED is to provide methods for evaluating unmet health-related needs across the EU. Consequently, an international assessment is essential.

Additionally, the case studies conducted on Crohn's disease and malignant melanoma^{2,3} highlighted that estimating all criteria and indicators within the framework requires considerable time and resources. To address this challenge and accelerate the filling of the NEED database⁴, a shorter version of the framework, which we call the "core NEED assessment framework", which contains the minimally required criteria to assess patient and societal unmet health-related needs, is presented in this report.



The definitions of the various concepts related to unmet needs as well as the rationale and scope of the NEED approach can be consulted in KCE report 377.¹

The NEED assessment framework 2024

The NEED assessment framework is structured around several dimensions, domains, criteria, and indicators, facilitating a comprehensive and standardised evaluation of unmet health-related needs for different health conditions.¹ The dimensions concern patient, societal, and future needs, as well as equity considerations. Within these dimensions, we defined three domains: health, healthcare, and social needs. The criteria outline the specific needs and the indicators enable to evaluate the extent to which the needs are currently being addressed.

Since the publication of the initial NEED assessment report in 2024¹, and before the Delphi process described in chapter 3, the framework underwent several modifications. Two criteria and six indicators were added or modified based on the findings of the study on the framework's applicability to rare diseases⁵ and the case studies on Crohn's disease² and malignant melanoma³:

- The criterion "*Availability of clinical evidence*", along with the related indicator "*Existence of clinical practice guidelines*", were added to the patient healthcare needs domain.⁵
- "*Heritability*" was incorporated as an indicator under the existing criterion "*Transmissibility*".
- "*Social connection needs*" was introduced as an indicator for the criterion "*Impact on social life*".
- The criterion "*Burden on informal caregivers*" was included in the society dimension in the social needs domain, with the related indicator "*Impact on informal caregiver's social life*", reflecting the same criterion previously used in other domains but with a different indicator for this domain.
- The quality of care indicator "*Clarity of information received*" was rephrased as "*Quality of information received*".
- "*Associated comorbidities*" was removed as an indicator for "*Impact on general health-related quality of life (HRQoL)*".

The version of the NEED assessment framework before the Delphi process included 25 criteria along with 46 indicators.

2 AIMS

The aims of this report are:

- **To describe the review and refinement** of the structure (domains and dimensions) and content (criteria and indicators) of the **NEED assessment framework** through international expert consensus and internal discussions;
- To propose a **core version** of the NEED assessment framework, encompassing the minimally required criteria for a meaningful unmet needs assessment.

3 METHODS

3.1 Modified Delphi study

This study used the Delphi method, which is a widely applied survey technique that seeks expert opinion and consensus on a certain topic.⁷ The Delphi method leveraged the collective insights of experts to create a more comprehensive and consensus-based framework that facilitates the identification and evaluation of unmet health-related needs. The iterative nature of the process ensured that the final framework is both evidence-based and adaptable, providing decision-makers with a valuable tool for addressing gaps in healthcare services and resources.

A modified Delphi method was employed to assess and refine the framework, by reaching consensus on its structure and content through expert consultation across EU countries. Unlike the traditional Delphi approach, which typically begins with open-ended questions, this study used a structured questionnaire based on the existing framework.⁸ Experts were asked to assess the framework through multiple-choice questions exploring their level of agreement. The Delphi process was conducted in two rounds of consultation, whereas traditional Delphi studies typically continue until a stable consensus is reached, without a predetermined number of rounds, often requiring multiple iterations. Data from the Delphi panel were collected via an online platform (LimeSurvey 5.6).

3.1.1 Participants

Experts were selected through the authors' existing professional and academic European networks, internet searches, and purposive snowball sampling. Invitations were extended to experts from public health institutes, health technology assessment (HTA) agencies, national medicines agencies, and pricing and reimbursement (P&R) agencies across all 27 EU Member States. Additionally, experts from European and national umbrella organisations of patient associations were invited to participate. One expert from each organisation was asked to take part in the Delphi survey. The participation was anonymous.

3.1.2 Data Collection

Prior to the survey launch, a pilot test was conducted with four researchers outside the research team in order to minimise the risk of misinterpretation of the instructions and survey items. The two-round Delphi survey took place between April and May 2024. Each of the 98 invited experts received a personal email with a link to the online survey in English. Participants were given three weeks to complete each round, and those who did not participate in the first round were excluded from the second one. To decrease non-response rates, up to two follow-up reminder emails were sent to experts who had not responded.

In the first round, participants were provided with a brief video introducing the NEED framework and explaining the purpose of the Delphi study. The first-round questionnaire consisted of closed questions seeking experts' opinion on the structure of the framework and the inclusion of each criterion and indicator, with four-point scale response options ('totally agree', 'agree', 'disagree', 'totally disagree') (Appendix 1). An additional response option was included for participants who felt unqualified to answer. Participants were also given the option to provide open-ended comments if they selected 'disagree' or 'totally disagree' for any question. These comments were taken into account to better understand the reasons for disagreement.

Consensus for the inclusion of a criterion or indicator in the framework was defined as at least 85% of respondents answering 'totally agree' or 'agree', with less than 5% responding 'totally disagree'. If consensus was not reached, the item was resubmitted to the second round. However, if there was a consensus for disagreement (i.e., more than 85% of responses were 'disagree' or 'totally disagree' and fewer than 5% selected 'totally agree'), the item was excluded. The second-round questionnaire focused on the items for which consensus had not been reached, asking participants to respond with

'yes', 'no', or 'not qualified to answer' to the same round 1 question (whether they agreed to include the specific criterion/indicator in the framework), while considering the feedback from the previous round. Participants were invited to provide comments for each question regardless of their responses.

In line with *Conducting and Reporting Delphi Studies* (CREDES) guidelines, our study adopted an *a priori* definition of consensus, setting it at 85% agreement during the second and final round, meaning that items with a level of agreement of more than 85% were kept.⁹ Items that did not achieve at least 60% consensus in the second round were excluded from the final framework. Items with an agreement between 60% and 85% underwent internal discussion within the NEED team and were adapted based on the Delphi participants' feedback.

In the second round, participants were also asked which criteria they would certainly keep in a core version of the NEED assessment framework. The multiple-choice question *"If we simplified the NEED framework, which [dimension] [domain] needs criteria would you certainly keep in the framework?"* was posed to the expert panel. Respondents were also provided with the option to add additional criteria under the category "Other". This question was systematically repeated for each combination of dimension and domain. Criteria that were selected by at least 80% of respondents were included in the core framework. The additional criteria suggested by the expert panel underwent internal discussion (see section 3.2) within the NEED team for potential inclusion in the framework.

3.2 Internal discussions

Following the Delphi process, modifications were made as a result of internal discussions, further informed by the results of national stakeholder consultations and insights from previous case-studies. It is important to note that the NEED assessment framework is not a fixed entity; rather, it is a dynamic and evolving tool. The evolution of the framework is guided by lessons learned from its practical application, novel insights into patient and societal needs, improved measurement methods, and potential future changes in patient and societal needs. This continuous feedback loop ensures that the framework enhances its quality and remains relevant to emerging challenges in public health.



4 RESULTS

Table 1 – Key results

- A panel of **26 experts** participated in the Delphi study, most worked for HTA agencies, particularly in Belgium and Germany.
- The NEED assessment framework 2025 includes **26 criteria and 46 indicators** to evaluate unmet health-related needs.
- The **core** version of the NEED assessment framework includes **13 minimally required criteria and 21 indicators**.

4.1 International consensus on the NEED assessment framework

4.1.1 Participants

Of the 98 experts invited, 26 participated in the two-round Delphi panel (Table 2). A panel of 27 experts participated in the first round of the Delphi study, while 26 participants filled out the second-round survey. Most experts worked in HTA and P&R agencies, followed by public health institutes and umbrella patient organisations. Seventeen EU Member States were represented, with a higher representation of experts from Belgium (three experts, 12%) and Germany (three experts, 12%).

Table 2 – Characteristics of participants

Characteristic	Category	N (%)
Country (N = 26*)		
	Austria	2 (7.7)
	Belgium	3 (11.5)
	Bulgaria	1 (3.8)
	Croatia	1 (3.8)
	Cyprus	1 (3.8)
	Estonia	1 (3.8)
	France	2 (7.7)
	Germany	3 (11.5)
	Hungary	1 (3.8)
	Ireland	1 (3.8)
	Malta	1 (3.8)
	The Netherlands	2 (7.7)
	Poland	1 (3.8)



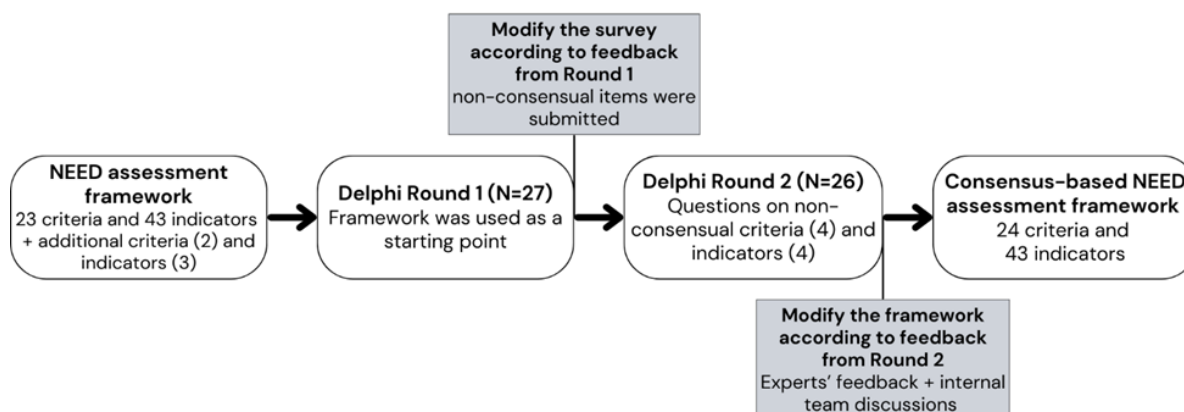
	Portugal	1 (3.8)
	Slovakia	1 (3.8)
	Spain	2 (7.7)
	Sweden	2 (7.7)
Area of expertise		
	Public health	3 (11.1)
	Medicine authorisation	2 (7.4)
	Pricing and reimbursement	5 (18.5)
	Health technology assessment	11 (40.7)
	Patient advocacy	3 (11.1)
	Other**	3 (11.1)
Years of experience		
	0 - 5 years	5 (18.5)
	5 - 10 years	5 (18.5)
	10 - 20 years	15 (55.6)
	> 20 years	2 (7.4)
Total		27 (100)

*N: number of participants; *One respondent represented an international organisation and was therefore not categorized under any specific country; **Other areas of expertise: EU affairs, pharmaceutical policy, and health economics*

4.1.2 Round 1 and 2 results

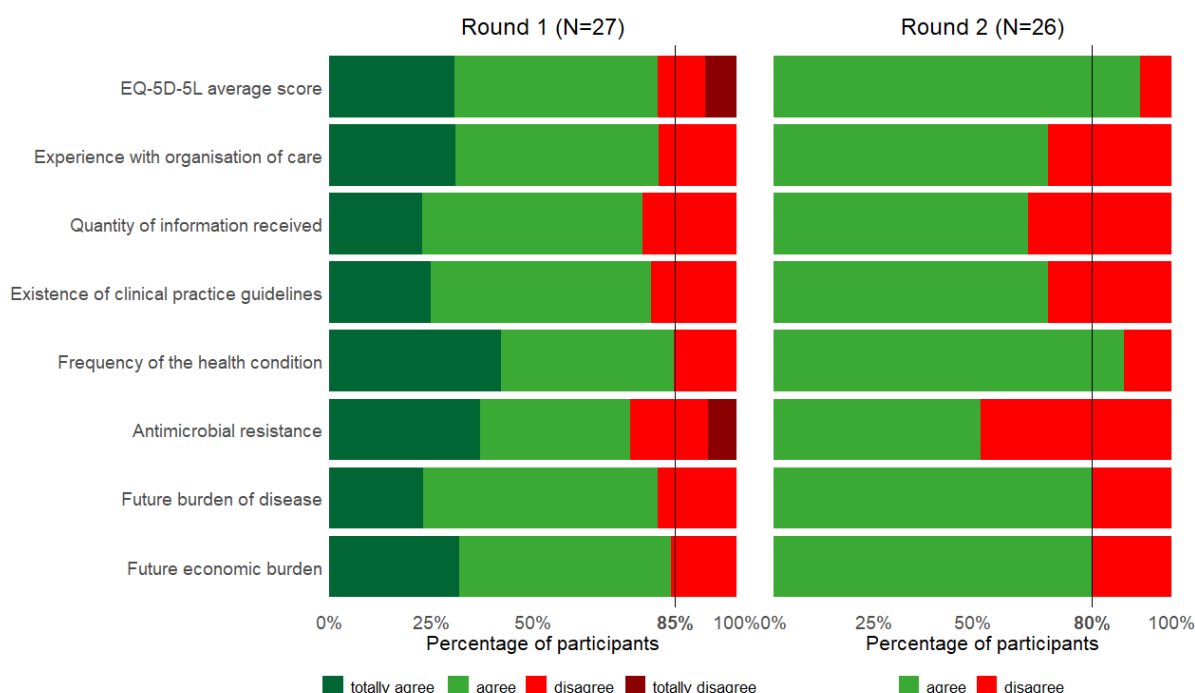
Figure 1 illustrates the iterative process used to develop the consensus-based NEED assessment framework, starting from an initial framework with 25 criteria and 46 indicators. After the first round, consensus was reached on the overall structure of the NEED assessment framework, i.e. four dimensions including equity as a transverse dimension and three domains. In addition to the structure of the framework, the experts agreed on 21 out of the 25 specific criteria and 42 out of the 46 indicators after the first round.

Figure 1 – Delphi study process



The four criteria for which consensus was not reached (*“Frequency of the health condition”*, *“Antimicrobial resistance”*, *“Future burden of disease”*, and *“Future economic burden”*) and the four indicators for which consensus was not reached (*“EQ-5D-5L average score”*, *“Experience with organisation of care”*, *“Quantity of information received”*, and *“Existence of clinical practice guidelines”*) were re-evaluated during the second round (Figure 2).

Figure 2 – Overview of rounds 1 and 2 results for non-consensual criteria after round 1



As a result of the second round, experts reached consensus on the criterion *“Frequency of the health condition”* and the indicator *“EQ-5D-5L average score”*. Two criteria and three indicators had a level of agreement between 60 and 85% and were therefore subject to internal NEED team discussion. Antimicrobial resistance had less than 60% consensus and was therefore removed from the NEED assessment framework (Table 3).



Table 3 – Results of the second Delphi round

Dimension	Domain	Criterion	Indicator	Consensus level of agreement (%)	
				R1	R2
Patient	Health	Impact on life expectancy		96%	-
			Years of life lost (per death)	100%	-
		Impact on general health-related QoL		100%	-
			Years of life lived with disability (per case)	92%	-
			EQ-5D-5L average score	81%	92%
		Impact on physical health		92%	-
			Experienced burden of physical symptoms related to the health condition	100%	-
			Pain or discomfort today compared to before the onset of the health condition	96%	-
		Impact on psychological health		92%	-
			Experienced burden of psychological symptoms related to the health condition	96%	-
			Anxiety or depression today compared to before the onset of the health condition	92%	-
		Impact on autonomy		96%	-
			Mobility today compared to before the onset of the health condition	92%	-
			Self-care today compared to before the onset of the health condition	92%	-
			Usual activities today compared to before the onset of the health condition	92%	-
	Healthcare	Treatment effectiveness		93%	-

Dimension	Domain	Criterion	Indicator	Consensus level of agreement (%)	
				R1	R2
			Effectiveness of current overall treatment	88%	
		Burden of treatment		96%	-
			Experienced burden of treatment	100%	-
			Experienced burden of side-effects of treatment	100%	-
		Quality of care		96%	-
			Experience with the organisation of care	81%	69%
			Quality of information received	88%	-
			Quantity of information received	77%	64%
			Involvement in treatment choice	96%	-
			Diagnostic timing	96%	-
		Accessibility		89%	-
			Treatment availability	96%	-
			Foregone care	91%	-
		Availability of clinical evidence		89%	-
			Existence of clinical practice guidelines	79%	69%
	Social	Impact on social life		92%	-
			Social support needs	92%	-
			Social connection needs	100%	-
		Impact on education		92%	-
			Years of education lost	86%	-



Dimension	Domain	Criterion	Indicator	Consensus level of agreement (%)	
				R1	R2
Society	Health	Impact on work		92%	-
			Changes in working conditions	96%	-
		Financial consequences		92%	-
			Average out-of-pocket healthcare costs per patient	96%	-
			Average non-healthcare costs per patient	96%	-
		Frequency		84%	88%
			Prevalence or incidence	91%	-
		Transmissibility		88%	-
			Contagiousness	100%	-
			Heritability	100%	-
Society	Health	Antimicrobial resistance		74%	52%
			Existing antimicrobial resistance to treatments used	95%	-
			Volume of antibiotics delivered to treat the disease	88%	-
		Burden on informal caregivers		93%	-
			Loss in informal caregivers' health-related quality of life	92%	-
	Healthcare	Value for money of SoC		92%	-
			Healthcare costs per unit of health gain	91%	-
		Preventability		93%	-
			Implementation of effective primary prevention strategies	92%	-
	Social	Productivity losses		96%	-

Dimension	Domain	Criterion	Indicator	Consensus level of agreement (%)	
				R1	R2
			Costs related to work absenteeism, presenteeism, or/and early labour force exits of patients	100%	-
			Costs related to work absenteeism, presenteeism or/and early labour force exits of informal caregivers	100%	-
		Environmental impact of SoC		96%	-
			Greenhouse gas emissions related to the standard of care	95%	-
			Hazardous waste related to standard of care	100%	-
			Use of natural resources and raw materials related to standard of care	100%	-
		Burden on informal caregivers		96%	-
			Impact on informal caregiver's social life	100%	-
Future	Health	Future burden of disease		81%	80%
			Future prevalence/incidence	100%	-
			Future years of life lost	100%	-
			Future years lived with disability	100%	-
	Healthcare and social	Future economic burden		84%	80%
			Future direct costs	100%	-
			Future indirect costs	100%	-

Abbreviations: R1: Round 1; R2: Round 2; QoL: quality of life; SoC: standard of care; **Bold:** Items without consensus



4.1.3 Modifications to criteria and indicators through the Delphi process

After careful consideration by the study team of the comments from the Delphi panel members, two criteria and three indicators with a level of agreement between 60 and 85% were revised and modified taking into consideration the panel's feedback:

- The quality of care indicator "*Experience with the organisation of care*" was rephrased to "*Coordination and continuity of care*" because the initial indicator was considered too vague by the experts.
- The indicators "*Quantity of information received*" and "*Quality of information received*" were merged into "*Usefulness of information received*" as recommended by the expert panel.
- The indicator "*Existence of clinical practice guidelines*" was redefined as "*Research Gaps*" within the new criterion "*Scientific Research*" that replaces the criterion "*Availability of clinical evidence*".
- The two 'future needs'-criteria were renamed "*Forecasted burden of disease*" and "*Forecasted economic burden*".

Following these updates, the NEED framework included 4 dimensions, 3 domains, 24 criteria, and 43 indicators.

4.2 The NEED assessment framework 2025

Following the Delphi process, and as part of refining the NEED framework, several additional modifications were made based on the case study findings and internal team discussions.

A new criterion "*Impact on sexual and reproductive health*" was introduced, accompanied by two related indicators: "*Impact on sexual health*" and "*Impact on reproductive health*". This addition was informed by findings from the Crohn's disease case study and the study on the applicability of the framework to rare diseases.^{2,5}

The two criteria called "*Burden on informal caregivers*" which pertained to societal health, and societal social needs respectively, were renamed as follows to provide more clarity: "*Burden on informal caregivers' health*" and "*Burden on informal caregivers' social life*". The indicator "*Impact on informal caregivers' health-related quality of life*" was renamed "*Impact on informal caregivers' health*" to better align with the survey question, which specifically assesses physical and psychological health of informal caregivers.

Several indicators were reworded for clarity and consistency. "*Usefulness of received information*" was renamed "*Received information*" to better reflect the three aspects assessed: the extent, usefulness, and understandability of the information received. "*Involvement in treatment choice*" was renamed "*Involvement in treatment decisions*" to ensure consistency with the survey question.

A new indicator, "*Secondary prevention*", was added to the framework within the quality of care criterion. Initially, secondary prevention was included in our definition of treatment, and therefore indirectly measured through the indicator "*Effectiveness of treatment*". However, in clinical practice, treatment and secondary prevention are typically considered separately, making it challenging for physicians to provide an evaluation of treatment effectiveness that includes secondary prevention. This distinction ensures a more precise assessment of both aspects of care, and highlights the importance of interventions that enable early disease detection, preventing progression and complications.

A new indicator, "*Perceived financial difficulties related to the health condition*", was introduced under the criterion "*Financial consequences*" to better reflect the patients' financial needs resulting from the health condition.

Furthermore, "*Heritability*" was removed from the framework. This criterion had been initially included based on suggestions from the study evaluating the framework's applicability to rare diseases.⁵ However, after careful consideration, it was realised that this suggestion pertained more the impact

on reproductive health than to the risk of transmission to the next generation. This impact is now addressed by the newly introduced indicator, *“Impact on Reproductive Health”*. What is more, measuring the risk of transmission to the next generation is complex and not solely dependent on genetic inheritability, as environmental factors must also be considered. It was determined that the propagation of a non-communicable health condition in the population was already adequately captured through the *“Frequency”* indicator.

Additionally, the criterion *“Forecasted economic burden”*, originally part of the healthcare and social domain, was refined into two distinct criteria: *“Forecasted healthcare costs”* (under the healthcare domain) and *“Forecasted productivity losses”* (under the social domain). This refinement enhances clarity by separately assessing healthcare expenditures and the more indirect economic impact of productivity losses.

Finally, future indicators were refined for clarity. *“Forecasted direct costs attributable to the health condition”* was renamed *“Forecasted healthcare costs attributable to the health condition”*, and *“Forecasted indirect costs attributable to the health condition”* was renamed *“Forecasted productivity losses attributable to the health condition”*.

These updates enhance the coherence, applicability, and comprehensiveness of the NEED framework. Following these modifications, the 2025-version of the NEED assessment framework includes 4 dimensions, 3 domains, 26 criteria, and 46 indicators (Table 4, in Appendix 2).

In Table 4, measures and data collection methods for each indicator are also proposed. In addition to patient surveys, patient interviews, literature reviews, and expert opinions, database analysis is another key data collection method. Indeed, various national and international databases contain valuable information for assessing the different criteria outlined in the framework. However, these databases can sometimes be challenging to use due to unclear documentation regarding the types of variables they contain or the lack of standardization in the way the data are presented. This makes it difficult to centralise and effectively use information from multiple sources.

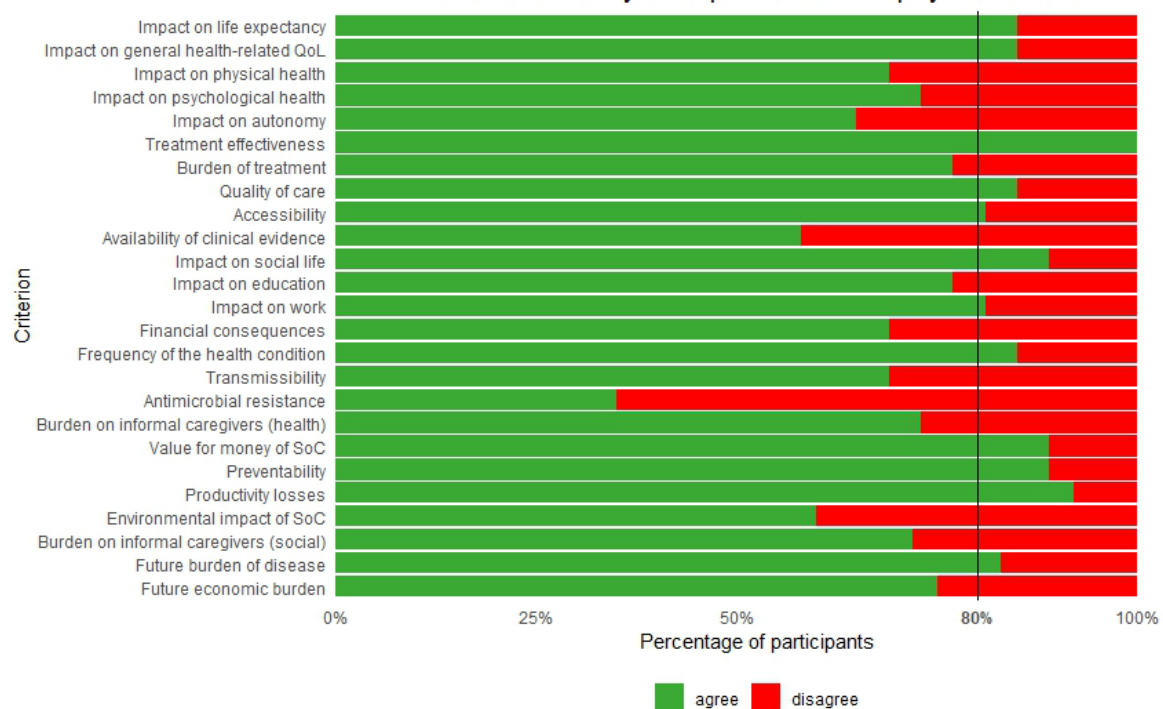
The definitions of the indicators included in the NEED framework 2025 are available in Table 5.

4.3 The core NEED assessment framework

In the second Delphi round, the experts identified twelve criteria to be included in the core NEED assessment framework (Figure 3). After expert consultation, the core framework comprised seven patient needs criteria, four societal needs criteria, and one future health criterion.



Figure 3 – Expert opinion on the criteria to be included in the core framework



While the expert panel reached consensus on including “*Impact on work*” as a criterion in the core version, only 77% agreed to include “*Impact on education*”. Despite the level of agreement being lower than the set threshold, the research team decided to nevertheless include “*Impact on education*”. Indeed, the team acknowledged that for children and adolescents, the effect of health conditions on their educational experiences can be at least as significant as the impact on work for adults. Conditions with early onset can disrupt schooling, affect cognitive and social development, and lead to long-term educational challenges that influence the individual’s future opportunities.

The core NEED assessment framework now includes 13 criteria and 21 indicators. These selected criteria and indicators will be the primary focus when incorporating data on new health conditions into the database (Table 6, in Appendix 3).

5 DISCUSSION

This report describes the update of a comprehensive framework for assessing unmet health-related needs across a variety of health conditions, as well as a shortened version, i.e., the core framework, including the minimally required criteria for meaningful unmet needs assessment.

Notably, there is no universally accepted definition of unmet needs, nor established frameworks to guide healthcare policymakers and innovators in this field. The strong consensus observed in this study highlights the potential of the NEED framework to address this gap and facilitate more structured, evidence-based decision-making. There is a necessity for a standardised framework to guide innovation and health policy making, with the NEED assessment framework emerging as a potential candidate. By leveraging shared data and pooling knowledge and resources, this framework provides a vital opportunity to address needs often neglected and underfunded due to their lack of financial appeal to the industry, fostering a more inclusive and equitable approach to health innovation.

It should be recognised that different types of decision-makers might approach the framework from varying perspectives, using it in different ways. This could affect the objectives of the NEED framework of promoting innovation to address unmet needs. For example, drug developers in the private sector will continue to consider primarily the financial viability of an innovation addressing an unmet need. Clinicians, on the other hand, will focus on ways to alleviate unmet needs using available therapies or management strategies, while academics will concentrate on evidence gaps that need to be filled to address unmet needs. Despite these stakeholders focusing on a narrower area of interest, the data collected through this framework allows to highlight areas within each of these perspectives which constitute the highest unmet needs. Moreover, it provides an opportunity to adopt a broader perspective. Stakeholders operating at a more comprehensive level, such as research funders and policy-makers, may use the framework in its entirety, benefiting from a cross-comparative analysis. This can include comparisons across unmet need areas within a specific health condition or across different diseases. The NEED framework thus allows for different uses and different focus points and does not prescribe how the criteria should be weighed in a decision-making process.

Multi-stakeholder discussions are necessary for developing an implementation model for the NEED framework that stimulates innovation in underserved disease areas. These discussions must consider real-life challenges, such as different levels of data maturity, the availability of evidence on unmet needs for a large variety of diseases, innovation development risks, and international differences in unmet needs.¹⁰ In the context where communication between the European Medicines Agency (EMA) and HTA agencies is already occurring, the EU HTA Regulation provides an opportunity to have this discussion and align ways to take unmet needs into account in regulatory and HTA decisions respectively.¹⁰

The EU-wide Delphi study achieved expert consensus on the NEED assessment framework, marking a major step forward in health needs assessment. Earlier models, such as those by Wright et al. (1998) and Stevens & Gabbay (1991), concentrated mainly on epidemiological data and gaps in healthcare.^{11, 12} While these approaches provided a foundation for recognising unmet needs, they did not incorporate a perspective as comprehensive and multidimensional as the NEED framework. Incorporating a multidisciplinary panel of experts from 17 EU Member States ensured diverse perspectives all the while reaching a strong consensus. The resulting framework offers an innovative and practical method for systematically addressing unmet needs at both national and EU levels. It sets the foundation for future research, paving the way for a more unified, needs-driven approach to healthcare policy and innovation.

Besides providing a framework for defining and assessing unmet health-related needs, the applicability of the NEED approach for making concrete decisions about specific health interventions for given diseases depends on the expansion of the data collection within NEED. This expansion requires both the financial sustainability of the NEED initiative and the support from different EU member states to continue the work. The strong consensus among experts on most aspects of the framework demonstrates its relevance, while the high participation rate reflects a commitment to



advancing the work. Several factors may explain the strong consensus among the participants in the Delphi panel. First, the NEED framework integrates multiple dimensions of health needs assessment, making it more holistic and adaptable to various healthcare contexts (Stevens & Gabbay, 1991).¹⁰ Second, the Delphi method itself may have facilitated convergence in expert opinions by allowing iterative feedback and reflection.⁷ Third, the pressing need for a structured approach in this field possibly contributed to the acceptance of the framework's key components.¹¹

Effectiveness of current treatment or standard of care was the one and only criterion that reached unanimity for inclusion in the core NEED framework. It demonstrates that there is a huge need amongst decision makers to have centralised information on unmet therapeutic needs in different disease areas.

This Delphi study nevertheless has some limitations. One limitation is that, while the Delphi methodology traditionally begins with open-ended questions to gather a broad range of expert insights, our approach deviated from this standard. Since the NEED framework had already been developed prior to the Delphi rounds, we used multiple-choice questions where experts selected their level of agreement with pre-defined statements instead of allowing for open-ended responses. This modification may have restricted the breadth of feedback, potentially limiting the opportunity to explore additional insights or alternative perspectives that could have been raised through open-ended questioning. To mitigate this risk, we had allowed respondents to suggest additional criteria and indicators through open-text responses, so all potential additions were taken into account.

The framework incorporated expert input from 17 out of the 27 EU countries. Certain regions were underrepresented, such as Northern and Eastern Europe. Consequently, the cross-cultural applicability of the findings may be somewhat limited. Additionally, half of the experts specialised in Health Technology Assessment (HTA), with an under-representation of other stakeholder groups such as clinical experts, patients, and civil society.

Finally, decisions regarding modifications to criteria and indicators that did not reach consensus were made internally. Although these adjustments were highly informed by expert feedback, a third round of consultation would have been preferable to ensure agreement to these changes.

The NEED framework should be viewed as a dynamic and evolving endeavour. As the European healthcare landscape continues to change, the framework may require further adaptation to address emerging public health challenges, medical advances, new insights, and structural shifts in healthcare systems. Furthermore, an adaptation for paediatric health conditions is essential, and this will be the focus of our next undertaking.

By focusing on a central set of criteria and indicators, the core framework allows for more rapid data collection, ensuring a streamlined approach to identifying unmet health-related needs while maintaining relevance for policymakers, researchers, and healthcare stakeholders. The fact that its development through the Delphi study resulted in the inclusion of “essential” criteria from all domains, can be interpreted as a validation of the overall structure of the framework.



6 CONCLUSION

By narrowing the scope to a central set of criteria and indicators, the core framework enhances usability in situations of limited availability of time and resources, while maintaining its ability to inform policy decisions, resource allocation, and healthcare planning across the EU.

The updated 2025 NEED assessment framework offers a method for identifying gaps and informing decision-making across the healthcare and social service sectors. By engaging a diverse panel of experts, the study has developed a framework that is both robust and adaptable, ensuring relevance across diverse EU contexts. The framework can be used by stakeholders (e.g., policymakers, healthcare providers, and organisations) to identify research gaps, allocate resources, or shape interventions aimed at addressing unmet needs. While this framework represents a substantial step forward, further research will be essential to refine its applicability. As the European landscape continues to evolve, there is a need for ongoing adaptation of the framework to accommodate emerging knowledge, needs, and changes in the EU's healthcare landscapes. We aspire for systematic unmet needs assessment, using a model such as the NEED assessment framework, to grow into a collective endeavour that drives evidence-based policy making and innovation while shedding light on the unmet needs that are often overlooked.



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■ APPENDICES

APPENDIX 1. QUESTIONNAIRE FOR THE FIRST ROUND OF THE DELPHI STUDY

Question	Answers
What is your name?	Open question
At what level does your organisation work?	National level European level Global level Other: (multiple choice)
Which country is your organisation based in?	List of 27 EU members + other
What is the role of the organisation that you work for?	Public health institute National medicine authority Pricing and reimbursement authority Health technology assessment agency Patient organisation Other (multiple choice)



Question	Answers
What is your main area of expertise?	Public health Medicine authorisation Pricing and reimbursement Health technology assessment Patient advocacy Other
How long have you been working in your organisation?	0 - 5 years 5 - 10 years 10 - 20 years > 20 years

SECTION 2: STRUCTURE OF THE FRAMEWORK

Question	Answers
Do you agree with structuring the framework according to three dimensions: 'patient needs', 'societal needs', and 'future patient and societal needs'?	1 = totally agree 2 = agree 3 = disagree 4 = totally disagree 5 = not qualified to answer
Do you agree with structuring and using 'equity' as a transversal dimension?	1 = totally agree 2 = agree 3 = disagree 4 = totally disagree

	5 = not qualified to answer
Do you agree with structuring the dimensions according to three domains: 'health', 'healthcare' and 'social' needs?	1 = totally agree 2 = agree 3 = disagree 4 = totally disagree 5 = not qualified to answer

SECTION 3: NEED FRAMEWORK CRITERIA AND INDICATORS

Dimension	Domain	question	Answers
Patients	Health		
		Do you agree with using the criterion 'impact on general health-related quality of life' to assess patient health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'Years Lived with Disability (YLDs) per case' as one of the indicators to measure the 'impact on general health-related quality of life'?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'EQ-5D average score' as one of the indicators to measure the impact on general health-related quality of life?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer



Dimension	Domain	question	Answers
		Do you agree with using the criterion 'impact on physical health' to assess patient health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'experienced burden of physical symptoms related to the health issue' as one of the indicators to measure the impact on physical health?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'pain or discomfort before the onset of the health condition compared to today' as one of the indicators to measure the impact on physical health?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'impact on psychological health' to assess patient health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree

Dimension	Domain	question	Answers
			A5 = I'm not qualified to answer
		Do you agree with using 'experienced burden of psychological symptoms related to the health issue' as one of the indicators to measure the impact on psychological health?	1 = totally agree 2 = agree 3 = disagree 4 = totally disagree 5 = not qualified to answer
		Do you agree with using 'anxiety or depression before the onset of the health condition compared to today ' as one of the indicators to measure the impact on psychological health?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'impact on autonomy' to assess patient health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'mobility before the onset of the health condition compared to today ' as one of the indicators to measure the impact on autonomy?	A1 = I totally agree A2 = I agree A3 = I disagree



Dimension	Domain	question	Answers
			A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'selfcare before the onset of the health condition compared to today ' as one of the indicators to measure the impact on autonomy?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'usual activities before the onset of the health condition compared to today ' as one of the indicators to measure the impact on autonomy?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'impact on life expectancy' to assess patient health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer

Dimension	Domain	question	Answers
		Do you agree with using 'Years of Life Lost (YLL) per death' as the indicator to measure the impact on life expectancy?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Please provide any comments on the patient health needs criteria and indicators.	Open question
Patients	Healthcare		
		Do you agree with using the criterion 'treatment effectiveness' to assess patient healthcare needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'effectiveness of treatment' as the indicator to measure treatment effectiveness?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer



Dimension	Domain	question	Answers
		Do you agree with using the criterion 'burden of treatment' to assess patient healthcare needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'experienced burden of treatment' as one of the indicators to measure burden of treatment?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'experienced burden of side-effects of treatment' as one of the indicators to measure burden of treatment?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'quality of care' to assess patient healthcare needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree

Dimension	Domain	question	Answers
			A5 = I'm not qualified to answer
		Do you agree with using 'experience with the organisation of care' as one of the indicators to measure quality of care?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'quantity of information received' as one of the indicators to measure quality of care?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'quality of information received' as one of the indicators to measure quality of care?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'involvement in treatment choice' as one of the indicators to measure quality of care?	A1 = I totally agree A2 = I agree



Dimension	Domain	question	Answers
			A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'diagnostic timing' as one of the indicators to measure quality of care?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'accessibility' to assess patient healthcare needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'treatment availability' as one of the indicators to measure accessibility?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer

Dimension	Domain	question	Answers
		Do you agree with using 'foregone care' as one of the indicators to measure accessibility?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'Availability of clinical evidence' to assess patient healthcare needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'existence of clinical practice guidelines' as the indicator to measure the availability of clinical evidence?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Please provide any comments on the patient healthcare needs criteria and indicators.	Open question
Patients	Social		
		Do you agree with using the criterion 'impact on social life' to assess patient social needs?	A1 = I totally agree



Dimension	Domain	question	Answers
			A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'social support needs' to assess unmet needs in terms of social support?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'social connection needs' to assess unmet needs in terms of social support?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'impact on education' to assess patient social needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer

Dimension	Domain	question	Answers
		Do you agree with using 'years of education lost' to assess unmet needs in terms of impact on education?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'impact on work' to assess patient social needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'changes in working conditions' as the indicator to measure the impact on work?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'financial consequences' to assess patient social needs?	A1 = I totally agree A2 = I agree A3 = I disagree



Dimension	Domain	question	Answers
			A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'average out-of-pocket healthcare costs per patient' as one of the indicators to measure financial consequences?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'average non-healthcare costs per patient' as one of the indicators to measure financial consequences?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Please provide any comments on the patient social needs criteria and indicators.	Open question
Society	Health		
		Do you agree with using the criterion 'frequency' to assess societal health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer

Dimension	Domain	question	Answers
		Do you agree with using 'incidence or prevalence' as the indicator to measure frequency?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'transmissibility' to assess societal health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'contagiousness' as one of the indicators to measure transmissibility?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'heritability' as one of the indicators to measure transmissibility?	A1 = I totally agree A2 = I agree A3 = I disagree



Dimension	Domain	question	Answers
			A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using the criterion 'antimicrobial resistance' to assess societal health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'existing antimicrobial resistance to treatments used' as one of the indicators to measure antimicrobial resistance?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'volume of antibiotic delivered to treat disease (proxy)' as one of the indicators to measure antimicrobial resistance?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer

Dimension	Domain	question	Answers
		Do you agree with using the criterion 'burden on informal caregivers' to assess societal health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'informal caregiver's quality of life' as the indicator to measure the burden on informal caregivers?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Please provide any comments on the societal health needs criteria and indicators.	
Society	Healthcare		
		Do you agree with using 'value for money of standard of care' to assess unmet societal healthcare needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer



Dimension	Domain	question	Answers
		Do you agree with using 'healthcare costs per unit of health gain' to assess unmet needs in terms of value for money of standard of care?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'preventability' to assess unmet societal healthcare needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'implementation of effective primary prevention strategies' to assess unmet needs in terms of preventability?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
Society	Social		
		Do you agree with using 'productivity losses' to assess unmet societal social needs?	A1 = I totally agree A2 = I agree

Dimension	Domain	question	Answers
			A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'costs related to work absenteeism, presenteeism, early labor force exits of patients' to assess unmet needs in terms of productivity losses?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'costs related to work absenteeism, presenteeism or/and early labor force exits of caregivers' to assess unmet needs in terms of productivity losses?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'environmental impact of standard of care' to assess unmet societal social needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer



Dimension	Domain	question	Answers
		Do you agree with using 'greenhouse gas emissions related to the standard of care' to assess unmet needs in terms of environmental impact of standard of care?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'hazardous waste related to standard of care' to assess unmet needs in terms of environmental impact of standard of care?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'use of natural resources and raw materials related to standard of care' to assess unmet needs in terms of environmental impact of standard of care?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'burden on informal caregivers' to assess unmet societal social needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree

Dimension	Domain	question	Answers
			A5 = I'm not qualified to answer
		Do you agree with using 'impact on informal caregiver's social life' to assess unmet needs in terms of burden on informal caregivers?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
Future	Health		
		Do you agree with using 'future burden of disease' to assess unmet future health needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'future prevalence/incidence' to assess unmet needs in terms of burden of disease?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer



Dimension	Domain	question	Answers
		Do you agree with using 'future years of life lost' to assess unmet needs in terms of burden of disease?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'future years lived with disability' to assess unmet needs in terms of burden of disease?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
	Healthcare and social		
		Do you agree with using 'future economic burden' to assess unmet future healthcare and social needs?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'future direct costs attributable to the health condition' to assess unmet needs in terms of economic burden?	A1 = I totally agree A2 = I agree

Dimension	Domain	question	Answers
			A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer
		Do you agree with using 'future indirect costs attributable to the health condition' to assess unmet needs in terms of economic burden?	A1 = I totally agree A2 = I agree A3 = I disagree A4 = I totally disagree A5 = I'm not qualified to answer

SECTION 4: FEEDBACK ON FIRST ROUND SURVEY

Question	Answers
Please provide any comments on the NEED framework.	Open question
Please provide any comments on the survey.	Open question



APPENDIX 2. THE NEED ASSESSMENT FRAMEWORK 2025

Table 4 – The NEED assessment framework 2025

Dimension		Domain	Criterion	Indicator	Measure	Suggested data collection method(s) *
EQUITY	PATIENT	Health	Impact on life expectancy	Years of life lost (per death)		Database analysis
			Impact on general health-related quality of life	Years of life lived with disability (per case)		Database analysis
				EQ-5D-5L average score	1) EQ-5D-5L average score: before disease 2) EQ-5D-5L average score: today 3) Difference in EQ-5D-5L average score before vs today	Patient survey
			Impact on physical health	Experienced burden of physical symptoms related to the health condition	% of participants who reported the physical symptom as moderately, very or extremely burdensome	Patient survey
				Pain/discomfort before disease vs today	1) % of participants who reported moderate, severe or extreme problems with pain/discomfort today 2) Difference in % of participants who reported moderate, severe or extreme problems with pain/discomfort before vs today	Patient survey and/or interview
			Impact on psychological health	Experienced burden of psychological symptoms related to the health condition	% of participants who reported the physical symptom as moderately, very or extremely burdensome	Patient survey and/or interview

Dimension		Domain	Criterion	Indicator	Measure	Suggested data collection method(s) *
				Anxiety/depression before disease vs today	1) % of participants who reported moderate, severe or extreme problems with anxiety/depression today 2) Difference in % of participants who reported moderate, severe or extreme problems with anxiety/depression before vs today	Patient survey and/or interview
				Impact on autonomy	1) % of participants who reported moderate, severe or extreme problems with mobility today 2) Difference in % of participants who reported moderate, severe or extreme problems with mobility before vs today	Patient survey and/or interview
				Self-care before disease vs today	1) % of participants who reported moderate, severe or extreme problems with self-care today 2) Difference in % of participants who reported moderate, severe or extreme problems with self-care before vs today	Patient survey and/or interview
				Usual activities before disease vs today	1) % of participants who reported moderate, severe or extreme problems with usual activities today 2) Difference in % of participants who reported moderate, severe or	Patient survey and/or interview



<i>Dimension</i>		Domain	Criterion	Indicator	Measure	Suggested data collection method(s) *
					extreme problems with usual activities before vs today	
			Impact on sexual and reproductive health	Impact on sexual health	% of participants who reported that the disease interfered moderately, a lot, or extremely with their sexual life	Patient survey and/or interview
				Impact on reproductive health	% of participants who reported that the disease interfered moderately, a lot, or extremely with their reproductive life	Patient survey and/or interview
		Healthcare	Treatment effectiveness	Effectiveness of current overall treatment (standard of care)	Treatment effectiveness in patient population: not effective, somewhat, moderately, very effective	Expert opinion
			Burden of treatment	Experienced burden of treatment	% of participants who reported that the treatment was moderately, very, or extremely burdensome	Patient survey and/or interview
				Experienced burden of treatment side-effects	% of participants who reported the side-effects as moderately, very, or extremely burdensome	Patient survey and/or interview
			Quality of care	Coordination and continuity of care	1) % of participants who feel that their care has sometimes, rarely, or never been well organised and planned over time	Patient survey and/or interview
					2) % of participants who do not have a single professional (or several professionals) who takes responsibility for coordinating their care	

Dimension		Domain	Criterion	Indicator	Measure	Suggested data collection method(s) *
					3) % of participants who reported that they sometimes, rarely, or never see the same healthcare provider for their regular check-ups or appointments	
				Received information	% of participants who reported sometimes, rarely, or never receiving useful and understandable information	Patient survey and/or interview
				Involvement in treatment decisions	% of participants who reported 'not really' and 'certainly not' being as involved as they would have liked in treatment decisions	Patient survey and/or interview
				Diagnostic timing	% of participants who received a diagnosis >x months after 1st appointment (to be adapted depending on health condition)	Patient survey and/or interview
				Implementation of effective secondary prevention strategies	Implementation of effective secondary prevention strategies: not at all, minimally, moderately, or fully implemented.	Expert opinion
			Accessibility	Treatment availability	Extent to which current treatment/management of [health condition] is available for the patient population: not available, important availability problems, some availability problems, no availability problems.	Expert opinion



<i>Dimension</i>		Domain	Criterion	Indicator	Measure	Suggested data collection method(s) *
				Foregone care	% of participants who within the last 12 months reported not receiving care when needed	Patient survey and/or interview
			Scientific research	Research gaps	Extent to which research gaps exist in areas: pathophysiology, diagnosis, pharmacopredictive biomarkers, prognostic biomarkers, treatment, primary prevention, secondary prevention, and other. Per area: No gap – Minor gaps – Moderate gaps – Major gaps.	Expert opinion
		Social	Impact on social life	Social support needs	% of participants who reported needing social support in at least one area but did not receive it	Patient survey and/or interview
				Social connection needs	% of participants who reported that their disease interfered moderately, a lot, or extremely with their relationships with their family, partner, friends or neighbours.	Patient survey and/or interview
			Impact on education	Impact on education	% of participants who reported that their schooling or studies were moderately, a lot, or extremely affected by their disease	Patient survey and/or interview
			Impact on work	Changes in working time	% of participants with remunerated employment since diagnosis who reduced their working hours or stopped working because of their disease	Patient survey and/or interview

Dimension		Domain	Criterion	Indicator	Measure	Suggested data collection method(s) *
	SOCIETY		Financial consequences	Average out-of-pocket healthcare costs per patient	Average out-of-pocket healthcare costs per patient per year	Database analysis in combination with literature review
				Perceived financial difficulties related to the health condition	% of participants who reported that disease or medical treatment had caused financial difficulties 'moderately', 'a lot', or 'extremely'	Patient survey and/or interview
				Non-healthcare costs per patient	Average non-healthcare costs per patient per year	Literature review
		Health	Frequency	Prevalence or incidence	Prevalence: number of cases at specific time per 100 000 population Incidence: number of new cases within one year per 100 000 population	Database analysis
			Transmissibility	Contagiousness	Basic reproduction number (R0)	Literature review
			Burden on informal caregivers' health	Impact on informal caregivers' health	% of proxy respondents who consider that their health was 'moderately', 'a lot', or 'extremely' affected by their role as carers.	Literature review and/or patient survey (for proxy respondents only)
		Healthcare	Value for money of standard of care	Healthcare costs per unit of health gain	Costs: Mean total cost of standard of care per patient (and discounted to the current year) Health gain: see indicator Treatment effectiveness of standard of care	Costs: Database analysis in combination with literature review Health gain: refer to indicator "Treatment effectiveness of standard of care"



<i>Dimension</i>		Domain	Criterion	Indicator	Measure	Suggested data collection method(s) *
		Social	Preventability	Implementation of effective primary prevention strategies	Implementation of effective primary prevention strategies: not at all, minimally, moderately, or fully implemented.	Expert opinion
			Productivity losses	Costs related to work absenteeism, presenteeism, or/and early labor force exits of patients	Average yearly cost of productivity losses per patient	Databases analysis in combination with literature review and patient survey
				Costs related to work absenteeism, presenteeism, or/and early labor force exits of informal caregivers	Average yearly cost of productivity losses per patient	Literature
			Environmental impact of standard of care	Greenhouse gas emissions related to the standard of care		Literature review
				Hazardous waste related to standard of care		Literature review
				Use of natural resources and raw materials related to standard of care		Literature review
			Burden on informal caregivers' social life	Impact on informal caregiver's social life	% of proxy respondents who consider that their social life was 'moderately', 'a lot', or 'extremely' affected by their role as carers.	Literature review and/or patient survey (for proxy respondents only)
	FUTURE	Health		Forecasted prevalence/incidence		Database analysis

Dimension	Domain	Criterion	Indicator	Measure	Suggested data collection method(s) *
		Forecasted burden of disease	Forecasted years of life lost		Database analysis
			Forecasted years lived with disability		Database analysis
	Healthcare	Forecasted healthcare costs	Forecasted healthcare costs attributable to the health condition		Database analysis
	Social	Forecasted productivity losses	Forecasted productivity losses attributable to the health condition		Database analysis

*Literature review as a data collection method is applicable to all indicators. The recommended data collection methods for each health condition might vary based on the quality of data available from the different sources.

Table 5 – The definitions of the indicators included in the NEED assessment framework 2025

Criterion	Indicator	Definition
Impact on life expectancy	Years of life lost (per death)	The number of years of life lost due to the health condition, per death.
Impact on general health-related quality of life	Years of life lived with disability (per case)	The number of years of life lost due to disability or ill-health caused by the health condition, per patient.
	EQ-5D-5L average score	A score measuring health-related quality of life along five dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression.
Impact on physical health	Experienced burden of physical symptoms related to the health condition	The level of burden of physical symptoms experienced by the patients due to the health condition.
	Pain/discomfort before vs today	The difference in the level of pain or discomfort today compared to before the onset of the health condition.
Impact on psychological health	Experienced burden of psychological symptoms related to the health condition	The level of burden of psychological symptoms experienced by the patients due to the health condition.



Criterion	Indicator	Definition
	Anxiety/depression before vs today	The difference in the level of anxiety or depression today compared to before the onset of the health condition.
Impact on autonomy	Mobility before vs today	The difference in the extent of mobility problems today compared to before the onset of the health condition.
	Self-care before vs today	The difference in the extent of self-care problems today compared to before the onset of the health condition.
	Usual activities before vs today	The difference in the extent of problems with doing usual activities today compared to before the onset of the health condition.
Impact on sexual and reproductive health	Impact on sexual health	The extent to which the health condition interfered with the patients' sexual life.
	Impact on reproductive health	The extent to which the health condition interfered with the patients' reproductive life.
Treatment effectiveness	Effectiveness of current overall treatment (standard of care)	The overall effectiveness level of the current treatment. Treatment may include various interventions such as medications, surgery, medical procedures, medical devices, physical therapy, psychological therapy, and other forms of (clinical) interventions to cure the specific health condition, to target symptoms caused by the condition, or to prevent complications.
Burden of treatment	Experienced burden of treatment	The level of burden of the current treatment for the health condition.
	Experienced burden of side-effects of treatment	The level of burden of side-effects of the current treatment for the health condition.
Quality of care	Coordination and continuity of care	Coordination and continuity of care refers to the patients' care being well organised and planned over time, e.g. having a healthcare professional responsible for care coordination, regular check-ups.
	Received information	The extent to which patients received useful and understandable information
	Involvement in treatment decisions	The extent to which patients would have liked to be more involved in the choices about the treatment for their health condition
	Diagnostic timing	The amount of time that has passed between a patient's first medical appointment and the diagnosis of their health condition.
	Secondary prevention	The extent to which effective secondary prevention strategies (if existing) are implemented for the given health condition.

Criterion	Indicator	Definition
Accessibility	Treatment availability	The extent of availability problems related to the current treatment, including problems related to both the logistic and financial accessibility of the treatment.
	Foregone care	Foregone care refers to not receiving health care (e.g. treatment, consultation, medical tests, rehabilitation or other) despite perceiving a need for it. This can be due to several reasons, including costs, waiting lists, or travel difficulties.
Scientific research	Research gaps	The extent to which knowledge gaps exist in the following areas: pathophysiology, diagnosis, pharmacopredictive biomarkers, prognostic biomarkers, treatment, primary prevention, secondary prevention, other.
Impact on social life	Social support needs	The extent to which patients needed social support because of their health condition without reaching it.
	Social connection needs	The level of impact a health condition has on patients' personal relationships, encompassing romantic relationships, parenting, friendships, or relationships with siblings.
Impact on education	Impact on education	The extent to which the health condition affected the patients' schooling or studies.
Impact on work	Changes in working time	The extent to which the health condition changed patients' ability to remain professionally active, considering factors such as working hours.
Financial consequences	Average out-of-pocket healthcare costs per patient	The annual average amount of money a patient pays for healthcare costs because of the health condition that are not covered by health insurance.
	Perceived financial difficulties related to the health condition	The extent to which the patients experience financial difficulties due to the health condition or medical treatment.
	Non-healthcare costs per patient	The annual average amount of money a patient pays for non-healthcare costs (e.g. accommodation, travel to and from healthcare facilities) because of the health condition that are not covered by health insurance.
Frequency	Prevalence or incidence	Prevalence: the total number of individuals in the population who have the health condition at a specific period of time. Incidence: the number of individuals who develop the health condition during a particular time period.
Transmissibility	Contagiousness	The extent to which a health condition can be directly or indirectly transmitted from one organism to another. When applicable (infectious diseases) this is often measured by



Criterion	Indicator	Definition
		the basic reproduction number (average number of secondary infections produced by a typical case of an infection in a population where everyone is susceptible).
Burden on informal caregivers' health	Impact on informal caregivers' health	The extent to which the health condition negatively impacts the health of informal caregivers.
Value for money of standard of care	Healthcare costs per unit of health gain	The disaggregated presentation of data on the total healthcare expenditures for the current standard of care, and treatment effectiveness of current standard of care (as measured by the indicator "Effectiveness of current overall treatment (standard of care)"..
Preventability	Implementation of effective primary prevention strategies	The extent to which effective primary prevention strategies are implemented for the given health condition.
Productivity losses	Costs related to work absenteeism, presenteeism, and/or early labor force exits of patients	The amount of costs due to the absence of patients from their workplace (i.e. time taken off work), lost productivity that occurs when patients are not fully functioning in the workplace, or exit the labour force earlier because of their health condition.
	Costs related to work absenteeism, presenteeism and/or early labor force exits of informal caregivers	The amount of costs due to the absence of informal caregivers from their workplace (i.e. time taken off work), lost productivity that occurs when informal caregivers are not fully functioning in the workplace, or exit the labour force earlier because of their caregiving activities.
Environmental impact of standard of care	Greenhouse gas emissions related to the standard of care	The estimated amount of direct greenhouse gas emissions (scope 1: emitted by healthcare providers) and indirect greenhouse gas emission (scope 2: derived from primary resources and scope 3: derived from products used by healthcare providers) related to the standard of care for the health condition.
	Hazardous waste related to standard of care	The estimated volume of hazardous (e.g. radioactive, infectious) waste generated as part of the standard of care for the health condition.
	Use of natural resources and raw materials related to standard of care	The estimated volume of natural resources and raw materials utilised in the standard of care for the health condition.
Burden on informal caregivers' social life	Impact on informal caregiver's social life	The extent to which the health condition negatively impacts informal caregiver's social life.
Forecasted burden of disease	Forecasted prevalence/incidence	The total number of individuals in the population who have the health condition at a specific period of time in the future.

Criterion	Indicator	Definition
		The number of individuals who develop the health condition during a particular time period in the future.
	Forecasted years of life lost	The future number of years of life lost due to the health condition.
	Forecasted years lived with disability	The future number of healthy years of life lost due to disability or ill-health caused by the health condition.
Forecasted healthcare costs	Forecasted healthcare costs attributable to the health condition	The amount of healthcare expenditures associated with the management of the health condition in future years.
Forecasted productivity losses	Forecasted productivity losses attributable to the health condition	The costs incurred from the cessation or reduction of work productivity as a result of the health condition in future years.



APPENDIX 3. THE NEED CORE FRAMEWORK

Table 6 – The NEED core framework

<i>Dimension</i>	<i>Domain</i>	<i>Criterion</i>	<i>Indicator</i>
PATIENT	Health	Impact on life expectancy	Years of life lost per death
		Impact on general health-related quality of life	Years Lived with Disability per case
			EQ-5D-5L average score
	Healthcare	Effectiveness of treatment	Effectiveness of current overall treatment (standard of care)
		Quality of care	Received information
			Involvement in treatment decisions
			Diagnostic timing
		Accessibility	Treatment availability
			Foregone care
	Social	Impact on social life	Social support needs
			Social connection needs
		Impact on work	Changes in working time
		Impact on education	Impact on education
SOCIETY	Health	Frequency	Incidence or prevalence
	Healthcare	Value for money of standard of care	Healthcare costs per unit of health gain
		Preventability	Implementation of effective primary prevention strategies

	Social	Productivity losses	Costs related to work absenteeism, presenteeism, or/and early labor force exits of patients
			Costs related to work absenteeism, presenteeism or/and early labor force exits of informal caregivers
FUTURE	Health	Forecasted burden of disease	Forecasted prevalence/incidence
			Forecasted years of life lost
			Forecasted years lived with disability