

KCE REPORT 401C

NEED

SYNTHESIS

NEED ASSESSMENT FRAMEWORK 2025: EU EXPERT CONSENSUS AND CORE VERSION – SYNTHESIS



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■ FOREWORD

Over the past few years, KCE and its partner Sciensano have been developing the NEED initiative, a robust system for identifying and assessing the unmet needs of patients and society. As its scope continues to grow, it gradually gets closer to reaching its European ambitions... and we couldn't be more delighted!

The ultimate aim of NEED is to bridge the gaps in our healthcare systems' ability to offer appropriate care to all, by promoting an approach centred not on supply, but on needs. Indeed, despite our technological achievements and a constant flow of novel healthcare solutions, many needs currently remain unmet because they are not adequately identified and assessed. Finding a structured and carefully considered way of taking into account the many needs that remain ignored or disregarded is the major challenge we are facing today.

KCE has been working on this topic since 2010, but its efforts have taken on new impetus in recent years with the launch of the NEED initiative as part of the Belgian Presidency of the Council of the European Union in 2024. Five reports were published in the wake of this event to present the assessment framework itself, but also to test and demonstrate the potential of this multi-use tool that can inform academic research, political decision-making, commercial development, clinical practice, etc.

The initial version of the NEED assessment framework included some twenty criteria for investigating the current and future needs of patients and society, including the social implications of health conditions. Far from limiting itself to the assessment of medical and therapeutic needs, it takes a truly systemic and holistic view.

As science and progress keep moving forward, it was already necessary to update this first NEED assessment framework to incorporate the lessons learned from the first case studies, but also to strengthen the European dimension of the project. A new version of the framework including 4 dimensions, 3 domains, 26 criteria and 46 indicators has been developed thanks to the contributions of numerous national and international experts. We would like to thank them all for their commitment to this project which could substantially improve healthcare systems' ability to respond to emerging challenges. We hope that these efforts will provide the necessary guidance to all stakeholders wishing to contribute to this initiative, and stimulate the data collection that will be crucial to its success.

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■ SYNTHESIS

1 THE NEED INITIATIVE

1.1 Context

The healthcare sector has been progressing with leaps and bounds over the past few decades. However, despite an ever-increasing range of treatments and services, **many unmet needs persist both for patients and for society at large**, because innovation efforts do not always adequately target areas where interventions are most required.

WHAT IS AN UNMET NEED?

Absence of treatment for a given disease is probably the textbook example of an unmet need, but there are many others: an effective treatment might have significant side effects, or there might be a lack of preventive measures, delays in diagnosis, access barriers to healthcare services, or high costs associated with healthcare or treatment for a given disease, etc.

To improve this situation, it would be useful for governments, healthcare authorities and other stakeholders to be able to **steer research and development efforts towards the areas where unmet needs are high**. This is often challenging, simply because we lack information on where the needs are high. As a result, health systems remain largely supply-driven.

This is where the NEED initiative comes in. It aims to provide a structured approach and a **scientific framework for the identification and assessment of patient and societal health-related unmet needs**. This makes it possible to collect scientific evidence on unmet needs for a large number of health conditions in a [central evidence database](#). This information can be used to inform a more needs-based approach throughout the development of health interventions and innovations.

NEED is short for Needs Examination, Evaluation and Dissemination.

1.2 Previous reports

KCE's interest in unmet needs and needs-driven healthcare is not new. As early as 2010 ([KCE Report 147](#)), it made a series of recommendations on the factors to be taken into account when reimbursing medicines, including their ability to meet unmet medical, therapeutic or societal needs. In 2016 ([KCE Report 272](#)), it developed a methodology to take patients' needs into account when choosing the diseases to be included in the Unmet Medical Need programme^a of the Belgian National Institute for Health and Disability Insurance (RIZIV/INAMI). A third study, published in 2022 ([KCE Report 348](#)), focused on a methodology for scientifically and structurally identifying the most important unmet needs of patients.

The NEED initiative builds on this expertise but broadens the scope to encompass not just medical or therapeutic needs, but **all health-related needs**, whether they concern individual patients or society as a whole, and it also considers the long-term perspective through the inclusion of criteria relating to future needs. It was given a major boost by the Belgian Presidency of the Council of the

^a Without going into too much detail, this programme enables patients to gain faster access to innovative treatments that are not yet available on the market. One of the conditions for a drug to benefit from this system is that it must target a health problem included on a list which is compiled once a year. See <https://www.inami.fgov.be/fr/themes/soins-de-sante-cout-et-remboursement/les-prestations-de-sante-gue-vous-rembourse-votre-mutualite/medicaments/remboursement-d-un-medicament/besoin-medical-non-rencontre-unmet-medical-need> for more information.



European Union in 2024, which had chosen the shift towards a more needs-driven system as one of its health priorities. As a result, five reports were published within the NEED initiative in 2024:

- A report about the NEED scientific framework for assessing unmet patient and societal needs ([Report 377/1](#)) – see chapter 2 for a brief description of this framework
- A case study on malignant melanoma ([Report 377/2](#))
- A case study on Crohn's disease ([Report 377/3](#))
- A report about the applicability of the framework to rare diseases ([Report 377/4](#))
- A report outlining a method to identify, assess and select health conditions (with potentially important unmet needs) for the NEED research programme ([KCE Report 391](#))

2 THE NEED ASSESSMENT FRAMEWORK

In a nutshell, the NEED assessment framework is a tool to **help researchers assess the unmet health-related needs associated with a specific health condition in a structured and standardised way**. It is constructed around four levels which are briefly explained below. The full framework can be found in Table 1.

2.1 Dimensions

The **dimensions** reflect the point of view from which needs are identified and assessed:

- **Patient needs** are those that arise from the direct impact of a health condition on the lives of the patients (e.g. the burden of symptoms, disruptions to social life).
- **Societal needs** relate to the repercussions of a health condition on the community (e.g. the cost to the healthcare system, the impact on productivity, etc.).
- The **future needs** (at patient or societal level) are those that might arise for example due to the increasing incidence of a health condition.
- **A fourth dimension**, equity, cuts across all other dimensions. Unmet needs in this dimension refer to unjust and avoidable differences between population groups (e.g. due to their socioeconomic situation).

2.2 Domains

Within each of the first three dimensions, the framework distinguishes three types of needs or **domains**:

- **Health needs** relate to the burden of the health condition for patients or society (e.g. to its impact on quality of life, psychological health, or life expectancy, the spread of the disease in the population).
- **Healthcare needs** are those that relate to various aspects of healthcare services such as treatment effectiveness, communication with healthcare professionals, etc.
- **Social needs** relate to the indirect impact of the health condition on affected individuals or on society as a whole (e.g. the need for social support isolation, inability to work, pollution or natural resource use of the healthcare sector, etc.).

2.3 Criteria

Each domain within a dimension contains a number of **criteria** that will be assessed, e.g., the impact of the health condition on life expectancy, the effectiveness of available treatments, the environmental impact of the standard of care, etc.

2.4 Indicators

The **indicators** are the measurable factors that will allow the researchers to assess to what extent the health-related needs identified by the criteria are met, e.g. the loss of life years, the burden of the health condition or of the available treatments, the impact of the health condition on the patient's usual activities, the greenhouse gas emissions generated by the standard of care, etc.

These indicators will be measured through a variety of approaches (used alone or in combination) such as literature reviews, database analyses, patient surveys, interviews with individual patients (or family/informal caregivers) or expert opinions.



3 2025: UPDATED FULL FRAMEWORK AND CORE VERSION

3.1 Before the European Consensus

The 2024 report on the NEED framework (Report 377/1) was written and published alongside the report on the applicability to rare diseases (377/4) and the case studies on melanoma (377/2) and Crohn's disease (377/3). The three latter reports generated insights that led to initial adaptations of the framework: two criteria and six indicators were added or modified.

After this first round of adaptations by the internal team, the framework included 25 criteria and 46 indicators.

3.2 European consensus

The framework was subsequently **submitted to experts from European countries** in order to reach a consensus on both the general structure of the framework and its individual criteria and indicators.

This international assessment is an essential step because the NEED initiative's ambition is to provide methods for assessing unmet health-related needs across the EU. However, it is by no means a final step: the framework will always remain a work in progress, requiring regular adaptations and updates to reflect new insights, emerging needs, and changes in the EU's healthcare landscapes.

A total of **26 experts from 17 EU Member States** agreed to participate in the assessment; Belgium and Germany had the highest representation, with three experts (12%) each. Most participating experts worked for governmental agencies involved in health technology assessment (HTA), pricing and reimbursement or public health.

A **wide consensus** was easily reached on the overall structure of the NEED assessment framework, as well as on most criteria (21 out of 25) and indicators (42 out of 46). Following the expert assessment, one criterion was removed completely, and two criteria and three indicators were modified by the NEED team taking into account the experts' feedback.

A full overview of the experts' input and of the resulting changes can be found in section 4.2 of the scientific report.

3.3 Additional changes following an internal team discussion

After the European expert assessment, a few more adjustments were made by the research team based on the case study findings and internal team discussions to enhance the coherence, applicability, and comprehensiveness of the framework. Most changes at this stage involved rephrasing or refining existing criteria or indicators, though a limited number of items were also added or removed. A full overview of these changes can be found in section 4.2 of the scientific report.

Following the internal team discussion, the full NEED assessment framework now includes 4 dimensions, 3 domains, 26 criteria and 46 indicators (see Table 1).

**Table 1 – The NEED assessment framework 2025**

Additions (“NEW”) and deletions (“OUT”) since the 2024 version of the framework are indicated in the table below. Other, minor changes (wording, split/merged indicators) are not detailed in the table but can be found in the scientific report.

Patient needs

EQUITY	 Patient health needs	
	Criterion	Indicator
	Impact on life expectancy	Years of life lost (per death)
	Impact on general health-related quality of life	Years of life lived with disability (per case)
		EQ-5D-5L average score
		OUT Associated comorbidities
	Impact on physical health	Experienced burden of physical symptoms related to the health condition
		Pain/discomfort before disease vs today
	Impact on psychological health	Experienced burden of psychological symptoms related to the health condition
		Anxiety/depression before disease vs today
	Impact on autonomy	Mobility before disease vs today
		Self-care before disease vs today
		Usual activities before disease vs today
	NEW Impact on sexual and reproductive health	NEW Impact on sexual health
		NEW Impact on reproductive health

EQUITY	 Patient healthcare needs	
	Criterion	Indicator
	Treatment effectiveness	Effectiveness of current overall treatment (standard of care)
	Burden of treatment	Experienced burden of treatment
		Experienced burden of treatment side-effects
	Quality of care	Coordination and continuity of care
		Received information
		Involvement in treatment decisions
		Diagnostic timing
		NEW Implementation of effective secondary prevention strategies



	Accessibility	Treatment availability
		Foregone care
	NEW Scientific research	NEW Research gaps

	 Patients' social needs	
	Criterion	Indicator
	Impact on social life	Social support needs
		NEW Social connection needs
	Impact on education	Impact on education
	Impact on work	Changes in working time
	Financial consequences	Average out-of-pocket healthcare costs per patient
		NEW Perceived financial difficulties related to the health condition
		Non-healthcare costs per patient

Societal needs

	 Societal health needs	
	Criterion	Indicator
	Frequency	Prevalence or incidence
	Transmissibility	Contagiousness
	Burden on informal caregivers' health	Impact on informal caregivers' health
	OUT Antimicrobial resistance	OUT Existing antimicrobial resistance to treatments used OUT Volume of antibiotics delivered to treat the disease

	 Societal healthcare needs	
	Criterion	Indicator
	Value for money of standard of care	Healthcare costs per unit of health gain
	Preventability	Implementation of effective primary prevention strategies



EQUITY	 Societal social needs	
	Criterion	Indicator
	<i>Productivity losses</i>	Costs related to work absenteeism, presenteeism, or/and early labour force exits of patients
		Costs related to work absenteeism, presenteeism or/and early labour force exits of informal caregivers
	<i>Environmental impact of standard of care</i>	Greenhouse gas emissions related to the standard of care
		Hazardous waste related to the standard of care
		Use of natural resources and raw materials related to the standard of care
	NEW <i>Burden on informal caregivers' social life</i>	NEW Impact on informal caregiver's social life

Future needs

EQUITY	 Future health needs	
	Criterion	Indicator
	<i>Forecasted burden of disease</i>	Forecasted prevalence/incidence
		Forecasted years of life lost
		Forecasted years lived with disability

EQUITY	 Future healthcare needs	
	Criterion	Indicator
	<i>Forecasted healthcare costs</i>	Forecasted healthcare costs attributable to the health condition

EQUITY	 Future social needs	
	Criterion	Indicator
	<i>Forecasted productivity losses</i>	Forecasted productivity losses attributable to the health condition

3.4 The core NEED assessment framework

During the EU expert assessment process, participating experts were also asked to identify the **minimally required criteria** for a meaningful assessment of unmet health-related needs. This resulted in a **core version of the framework (see Table 2) including 13 criteria and 21 indicators**, which will be the primary focus when incorporating data on new health conditions into the database.

Table 2 – The core NEED assessment framework

Patient needs – core framework

EQUITY	Patients' health needs	
	Criterion	Indicator
	Impact on life expectancy	Years of life lost (per death)
	Impact on general health-related quality of life	Years of life lived with disability (per case)
		EQ-5D-5L average score

EQUITY	Patients' healthcare needs	
	Criterion	Indicator
	Treatment effectiveness	Effectiveness of current overall treatment (standard of care)
	Quality of care	Received information
		Involvement in treatment decisions
		Diagnostic timing
	Accessibility	Treatment availability
		Foregone care

EQUITY	Patients' social needs	
	Criterion	Indicator
	Impact on social life	Social support needs
		Social connection needs
	Impact on work	Changes in working time
	Impact on education	Impact on education



Societal needs – core framework

EQUITY	 Societal health needs	
	Criterion	Indicator
	Frequency	Prevalence or incidence

EQUITY	 Societal healthcare needs	
	Criterion	Indicator
	Value for money of standard of care	Healthcare costs per unit of health gain
	Preventability	Implementation of effective primary prevention strategies

EQUITY	 Societal social needs	
	Criterion	Indicator
		Costs related to work absenteeism, presenteeism, or/and early labour force exits of patients
		Costs related to work absenteeism, presenteeism or/and early labour force exits of informal caregivers

Future needs – core framework

EQUITY	 Future health needs	
	Criterion	Indicator
		Forecasted prevalence/incidence
		Forecasted years of life lost
		Forecasted years lived with disability

4 CONCLUSION

On the face of it, this new NEED report introduces no major changes: after all, the structure of the framework remains the same, and the set of criteria and indicators only underwent limited adjustments. However, it deals with developments that are significant in others ways.

By submitting their work to a panel of European experts and achieving a broad consensus among these experts, the NEED researchers have ensured that their framework is **acceptable and relevant not just in Belgium, but across diverse European contexts**. This is an important step towards the EU-wide use of this essential tool that can be used for identifying gaps, allocating resources, or shaping interventions aimed at addressing unmet needs.

The development of a core version of the NEED framework is another important achievement, because it provides **a more practical and actionable tool for assessing unmet health-related needs**. This carefully selected core set of criteria and indicators will allow research teams and other stakeholders to perform assessments that require less time and resources, but are still relevant to inform healthcare planning and decision-making. This will hopefully speed up the process of filling up the NEED evidence database with a basic set of data on unmet needs for as many health conditions as possible.

These are two important steps in the further development of the NEED initiative. Nonetheless, both the full and core version of the framework will remain a **work in progress**, requiring regular adaptations and updates to reflect new insights on unmet needs and the development of new measurement methods, accommodate emerging needs and changes in the EU's healthcare landscapes.

The framework is meant to be a **versatile tool** that can be used in different ways by different types of stakeholders (policymakers, clinicians, academic researchers, commercial developers, etc.) to support decision-making based on their specific perspectives and requirements. However broad or narrow their area of interest, the data collected through the framework can help them identify the areas of high unmet needs that are particularly relevant to them.

However, the applicability of the NEED approach for decision-making will hinge on the expansion of the **data collection**, which requires both the financial sustainability of the NEED initiative and the help of other EU member states to continue the work.



■ RECOMMENDATIONS^b

RECOMMENDATIONS RELATED TO THE 6TH NEED REPORT

The recommendations formulated in KCE report 377 are still applicable. Based on the evolutions of the national and international context, we added new ones and made some of them more concrete in the current recommendations.

To the health ministers in the EPSCO Council, the European Commissioner for Health and Animal Welfare, and the European Commissioner for Startups, Research and Innovation

1. Consider using the criteria and indicators included in the NEED framework 2025 to develop incentive mechanisms for innovations, inform health policy decisions across all dimensions of health (including prevention, treatment, and support) , and allocate resources for research funding.
2. Incorporate the study of unmet health-related needs of a variety of health conditions using the NEED framework into the EU Framework Program 10 (FP10) and the EU4Health program. The NEED initiative can address critical challenges outlined in the FP10, such as improving healthcare access and developing innovative therapeutic solutions. To foster a competitive R&D market, the EU should invest in and support R&D in areas with high unmet health-related needs, based on explicit and comparable criteria across health conditions.

To the European Medicines Agency and national medicines agencies

3. Consider using the NEED framework 2025 or the core NEED framework to define or describe unmet health-related needs in the context of innovation incentives.
4. Consider using the NEED framework 2025 or the core NEED framework to define the scientific evidence requirements to be submitted by companies that apply for innovation incentives, early access programmes, or orphan designation.

To the European HTA coordination group

5. Use evidence on unmet patient and societal needs in the joint scientific consultations and joint clinical assessments of health technologies.
6. Use evidence on unmet patient and societal needs in prioritising and selecting health technologies beyond medicinal products for joint clinical assessment.

To the Ministers of Science Policy and BELSPO, to the Belgian ministers of the federated entities responsible for health, the Belgian Health data agency, and to the administrations responsible for public health and healthcare in Belgium

7. Support the broadening of the NEED initiative to an international scope, by promoting the inclusion of the unmet needs assessment into the EU4Health program or FP10 and facilitate, encourage, and continue the European discussion on unmet needs assessment.
8. Support the continuing filling of the NEED database as a topic in the Science4Policy programme 2025-2026 of BELSPO, in order to bridge the potential gap between BELSPO funding (end 2026) and potential EU funding.

^b The KCE has sole responsibility for the recommendations.

9. Support the joint efforts of Sciensano and KCE to centralise and link data on NEED framework indicators from existing registries into the NEED database to increase relevance of the database for policy makers, researchers, and other stakeholders. The disease registries play a crucial role in scientific research by holding a wealth of information in Belgium (and abroad). However, the lack of cross-linkage limits their usability for healthcare decisions requiring a cross-disease perspective.

To the Belgian Federal Minister of Social Affairs and Public Health and the Belgian ministers of the federated entities responsible for health

10. Continue to support a needs-driven approach to healthcare policy. More specifically, take patient and societal unmet health-related needs into account when developing strategies and policy notes to improve efficiency of care for specific patient groups and draw on the NEED initiative to help define and achieve specific healthcare objectives.

To the pricing and reimbursement organisations in the European Union:

Recommendations 11 and 12 below apply to all types of health services, not only pharmaceutical applications.

11. Align the requirements regarding the unmet health-related needs criteria for which evidence must be submitted in the context of a reimbursement request with the criteria of the (core) NEED assessment framework 2025. More specifically,
 - a. Require data on current (and/or forecasted) unmet health-related needs at patient and societal level, in terms of health, healthcare and social needs;
 - b. Require data on the impact of new interventions on the most important unmet needs.
12. Align the requirements regarding the unmet health-related needs criteria for which evidence must be submitted in the context of an application for early or fast access with the criteria of the (core) NEED assessment framework 2025. More specifically,
 - c. Require data on current (and/or forecasted) unmet health-related needs at patient and societal level, in terms of health, healthcare and social needs;
 - d. Require data on the expected impact of new interventions on the most important unmet needs.

To the national Health Technology Assessment (HTA) Agencies in Europe

13. Use evidence about unmet patient and societal needs in the health technology assessment processes, and in prioritising health technologies to be assessed.

To researchers, research funders, patient organisations, and the industry

14. Align research and development of new healthcare interventions with significant unmet needs of patients and society.
15. Consider using the criteria included in the (core) NEED assessment framework 2025 to allocate research funding.
16. Consider applying the (core) NEED assessment framework 2025 when carrying out research on unmet needs and submitting the data to the NEED team for inclusion in the NEED database.
17. Share experiences with the application of the NEED assessment framework 2025 with the NEED team in order to improve and refine the framework.



COLOFON

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- Finally, this report has been approved by common assent by the Executive Board.
- Only the KCE is responsible for errors or omissions that could persist. The policy recommendations are also under the full responsibility of the KCE.

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