



Needs Examination, Evaluation and Dissemination (NEED): assessment framework



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Some context

The healthcare sector has been progressing with leaps and bounds for the past few decades, and hardly a week or even a day goes by without a new perspective, a more targeted treatment or a better strategy emerging in one area or another. However, despite an ever-increasing range of treatments and services, **many unmet needs remain both for patients and for society at large** because the available offer, though ample overall, does not always adequately cover all areas where interventions might be required.

Needs and unmet needs

In the broadest sense of the term, **needs** can be defined as the elements that are required for our survival, well-being and development. They are the fundamental conditions that must be met to ensure our physical, psychological and social well-being, such as access to food and drinking water, safe living and working conditions, meaningful interpersonal relationships and access to healthcare. An **unmet need** arises when the available offer or supply does not, or not completely, meet existing needs.

The concept of **unmet medical needs** has recently gained prominence, particularly in the context of "compassionate use programmes" which make it possible to use drugs that are not (yet) officially authorised in situations where no satisfactory alternative is available on the market.

1 General note: all the references used in this document can be found in the scientific report "Needs examination, evaluation and dissemination (NEED): assessment framework" (KCE Report 377C1), available on www.kce.fgov.be or on <https://health-needs.eu/index.php/en/>

The NEED initiative has broadened this concept to take into account **three types of needs**: health needs, healthcare needs (which include medical needs) and social needs.

Indeed, while an illness for which there is no treatment at all probably remains the textbook case of an unmet healthcare need, this concept also encompasses a host of other situations. For example, a treatment may be available but have numerous drawbacks, lose effectiveness over time or fail to prevent disability. When treatment development is the main focus in addressing a disease, this can lead to neglecting other crucial aspects such as prevention, diagnosis, coordination/organisation of care, information available to patients, practical or financial support, etc.

A supply-driven model

There can be many reasons for these “gaps” in the available offer. Despite significant investments in research, many diseases still lack adequate solutions, while others receive insufficient funding for meaningful progress. The development of pharmaceutical treatments often hinges on extensive background research into the disease. Moreover, the pharmaceutical industry’s profit-driven nature often results in inadequate knowledge sharing among developers, leading to fragmented progress and temporary monopolies on products.

However, another factor that plays a major role is **the way the innovation ecosystem and related policies and procedures currently work**. Indeed, even though altruistic motivations and a sincere desire to remedy human suffering are often important drivers in the health and healthcare sector, it is not free from the influence of financial logic. As a result, new developments tend to be concentrated in economically profitable areas (like those where the potential market is large or where solutions are relatively easy to develop) and to focus on products that can be sold (like medications, devices, apps...) rather than on other types of interventions that might be just as useful (like primary prevention, improving the organisa-

tion of care...). Unfortunately, these days, these profitable areas are often also those where both our medical knowledge and the available offer are already well-developed.

This issue is compounded by the fact that, while governments and health-care authorities do offer incentives to encourage innovation in areas where it is lagging behind, **they often struggle to steer it towards the areas where unmet needs remain highest because they lack information on where the highest unmet needs are**. As a result, the new products and services that are assessed, authorised and potentially reimbursed will typically be those the commercial players choose to develop. This means the system is currently driven mainly by supply, not by needs.

NEED: towards a needs-driven approach

Today, this supply-driven model is clearly reaching its limits in terms of affordability and relevance. It is time for (the representatives of) society to regain control of innovation, investments and health strategies, so they can proactively be directed towards those areas where they can generate the greatest added value.

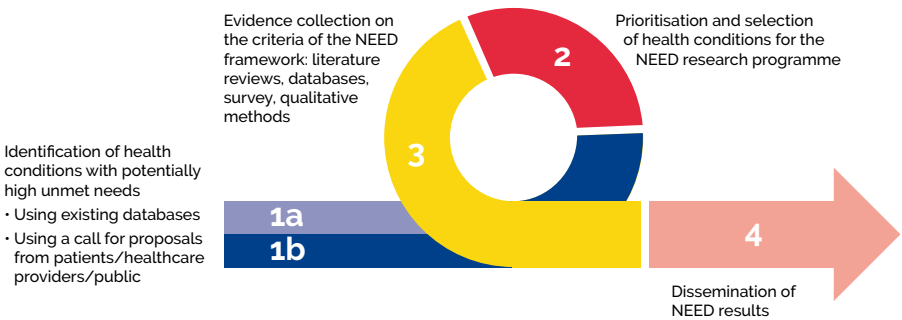
In short, we need to reflect on a much broader scale about the health-related needs of patients and society that should be prioritised, so that these needs can then be taken into account throughout the development of healthcare interventions, but also before this development process starts. To achieve this proactive, needs-based approach, a necessary first step is to **identify** the health conditions for which major needs remain despite the current offer of treatments and services, to **measure** these needs and to **assess** their importance.

The NEED initiative aims to **streamline** this process by providing a structured approach and a scientific assessment framework that identifies patient and societal needs, which will be further refined over time. The overall approach relies on a four-stage implementation model (see figure).

The ultimate aim of NEED is to set up a **research infrastructure** to systematically compile data on unmet health-related needs for a wide range of health conditions, both from a patient-centred perspective and from the perspective of society as a whole. It focuses on the health condition in its current context, i.e. taking into account existing treatments and other services.

For each health condition, scientific evidence will be collected and placed in a **European database**. This information source will help decision-makers to better take unmet needs into account when authorizing and assessing new health products and services, and will also help the other players involved (patient organisations, researchers and research funders, health insurance funds, etc.) to set their priorities for action.

The 4-step NEED implementation model



Source: KCE

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The NEED assessment framework

A major step in the NEED initiative has been the creation of an assessment framework defining the criteria, indicators and data sources for identifying the unmet needs of patients and society for a given health condition. This is the tool that will be used to populate the future database of unmet needs. The assessment of the overall level (low, medium or high) of unmet needs for each health condition will be tackled at a later stage.

The assessment framework has also been **tested on two health conditions**, Crohn's disease and malignant melanoma. The aim of the framework is to be applicable for identifying unmet needs across all health conditions. In a first step, we evaluated its **suitability for rare diseases** (KCE report 377C4).

To develop the NEED assessment framework, the research team drew on recent literature reviews and consultations with key stakeholders. These efforts resulted in a tool structured around several dimensions, domains, criteria and indicators.

The foundations of the NEED assessment framework

- The **dimensions** relate to the point of view from which needs are identified and assessed (the patient's perspective, society's perspective and future needs + the cross-cutting dimension of equity).
- The **domains** relate to the type of need (health need, healthcare need or social need).
- The **criteria** are the different needs that should be met within each dimension, classified by domain.
- The **indicators** are measures used to assess how far the health-related needs identified by the criteria are actually being met.

Dimensions

Patient (health/healthcare/social) needs are the needs that arise from the direct impact of a health condition on the lives of the patients. Examples include the need to enjoy a good quality of life despite illness, or the need to have access to effective treatment.

Beyond their impact on patients, health conditions also have repercussions on the community, which in turn give rise to **societal needs**. When a disease is very common, for example, there may be a need for (more) effective treatments or preventive measures to mitigate its collective impact in terms of lost productivity, cost to the healthcare system, etc.

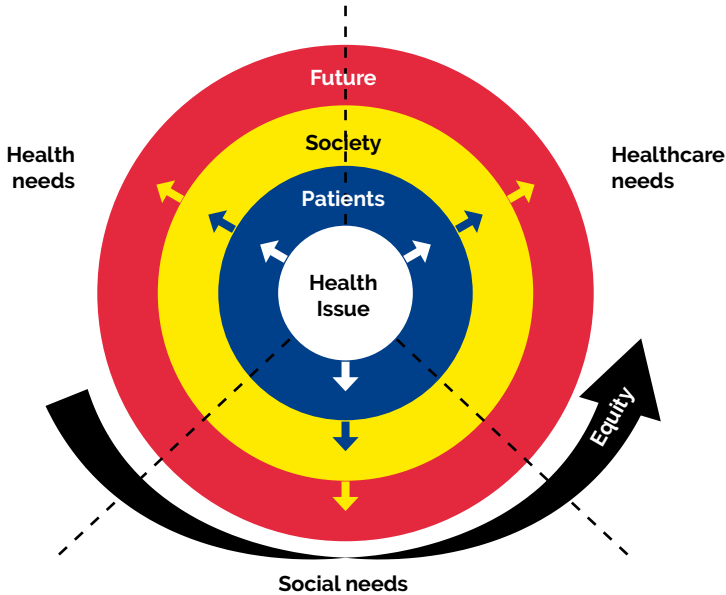
Finally, a disease may also be associated with **future** needs at patient or societal level, for example due to increasing incidence and/or prevalence. It is important to try to predict and anticipate these trends.

Equity

Equity is a fourth dimension that cuts across the other three. It refers to the absence of unjust and avoidable differences between population groups.

For some of the criteria in the NEED assessment framework, unmet needs are likely to vary between population groups (e.g. by age, gender, socio-economic level, etc.). It would therefore be appropriate to collect data on these differences in order to identify possible inequities. The question of equity should also, more broadly, be taken into account in the weighting and ranking of unmet health-related needs.

Relationships between health condition, patient needs, societal needs, future needs, and equity



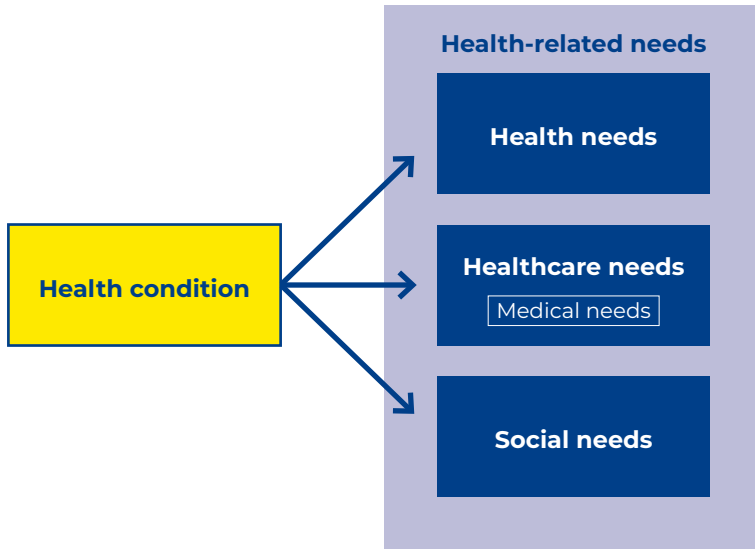
Source: KCE

Domains

The needs of patients, society and the future fall into three main areas (see figure):

- **Health needs** are those that are directly linked to the burden of disease for patients and the community, in terms of suffering, loss of quality of life, etc.
- **Healthcare needs** are needs for health services in the broadest sense of the term (treatment, nursing care, prevention, etc.).
- **Social needs** cover all other types of needs, i.e. needs linked to health in a more indirect way, such as the need to maintain a professional activity, or avoiding an environmental impact.

Relationships between the various domains of health-related needs



Source: KCE

Criteria

In its final version, the NEED framework includes a total of **23 criteria** (listed in full in the table you will find at the end of this brochure) for identifying health-related needs, which together cover all the dimensions and domains of need.

Thirteen criteria were used to identify patients' needs:

- Five criteria for **health needs** – impact of the health problem on health-related quality of life, physical health, psychological health, autonomy and life expectancy.
- Four for **healthcare needs** – treatment effectiveness, burden of treatment, quality of care and accessibility.
- Four for **social needs** – impact on social life, on education, on work, and financial consequences.

2. The NEED assessment framework

Eight criteria were used to identify the **societal needs**:

- Four for **health needs** – frequency, transmissibility, possible antimicrobial resistance and burden on informal caregivers (loss of quality of life).
- Two for **healthcare needs** – value for money of the standard of care and preventability.
- Two for **social needs** – productivity losses and environmental impact of standard of care.

Finally, two criteria were used to identify **future needs**, namely the future burden of disease (which relates to future health needs) and its future economic burden (indicative of future care and social needs) in a scenario where the existing situation remains unchanged.

Indicators

Each of the abovementioned criteria is assessed by one or more concrete, **measurable indicators** (43 indicators in total, see table). For each indicator, the researchers have also identified the most appropriate approach(es) for collecting the corresponding data (literature review, database analysis, patient survey, individual patient interviews, expert opinion, or a combination of these approaches). Patient involvement is of paramount importance in the data collection process, which is discussed in more detail in the scientific report (KCE Report 377C2).

A few examples of indicators

- Two indicators were selected to **measure the impact of a health condition on physical health** (under “patients’ health needs”): the experienced burden of physical symptoms and the presence of pain or discomfort before the onset of the health condition and today. For these two indicators, the preferred method of data collection is a patient survey coupled with individual interviews.

- Two indicators have been selected to measure **the financial consequences of the health condition for patients** (under “patients’ social needs”): the out-of-pocket healthcare expenditure that patients have to cover themselves (co-payments, supplements, uncovered costs, etc.), with the analysis of existing databases as the preferred data source, and the “non-healthcare costs” related to the illness (e.g. travel costs to healthcare facilities, costs for adapting the home environment), for which data will be collected through individual interviews with patients.
- Three indicators have been chosen to measure **the environmental impact of standard treatment** (under society’s social needs): the greenhouse gas emissions associated with treatment, the waste, and the use of natural resources and raw materials related to the standard of care. Here, literature data and expert opinion are preferred.

How will this be put into practice?

We already mentioned that this study is only the first step of a more ambitious project. The evaluation framework will be used to create a vast online database compiling unmet needs for a large number of health conditions.

The information collected will be presented in a way that makes it easy to assess whether or not the needs are being met (see examples in the box below) and to identify the areas that should be prioritised for new interventions, both within a given health problem and more broadly across different health problems.

Examples of an assessment of unmet needs for the “Impact on physical health” criterion (under “patients’ health needs”)

On the basis of the data collected through the online patient survey, needs related to the physical impact of the disease and measured by the indicator “**experienced burden of physical symptoms**” could, for example, be defined as not met if at least 20% of patients with the health condition describe their physical symptoms as “fairly” or “very burdensome”. This would result in a red light behind the criterion for that particular condition.

For the “**pain/discomfort before diagnosis vs now**” indicator, unmet needs could be measured for instance by the percentage of respondents reporting (moderate, severe or extreme) pain/discomfort that was not present before the onset of the health condition.

Potential users of this database are, for example, the bodies involved in the (temporary) reimbursement of medicines or medical devices, health technology assessment (HTA) bodies, medicines agencies and research funders, both nationally and internationally. However, it could also be useful to many other stakeholders (patient associations, mutual insurance companies, healthcare providers, researchers, etc.) to fuel their communication initiatives, to focus their activities more on patients and their needs, etc.

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Conclusion

NEED offers a holistic assessment framework to identify and measure, in a scientific and transparent way, the unmet health-related needs of patients and society. This innovative tool will continue to be refined through its use, particularly with regard to the choice and definition of the criteria and indicators.

Its major **strengths** are the fact that it attempts to paint a comprehensive picture of unmet needs, including not only treatment needs, but all health needs, healthcare needs and social needs. The inclusion of criteria relating to future needs also enables it to consider a long-term perspective.

However, the NEED initiative also comes with major **challenges** relating to patient involvement, data availability and sufficient resources to study a significant number of diseases in a timely manner.

More importantly, NEED will need to convince all parties involved in health-care and in the health innovation field: politicians, HTA bodies, medicines agencies, pricing and reimbursement agencies, health insurance funds, researchers, industry and, of course, patients and their associations. Only with their support, willingness, and active participation will a needs-based approach eventually become the norm.

4

Framework for the identification and measurement of health-related Needs





PATIENTS' HEALTH NEEDS

Criterion	Indicator
Impact on general health-related quality of life <i>The extent to which a health condition impacts the general health-related quality of life of patients.</i>	Years of life lived with disability (per case)
	EQ-5D-5L average score
	Associated comorbidities
Impact on physical health <i>The extent to which a health condition impacts the physical health of patients.</i>	Experienced burden of physical symptoms related to the health condition
	Pain/discomfort before vs today
Impact on psychological health <i>The extent to which a health condition impacts the psychological health of patients.</i>	Experienced burden of psychological symptoms related to the health condition
	Anxiety/depression before vs today
Impact on autonomy <i>The extent to which a health condition impacts the autonomy of patients.</i>	Mobility before vs today
	Self-care before vs today
	Usual activities before vs today
Impact on life expectancy <i>The impact of a health condition on life expectancy of patients.</i>	Years of life lost (per death)

4. Framework for the identification and measurement of health-related Needs





PATIENTS' HEALTHCARE NEEDS

Criterion	Indicator
Treatment effectiveness <i>The extent to which the current overall treatment is effective.</i>	Effectiveness of current overall treatment (standard of care)
Burden of treatment <i>The extent to which the current overall treatment is burdensome for patients.</i>	Experienced burden of treatment
	Experienced burden of side-effects of treatment
Quality of care <i>The extent to which the care provided, including its organisation, provision of information, involvement in decisions, and diagnostic processes, meets quality standards.</i>	Experience with the organisation of care
	Quantity of information received
	Clarity of information received
	Involvement in treatment choice
	Diagnostic timing
Accessibility <i>The extent to which treatment is available and ease with which patients have access to the care they need.</i>	Treatment availability ^a
	Forgone care ^b

- a. A treatment is considered to be available if it is largely accessible both logistically and financially to the patient population. Availability problems might concern key treatments that are not authorised in Belgium, authorised but not commercialised, commercialised but expensive and not reimbursed, or treatments that regularly experience shortages.
- b. Foregone care refers to not using health care despite perceiving a need for it. This can be due to several reasons, including costs, waiting lists or travel difficulties.

4. Framework for the identification and measurement of health-related Needs





PATIENTS' SOCIAL NEEDS

Criterion	Indicator
<p>Impact on social life <i>The impact of the health condition on patients' social life, including on their social support needs and their capacity to establish meaningful relationships with the community, family and/or friends.</i></p>	Social support needs
<p>Impact on education <i>The impact of the health condition on patients' education.</i></p>	Years of education lost
<p>Impact on work <i>The impact of the health condition on patients' working conditions, including capacity to work, working hours and working environment.</i></p>	Changes in working conditions
<p>Financial consequences <i>Costs borne by patients to be able to access reimbursed or non-reimbursed healthcare.</i></p>	Average out-of-pocket healthcare costs per patient
	Average non-healthcare costs per patient

4. Framework for the identification and measurement of health-related Needs





SOCIETAL HEALTH NEEDS

Criterion	Indicator
<p>Frequency <i>How common a health condition is with reference to the size of the population (the population at risk) and a measure of time.</i></p>	Prevalence or incidence
<p>Transmissibility <i>The extent to which a health condition can be transmitted from one organism to another.</i></p>	Contagiousness
<p>Antimicrobial resistance <i>The extent to which, due to drug resistance, antibiotics or other antimicrobial medicines used to treat or manage a health condition are ineffective, or infections related to a health condition become increasingly difficult or impossible to treat.</i></p>	Existing antimicrobial resistance to treatments used
	Volume of antibiotics delivered to treat the disease (proxy)
<p>Burden on informal caregivers <i>The extent to which the quality of life of informal caregivers is affected by their caregiving activities.</i></p>	Loss in informal caregivers' quality of life

4. Framework for the identification and measurement of health-related Needs





SOCIETAL HEALTHCARE NEEDS

Criterion	Indicator
<p>Value for money of standard of care <i>The health gain achieved for the level of healthcare spending associated with the standard of care for a health condition. It allows for the identification of inefficiencies in the healthcare system.</i></p>	<p>Healthcare costs per unit of health gain (disaggregated presentation of total healthcare expenditures and total health effects of standard of care)</p>
<p>Preventability <i>The extent to which a health condition can be avoided or mitigated through primary prevention strategies.</i></p>	<p>Implementation of effective primary prevention strategies</p>

4. Framework for the identification and measurement of health-related Needs





SOCIETAL SOCIAL NEEDS

Criterion	Indicator
Productivity losses <i>The costs related to work absenteeism^c, presenteeism^d, early labor force exits of patients with the health condition and their caregivers.</i>	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 caregivers
Environmental impact of standard of care <i>The impact of the management of a health condition on the natural environment.</i>	Greenhouse gas emissions related to the standard of care
	Hazardous waste related to standard of care
	Use of natural resources and raw materials related to standard of care

- c. Absenteeism refers to the absence of an employee from their workplace (i.e. time taken off work) due to a health condition.
- d. Presenteeism refers to the lost productivity that occurs when employees are not fully functioning in the workplace because of a health condition. Even though the employee may be physically at work, they may not be able to fully perform their duties.

4. Framework for the identification and measurement of health-related Needs





FUTURE NEEDS

Criterion	Indicator
Future burden of disease (health needs) <i>The impact of a health condition on the health of future generations.</i>	Future prevalence/incidence
	Future years of life lost
	Future years lived with disability
Future economic burden (healthcare/social needs) <i>The impact of a health condition on future healthcare expenditures and productivity, in monetary terms.</i>	Future direct ^e costs
	Future indirect ^f costs

- e. Direct costs include costs of treating the health condition, such as healthcare system costs for diagnosis, treatment and management of the health condition and patients' own healthcare (e.g. over-the-counter medication) and non-healthcare costs (e.g. travel).
- f. Indirect costs include costs related to lost workforce productivity resulting from the health condition and its management, affecting patients and their informal caregivers.

Sources and references

This brochure is based on the "Needs examination, evaluation and dissemination (NEED): assessment framework" scientific report (KCE Report 377C2), available on www.kce.fgov.be or on <https://health-needs.eu/index.php/en/> (2024).

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