The validation of the Needs Examination, Evaluation, and Dissemination assessment framework within the European Union: a modified Delphi study

Rani Claerman[1],*, Laurence Kohn[2], Muriel Levy[2], Irina Cleemput[2], Claudia Schönborn[2], Charline Maertens de Noordhout[2], Robby De Pauw[1,3]

[1]Department of Epidemiology and Public Health, Sciensano, Brussels, Belgium
[2]KCE, Belgian Health Care Knowledge Centre, Brussels, Belgium
[3]Department of Rehabilitation Sciences, Ghent University, Ghent, Belgium

*Corresponding author. Department of Epidemiology and Public Health, Sciensano, Rue Juliette Wytsman 14, 1050 Ixelles, Belgium. E-mail: rani.claerman@sciensano.be.

Abstract

The NEED (Needs Examination, Evaluation, and Dissemination) assessment framework was designed to identify and measure unmet health-related needs of patients and society across various health conditions, aiding the development of needs-driven healthcare policy and innovation. The framework consists of 25 needs criteria and 46 associated indicators that assess whether these needs are met or not. This study aims to validate the framework at the European Union (EU) level using a modified Delphi approach. We selected national and European institutes for the Delphi process based on their roles in public health, health technology assessment (HTA), medicine authorization, pricing and reimbursement (P&R), and patient advocacy. Using a modified Delphi approach, experts provided feedback on the framework's structure (dimensions and domains), health-related needs criteria, and indicators. Two Delphi rounds were conducted via online questionnaires. A panel of 26 experts participated in both rounds of the study. The majority of the participants reported expertise in HTA (50%) and P&R (15%), followed by patient advocacy (15%) and public health (8%). Seventeen EU Member States were represented, with a higher representation of experts from Belgium (12%) and Germany (12%). The NEED framework based on expert consensus consists of 4 dimensions, 3 domains, 24 criteria, and 43 indicators. The modified Delphi technique proved effective for validating the NEED framework at the EU level. This marks a critical first step toward consensus on defining and identifying unmet health-related needs, paving the way for a more needs-driven healthcare policy and innovation landscape.

Introduction

Unmet needs arise when the current health interventions fall short of achieving ideal health and can be addressed through pharmaceuticals, healthcare interventions, social services, or policies. The current health innovation ecosystem is predominantly supply driven, often failing to adequately address critical unmet needs such as those in mental health and antimicrobial resistance [1]. Pharmaceutical research and development (R&D) tend to prioritize profit margins, leading to limited investment in areas of greatest public health concern [2–4]. Regulatory frameworks primarily focus on evaluating individual technologies without considering the broader societal health needs, resulting in inefficiencies and inequities in the allocation of resources [5]. Moreover, the focus on drug development overshadows other health interventions, such as preventive measures and cross-sector strategies that address the social and commercial determinants of health.

A transition toward needs-driven healthcare innovation requires a systematic approach to identify and prioritize unmet needs across diseases. Health needs assessment has long been recognized as a critical tool in public health planning and resource allocation, with early research highlighting its importance for bridging the gap between population needs and available healthcare services [6, 7]. More specifically, previous research has highlighted the gaps between public health needs and R&D, especially in terms of

pharmaceutical agendas and under-researched medical conditions [8–10]. Despite its recognized importance, a comprehensive framework with clear criteria and indicators for evaluating unmet health-related needs across a wide spectrum of disease areas, at both individual and societal levels, has yet to be fully established. Several European and national initiatives, including the European Union's (EU) PRIME and Belgium's unmet medical need programs, aim to support the development of medicines for unmet medical needs [11–13]. However, the term 'unmet medical needs' remains inconsistently defined across the healthcare sector [14–17]. In response, the Belgian Health Care Knowledge Centre (KCE), in collaboration with Sciensano, launched the Needs Examination, Evaluation, and Dissemination (NEED) project to create an evidence-based database that identifies unmet health-related needs across various conditions, using standardized methods to provide high-quality scientific evidence [18]. This approach aligns with prior initiatives for an evidence-driven methodology in needs assessment, emphasizing the importance of systematically addressing gaps in healthcare services [7].

Various definitions of unmet needs coexist, and therefore, the NEED initiative made an attempt to define health-related needs as the needs related to a particular health condition, which includes the health, healthcare, and social needs of individuals affected by the condition, as well as broader societal needs that are the consequences of the condition on society [18]. To systematically identify and

measure those unmet needs, the NEED project developed an evidence-based approach, the so-called NEED assessment framework. The framework includes criteria that define these needs and indicators that evaluate if the needs are being addressed. The unmet needs criteria and indicators will serve as the building blocks for the first European unmet needs database which will include scientific evidence for each criterion of needs related to different health conditions. The ultimate aim of the framework is to allow all healthcare and healthcare innovation stakeholders to efficiently address unmet needs when making policy decisions and setting health and research priorities. While the foundations of the theoretical framework have been established, the framework has a dynamic character and has evolved since its first publication [18].

The aims of the current study were to reach expert consensus on the structure of the NEED assessment framework as well as the health-related needs criteria and indicators and to gain consensus on this framework at the EU level. The first version of the NEED framework included 23 criteria that represent the diverse needs by domain and within each dimension and 43 related indicators allowing to estimate to what extent the needs are met or not. In order to pursue agreement on the structure and content of the unmet needs assessment framework, we conducted an EU-wide Delphi survey among the stakeholders, including the intended end users of the European database.

The study uses the Delphi method which is a widely applied survey technique that seeks expert opinion and consensus on a certain topic [19]. By incorporating the perspectives of experts from diverse disciplines and European regions, it ensures that the NEED assessment framework captures a wide range of views and experiences, resulting in a framework that is applicable across different settings. The framework's flexible adaptation to different contexts makes it an essential tool for continuous needs assessment as needs evolve. The Delphi method leverages the collective insights of experts to create a comprehensive and consensus-based framework that facilitates the identification and evaluation of unmet health-related needs. The iterative nature of the process ensures 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.

Methods

Study design

In this study, the modified Delphi method has been used to assess the framework, meaning to seek consensus on the structure and content of the framework through consultation with experts across the EU. This Delphi was conducted in two rounds of consultation. An online platform (LimeSurvey 5.6) was used to collect data from the Delphi panel.

NEED assessment framework

The unmet needs assessment framework is built around several dimensions, domains, criteria, and indicators [18]. The dimensions focus on patient, societal, and future needs, along with equity aspects, to enable a comprehensive and reliable evaluation of unmet needs related to specific health conditions. These dimensions encompass three key domains: health, healthcare, and social needs. Specific criteria were defined for the assessment of health-related needs. Since the publication of the report on the NEED assessment framework, additional criteria and indicators have been included following internal team discussions. The version of the NEED framework which was submitted to the Delphi study included 25 criteria and 46 related indicators (Supplementary Table S1). The recently added criteria and indicators were based on the results from the study on the applicability of the framework to rare diseases and the case studies on Crohn's disease and malignant melanoma [20–22].

Participants

The experts were identified through the authors' existing professional and academic European networks, internet searches, and purposive snowball sampling. We extended invitations to experts from public health institutes, health technology assessment (HTA) agencies, national medicines agencies, and pricing and reimbursement (P&R) agencies across the 27 EU Member States. Additionally, we invited experts from both European and national umbrella organizations of patient associations. One expert from each organization was asked to participate to the Delphi survey. Out of the 98 invited candidates, 26 experts participated in the two-round Delphi panel. The participation was anonymous.

Data collection

The two-round surveys were conducted from April to May 2024. The survey was piloted with four researchers who did not belong to the research team to reduce the risk of misinterpretation of statements and instructions. All invited 98 experts were e-mailed a personal internet link to an online survey in English, which enabled them to respond to the questions. Participants had 3 weeks to complete each round and those who did not take part in the first round were excluded from the second round. Up to two follow-up reminder e-mails were sent to non-respondents to minimize non-response rates [23].

During the first round, the participants were provided with a brief video that introduced the NEED framework and the purpose of the Delphi study. The first-round questionnaire consisted of closed questions with four-point scales ('totally agree', 'agree', 'disagree', and 'totally disagree') concerning the structure of the framework and inclusion of each criterion and indicator. There was an additional response option for participants who were not qualified to answer the question. The survey included a feature allowing participants to provide optional open-ended comments when selecting the response 'disagree' or 'totally disagree' to any question. We qualitatively assessed these comments to understand the reasons underlying their disagreement.

We defined consensus for the inclusion of criteria and indicators as 85% or more of respondents selecting 'totally agree' or 'agree' and <5% selecting 'totally disagree', consistent with approaches used in previous Delphi studies [19, 24]. If no consensus was reached, the item was submitted 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 contained questions on the non-consensual items. Participants were asked to respond 'yes/no/not qualified to answer' on the inclusion of the items considering the experts' feedback from the previous round. During the second round, the participants could provide comments and feedback after every question regardless of the response. 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 [25]. When the level of agreement was between 60% and 85%, the items were subject to NEED team internal discussion and adapted conforming to the feedback of the experts, whereas items with less than 60% consensus were excluded from the final framework.

Results

Participants

A panel of 27 experts participated in the first round of the Delphi study, while 26 participants filled out the second-round survey (Table 1). Most of the experts worked in HTA agencies and P&R agencies, followed by national medicine authorities, and umbrella

patient organizations. Seventeen EU Member States were represented, with a higher representation of experts from Belgium (three experts, 12%) and Germany (three experts, 12%).

Results Rounds 1 and 2

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 structure of the NEED assessment framework, i.e. four dimensions including equity as transversal dimension and three domains (Supplementary Table S2). In addition to the structure of the framework, the experts agreed on 21 out of the 25 criteria and 42 out of the 46 indicators after the first round (Table 2). The four non-consensual criteria (frequency of the health condition, antimicrobial resistance, future burden of disease, and future economic burden) and the four non-consensual indicators

Table 1. Characteristics of participants (final Delphi round; *N*: number of participants)

Characteristic	Category	N (%)
Country (*N* = 25)[a]		
	Austria	2 (8.0)
	Belgium	3 (12.0)
	Croatia	1 (4.0)
	Cyprus	1 (4.0)
	Estonia	1 (4.0)
	France	2 (8.0)
	Germany	3 (12.0)
	Hungary	1 (4.0)
	Ireland	1 (4.0)
	Malta	1 (4.0)
	The Netherlands	2 (8.0)
	Poland	1 (4.0)
	Portugal	1 (4.0)
	Slovakia	1 (4.0)
	Spain	2 (8.0)
	Sweden	2 (8.0)
Area of expertise		
	Public health	2 (7.7)
	Medicine authorization	1 (3.9)
	Pricing and reimbursement	4 (15.4)
	Health technology assessment	13 (50.0)
	Patient advocacy	3 (11.5)
	Other	3 (11.5)
Years of experience		
	0–5 years	7 (26.9)
	5–10 years	4 (15.4)
	10–20 years	13 (50.0)
	>20 years	2 (7.7)
Total		26 (100)

a: Excluding representative of an international organization.

(EQ-5D-5L average score, experience with organization of care, quantity of information received, and existence of clinical practice guidelines) were re-evaluated during the second round (Fig. 2).

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 subject to internal NEED team discussion. Antimicrobial resistance had less than 60% consensus and was therefore removed from the NEED assessment framework (Table 2).

Modifications to criteria and indicators after Delphi process

After careful consideration of the comments of the Delphi panel members by the study authors, two criteria and three indicators with a level of agreement between 60% and 85% were revised and modified taking into consideration the expert panel's feedback. The quality-of-care indicator 'Experience with the organization of care' was rephrased to 'Coordination and continuity of care' because the initial indicator was unspecific, not validated and too vague according to 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. Additionally, the indicator 'Existence of clinical practice guidelines' was redefined as 'Research Gaps' that measures the criterion 'Scientific Research'. At the level of criteria, the two future needs criteria were refined to 'Forecasted burden of disease' and 'Forecasted economic burden'. Following these updates, the NEED framework now includes 4 dimensions, 3 domains, 24 criteria, and 43 indicators, providing a robust structure for the assessment of unmet health-related needs.

Discussion

The objectives of the Delphi study were to reach expert consensus on the dimensions and domains, health-related needs criteria, and indicators of the NEED assessment framework and to evaluate the validity of the framework on the EU level. Following a two-round Delphi consultation, the updated framework now includes 24 criteria and 43 indicators to evaluate unmet health-related needs.
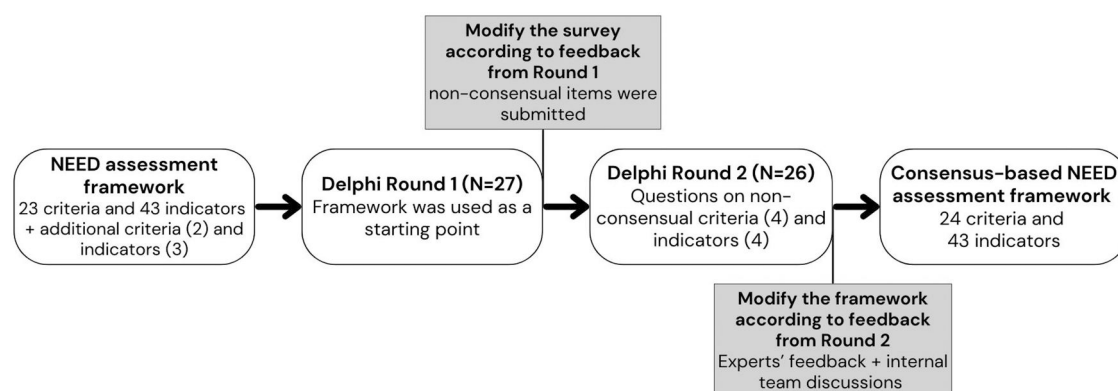
Modifications to criteria and indicators after Delphi process

Three non-consensual indicators were adjusted in response to the comments provided by the Delphi panel. One of the indicators of healthcare quality, 'Experience with the organization of care' was considered as not specific enough. The literature often highlights the lack of integrated care, which relies on continuity and coordination, among healthcare professionals [20]. After internal discussion,

Figure 1. Delphi study process.

Table 2. Overview of all criteria and indicators with their percentages of consensus after Rounds 1 and 2[a]

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	–
			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 organization 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	–
		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	–
Society	Health	Frequency		**84**	88%
			Prevalence or incidence	91	–
		Transmissibility		88	–
			Contagiousness	100	–
			Heritability	100	–
		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	–
			Costs related to work absenteeism, presenteeism, or/ and early labor force exits of patients	100	–
			Costs related to work absenteeism, presenteeism or/ and early labor force exits of caregivers	100	–

(continued)

Table 2. Continued

Dimension	Domain	Criterion	Indicator	Consensus level of agreement (%)	
				R1, %	R2
		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	–

a: R1, Round 1; R2, Round 2; QoL: quality of life; SoC: standard of care. Bold, non-consensual items; –, consensual items.
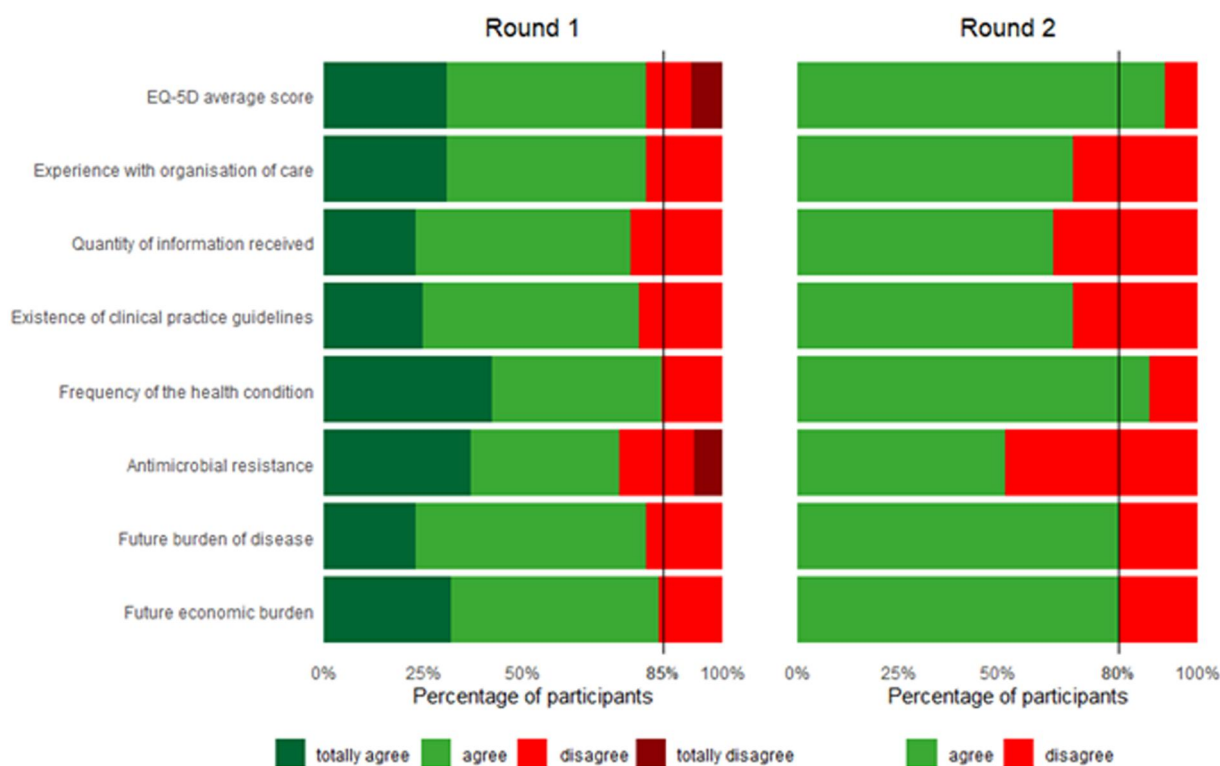
Figure 2. Overview of Rounds 1 and 2 results for non-consensual criteria and indicators after Round 1.

the indicator was revised and changed to '*Coordination and continuity of care*', as these universally accepted concepts are key to patients' healthcare experiences [26–28]. In addition, the panel criticized the emphasis on quantity over the quality of information. Patients should receive clear, understandable, and tailored information. Therefore, '*Quantity of information received*' and '*Quality of information received*' were merged into a single indicator, '*Usefulness of information received*' following the OECD's Patient-Reported Indicator Survey, which serves as the measurement method for this indicator [29].

The existence of clinical practice guidelines was initially included in the framework to measure the criterion '*Availability of clinical evidence*'. However, following the second-round survey, experts disagreed with this indicator, citing the delay between the emergence of

clinical evidence and the establishment of guidelines. In response, further discussions led to a revision of this criterion to '*Scientific Research*' and the indicator to '*Research Gaps*', reflecting the need to capture gaps in research relevant to specific health conditions. Previous research also emphasizes concerns about insufficient evidence and research [20].

Antimicrobial resistance (AMR) was removed from the NEED assessment framework as a criterion for societal health needs due to low expert agreement. Initially included for its significant public health and societal impact, experts argued that AMR is a specific issue that requires its own framework, rather than fitting into a general one [18]. Since AMR research primarily focuses on communicable diseases, and the NEED framework aims to address all health conditions, AMR, and its related indicators were excluded.

While 80% of experts agreed on the two future needs criteria after the second round, several suggested reformulating. Following internal discussions, '*Future burden of disease*' and '*Future economic burden*' were revised to '*Forecasted burden of disease*' and '*Forecasted economic burden*', aligning with the comprehensive forecasts produced by the Global Burden of Disease Study [30]. The expert panel acknowledged the importance of evaluating the future impact of health conditions when sufficient data are available, as trends in disease and economic burden are crucial for policymakers and society.

After considering the results of the Delphi study, the updated NEED framework based on expert consensus consists of 4 dimensions, 3 domains, 24 criteria, and 43 indicators.

Strengths and limitations

This study is the first to systematically validate a comprehensive framework for assessing unmet health-related needs across diverse health conditions. Notably, there is no consensus on the definition of unmet needs, nor are there established frameworks to guide healthcare policy and innovation in this area. By integrating expert perspectives, this study addresses a critical gap, advancing a validated tool that aligns with both societal and patient priorities.

The validation of the NEED assessment framework through this EU-wide Delphi study represents a significant advancement in the field of health needs assessment. Previous approaches, such as those by Wright et al. and Stevens and Gabbay, primarily focused on epidemiological data and on identifying gaps in healthcare [6, 31]. While these methods laid the groundwork for understanding unmet needs, they lacked the comprehensive, multidimensional approach embodied by the NEED framework.

The study's use of a modified Delphi approach facilitated structured engagement with a multidisciplinary panel of experts from 17 EU Member States, ensuring diverse input and strong consensus. The resulting framework provides an innovative and practical approach for systematically addressing unmet needs at both national and EU levels. The validated NEED assessment framework lays the groundwork for future research, paving the way for a more unified and needs-driven approach to healthcare policy and innovation.

Within our EU-wide Delphi study on validating the NEED assessment framework we encountered challenges in reaching consensus among a diverse panel of experts. This might reflect the complexity of integrating different healthcare systems and cultural perspectives across EU countries. However, these differences may ultimately contribute to a broadly accepted framework. Health-related needs may vary across member states, making it difficult to establish universally applicable indicators. As the European healthcare landscape evolves, the NEED framework may also need to be further adapted to reflect these changes (e.g. epidemics).

Although the resulting framework included expert opinions from 17 EU countries, the panel did not include representatives from every EU member state, resulting in the underrepresentation of certain regions (e.g. Northern and Eastern Europe). As a result, the cross-cultural relevance of our findings is notably constrained. Additionally, half of the experts had expertise in HTA, which resulted in the expert panel not being fully representative of the broader stakeholder groups (e.g. healthcare professionals).

Lastly, final decisions regarding modifications to non-consensual criteria and indicators were made internally. Although these modifications were grounded in the feedback provided by experts, conducting a third round of consultation would have been preferred to achieve consensus on the modifications of the criteria and indicators.

Policy implications and future research

This EU-wide Delphi study on the NEED assessment framework offers several important policy implications and research directions. Policymakers can use the consensus-based framework to enable cross-country comparisons, prioritize resource allocation, and develop evidence-based interventions targeting the most critical health gaps across the EU. By highlighting specific unmet needs and research gaps, the framework also helps direct funding and innovation toward areas requiring further exploration. Future research could focus on evaluating the framework's applicability across different populations (e.g. children), for specific health conditions (e.g. infectious diseases) or specific health challenges (e.g. public health crises).

Conclusion

In conclusion, this EU-wide Delphi survey of 26 experts has established a comprehensive, consensus-based framework for assessing unmet health-related needs. The updated NEED assessment framework offers a critical tool 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 organizations) to identify 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 needs and changes in the EU's healthcare landscapes.

Supplementary data

Supplementary data are available at *EURPUB* online.

Conflict of interest: None declared.

Data availability

The questionnaires and data that support the findings of this study are available from the corresponding author, R.C., upon reasonable request.

Key points

- A modified Delphi approach successfully validated the framework at the EU level, incorporating expert feedback across multiple healthcare sectors.
- The study highlights the importance of engaging diverse stakeholders in the assessment process to ensure that both societal and patient priorities are addressed.
- By defining unmet health-related needs, the NEED framework has the potential to inform policy decisions, leading to more needs-driven and effective healthcare interventions.
- The validated NEED framework can guide public health policy at the EU level by providing evidence-based insights into where healthcare systems need to be reoriented to address unmet needs, potentially improving health outcomes and resource allocation.

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