International Advisory Committee Meeting
20 November 2023, Brussels, Belgium

NEED: Needs **E**xamination, **E**valuation and **D**issemination
"Identifying patient and societal needs for a more needs-driven innovation and policy in healthcare."

FLASH REPORT

An international advisory committee meeting was set up to discuss the progress and early findings of the NEED project (Needs Examination, Evaluation and Dissemination). The meeting, expertly coordinated and chaired by Irina Cleemput (KCE; Belgian Health Care Knowledge Centre) and Robby De Pauw (Sciensano; Belgian Public Health Institute), encompassed a diverse array of topics.

1) Presentation of the NEED assessment framework (Charline Maertens de Noordhout, KCE)

The NEED project's background, scope, and objectives were presented. Attendees were provided with insights into the latest version of the NEED assessment framework, comprising three dimensions (patient, society, future), three domains within each dimension (health, healthcare and social needs), and several related criteria and indicators.

2) Learnings from two case studies (Claudia Schönborn, KCE)

Two case studies were performed in 2023 to test the general NEED framework, one on Crohn's disease and one on malignant melanoma. Several lessons were learnt from these case studies, and both positive outcomes and challenges were discussed. Both case studies highlighted important psychological implications of the disease and patients reporting a lack of psychological support. In addition, Crohn patients reported fatigue as being the most burdensome symptom, as well as a high impact of the disease on working ability. For melanoma, the study showed that low awareness of the risk led to a delay of access to care.

3) Applicability of the NEED assessment framework to rare diseases (Isabelle Huys, KUL)

The NEED assessment framework was developed to apply to all health conditions. However, as rare diseases are often considered a separate category with specific features that might not apply to more common diseases, a separate study evaluated the applicability of the general NEED framework to rare diseases. The study explored the different definitions of rare diseases, reconsidered NEED criteria/indicators in the context of rare diseases and identified methodological challenges related to rare diseases. The preliminary results of this research were presented.

4) Discussion and Q&A (Everyone)

A dynamic discussion took place on the NEED assessment framework, its application to rare diseases, and its potential impact on healthcare policy and innovation. A discussion unfolded about the terminology to use. While NEED uses the term 'health-related unmet patient and societal needs', other

terms circulate, each with their own implicit meaning and connotations. The broad scope of NEED, going beyond pure medical needs, was generally appreciated and considered relevant.

Other discussions related to the criteria included in the framework. A few additional criteria were suggested and also questions were posed about the potential overlap between criteria. With regards to the potential impact of a NEED database on national or international healthcare policy and innovation, it was highlighted that the actual use of the evidence collected on patient and societal needs for decision making (appraisal) requires more thinking, but that the availability as such of the evidence is important to make decisions more evidence-based.

The extent to which the framework is applicable for decision making on the European level requires further study: e.g. to what extent patient needs differ significantly between member states?

It should be clarified that the database will not include concrete recommendations on solutions for meeting the needs. Also, the database will not include weights for the different indicators of need or include what are *meaningful* reductions of need. This should all be part of the appraisal process, where e.g. patient representatives can explain what is a meaningful reduction of needs.

5) Presentation of the four-step implementation model for NEED research (Muriel Levy, KCE)

First, the four-step NEED implementation model was presented and then each step was explained in more detail:

(1) Identification of health conditions with potentially high unmet needs
 1a. Using existing databases
 1.b. Using a call for proposals from patients/healthcare providers/public
(2) Prioritisation and selection of health conditions for the NEED research programme
(3) Evidence collection on the criteria of the NEED framework, and
(4) Dissemination of results

6) Applicability of the 4-step implementation model to rare diseases (Isabelle Huys, KUL)

The study that examined the caveats of applying the four-step implementation model to rare diseases was presented. There are challenges related to the identification, prioritisation, selection and evidence collection. For instance, focus on databases or existing sources is insufficient to reach that goal, a multi-method approach is recommended.

7) Discussion and Q&A (Everyone)

Discussion took place on the NEED 4-step implementation model and its applicability to rare diseases.

Related to the call for NEED research proposals (step 1 of the implementation model), it was suggested to apply certain quality criteria for eligibility of submitted topics.

Related to the dissemination of the results, a main message from the participants was that it requires more thought *how* and *to whom* the results are disseminated. The importance of the practicality of the tool(s) provided to derive information from the NEED database was also highlighted. Finally, it is important that the database contains sufficient data of high quality on multiple diseases to make it practically useful. This will require partnerships with researchers willing to do NEED research according to the methodology and high-quality standards imposed by NEED. Besides evidence on the criteria, it was highlighted that background information on the condition, including risk factors, current standard of care, co-morbidities, etc. is also very important to allow for an appropriate response to the expressed needs.

8) Governance structure & funding (Irina Cleemput, KCE)

In this last session of the meeting, experiences from existing governance structures (e.g. IHSI, Beneluxa) were shared, highlighting their strengths and weaknesses, followed by a general brainstorming on how the NEED project could evolve from an organisational, governance and funding perspective.

9) Brainstorming on organization, governance and financing of a NEED research infrastructure in the EU (everyone)

There are several possibilities for the governance structure, going from a legal entity to a voluntary collaboration. For the funding there are several possible sources at EU level. It should be explored in which programme NEED would fit best. Demonstration of use cases will be necessary, irrespective of the targeted funding programme. Following the discussions and brainstorming, several key **take-away messages** were noted, including (but not limited to):

- The importance of support from the different European member states. The upcoming Belgian EU presidency is an important opportunity for this project.
- NEED serves multiple stakeholders (e.g. researchers, regulators, HTA bodies, policy makers, patient associations,…). Targeted communication to each specific target group on the added value of a NEED evidence database is recommended.
- NEED should invest in developing additional concrete examples of how NEED could support decision making.

10) Closing and next steps (Irina Cleemput, KCE)

The NEED team thanked the different project partners and the participants to the meeting for the fruitful discussions. It will continue the work, taking the different comments into account. A meeting with Belgian stakeholders is also planned and might add to the reflections.

The short-term upcoming activities of NEED involve:

- The launch of the call for NEED research proposals in January 2024, the prioritization of research topics (March 2024), the selection of two additional case studies (April 2024), and the collection of data for these case studies.
- The publication of the NEED reports, including a dedicated report on rare diseases, in March 2024.
- The development of the database with first contents (March 2024)

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