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Introduction of new health technologies – is the patient being heard?

OPINIONS

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Patients and service users are not really involved in the process for assessing new health technologies. Other countries have much better systems in place, and these should be adopted in Norway.

The system for assessing which health technologies should be introduced and financed by the Norwegian health service is called *Nye metoder* (new technologies). Despite both the white paper on priority setting (1) and the white paper on medicinal products (2) stipulating that patient and service user

involvement needs to take place in prioritisation processes at all levels, this seldom happens. The Norwegian government's Hurdal platform also describes the importance of greater patient involvement and aims to facilitate this (3). The current status is that patients are only included in parts of the system as observers, and have little input in the decision-making.

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Clinicians and academics have been critical of the lack of involvement of patients and clinicians. Kristiansen and Syse recently discussed the involvement of clinicians in an article in the Journal of the Norwegian Medical Association (4), and a new evaluation of the *Nye metoder* system points to the need for greater involvement of clinicians and patients (5).

Why is patient involvement important?

Patients have unique knowledge, perspectives and experiences, and they are experts in living with an illness. They may have insight that has not been reported in published literature and can provide information on what would have the most value in new treatments.

Patients are also the ones who are most affected by the decisions made. Patient involvement facilitates transparency, credibility, commitment and ownership of the technology assessments and decisions. The evaluation of *Nye metoder* pointed to mistrust between the parties (5). Our assessment is that patient involvement is absolutely crucial for increasing confidence in the system.

How does it work in other countries?

Through the collaboration with other European authorities and organisations, the Norwegian Medicines Agency and the Norwegian Institute of Public Health are well acquainted with the systems developed to involve patients, such as the National Institute for Health and Care Excellence (NICE) in England and the European Network for Health Technology Assessment (EUnetHTA) (6, 7). There are also resources, such as the European Patients' Academy on Therapeutic Innovation (EUPATI) etc. (8). Patient involvement is systematic in a number of countries, e.g. England, Germany, the Netherlands, France, Canada and Scotland (9–14). Common to all of these is that the patient is systematically included throughout the entire process, from technology notification, through the health technology assessment phase, all the way until the decision is made.

> ***«Common to all of these is that the patient is systematically included throughout the entire process»***

Based on our observations of other countries, we believe that Norwegian patient organisations should demand that *Nye metoder* facilitate patient involvement without delay. In the Norwegian context, this could entail, for example, establishing clear timelines, including advance notification of deadlines. Notifications and patient involvement invitations could be sent out at the same time as the Ordering Forum orders and initiates a technology assessment. *Nye metoder* should establish a clear point of patient contact, with responsibility for notification, collection of patient input and ensuring that processes are straightforward and efficient.

Patient organisations would need to appoint a participant. This may be a challenge in the case of rare diseases, but other countries solve this by appointing representatives from broader categories of diseases. Patient input is provided via a form in which they are asked about the burden of disease for themselves and their families, the treatment burden and their expectations for new treatment. These forms are virtually the same in all countries, and include guidance on how to complete them.

We consider these forms to be well-designed, and before being introduced in Norway all they would require is a translation (6–8, 11, 13, 14). We believe the forms are more or less a ready-made solution to adopting the system in Norway. The goal is for the patient input to be included in the Norwegian Medicines Agency's technology assessment report, and for the Decision Forum to describe how the patient input is used in the decision-making.

Why is a pharmaceutical company interested in this?

Some might argue that patient input will be biased according to their own interests. The Decision Forum, the Norwegian Hospital Procurement Trust and the Norwegian Medicines Agency are particularly interested in focusing on cost in assessments, and suppliers have an obvious interest in selling their products. All input should therefore be collected and considered openly, with the opportunity for discussion.

> ***«Patient involvement will require resources and training, but it is absolutely vital for ensuring transparent decision-making and fostering trust in the system»***

We consider the *Nye metoder* system to be lacking in transparency. It offers little justification for decisions that are made, and does not facilitate discussion or inclusion (5). The evaluation of *Nye metoder* also indicates that parts of the system are perceived as a 'black box'.

Patient involvement will require resources and training, but it is absolutely vital for ensuring transparent decision-making and fostering trust in the system. The tools are there, the processes are there, and the politicians say that it should happen. Our assessment is that the patient associations and other relevant

parties should familiarise themselves with how patient involvement works in other countries, and demand the same of *Nye metoder*. There is no reason to wait.

REFERENCES

1. Meld. St. 34 (2015–2016) Verdier i pasientens helsetjeneste – Melding om prioritering. https://www.regjeringen.no/no/dokumenter/meld.-st.-34-20152016/id2502758/ Accessed 9.3.2022.

2. Meld. St. 28 (2014–2015) Legemiddelmeldingen. Riktig bruk – bedre helse. https://www.regjeringen.no/no/dokumenter/meld.-st.-28-20142015/id2412810/ Accessed 9.3.2022.

3. Hurdalsplattformen – for en regjering utgått fra Arbeiderpartiet og Senterpartiet 2021–2025. https://www.regjeringen.no/no/dokumenter/hurdalsplattformen/id2877252/ Accessed 9.3.2022.

4. Kristiansen IS, Syse A. Legers rolle i Nye metoder. Tidsskr Nor Legeforen 2021; 141. doi: 10.4045/tidsskr.21.0823. [PubMed][CrossRef]

5. Proba samfunnsanalyse. Evaluering av systemet for Nye metoder i spesialisthelsetjenesten. Rapport nr. 16/2021. https://proba.no/rapport/evaluering-av-systemet-for-nye-metoder-i-spesialisthelsetjenesten/ Accessed 9.3.2022.

6. National Institute for Health and Care Excellence. Contributing to clinical guidelines: How organisations representing patients and carers can get involved. https://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Developing-NICE-guidance/Factsheet-2-contribute-to-developing-clinical-guidelines.pdf Accessed 9.3.2022.

7. EU network for HTA (EUnetHTA). EUnetHTA patient input template. https://www.eunethta.eu/wp-content/uploads/2019/11/2019-09-30_EUnetHTA_Patient-input-template_final.pdf?x50316 Accessed 28.12.2021.

8. EUPATI. Guidance for patient involvement in HTA. https://toolbox.eupati.eu/resources/guidance-for-patient-involvement-in-hta/ Accessed 28.12.2021.

9. National Institute for Health and Care Excellence. Nominating patient experts: a factsheet for patient and carer organisations. https://www.nice.org.uk/Media/Default/About/NICE-Communities/Public-involvement/Developing-NICE-guidance/Nominating-Patient-Experts.pdf Accessed 9.3.2022.

10. The Federal Joint Committee (G-BA). Patient Involvement.https://www.g-ba.de/english/structure/ Accessed 9.3.2022.

11. Contribution des associations de patients et d'usagers aux évaluations des médicaments et des dispositifs médicaux. Questionnaire de recueil du point de vue des patients et usagers pour l'évaluation d'un médicament. https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.has-sante.fr%2Fupload%2Fdocs%2Fapplication%2Fvnd.openxmlformats-officedocument.wordprocessingml.document%2F2019-12%2Fquestionnaire_has_contrib_asso_med_1.docx&wdOrigin=BROWSELINK Accessed 9.3.2022.

12. Zorginstituut Nederland. Onderzoek patiëntenperspectieven in kwaliteitsstandaarden. https://www.zorginstituutnederland.nl/publicaties/rapport/2021/06/28/rapportage-patienten-gelijkwaardiger-aan-het-woord Accessed 9.3.2022.

13. Pan-Canadian Oncology Drug review. A guide for patient advocacy groups. https://htai.org/wp-content/uploads/2018/02/PCISG-Resource-pCODR_Patient_Guide_May13.pdf Accessed 9.3.2022.

14. Scottish Medicines Consortium. The participation toolkit.Why use surveys and questionnaires? https://htai.org/wp-content/uploads/2018/02/PCISG-Resource-SHCToolkit_Surveys_and_Questionnaires_Jun.pdf Accessed 9.3.2022.

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