



Health Reform Monitor

The 2018 establishment of a national expert panel for patients with serious life-threatening disease in Norway^{☆,☆☆}

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ABSTRACT

The discussion on priority setting in Norwegian healthcare has resulted in several white papers and the establishment of a Council for priority setting from 2007–2017. In 2009 the Council discussed and proposed a system for renewed evaluation by an expert panel for cancer patients, as was in place in Denmark. However, the Directorate of Health found that patients already had the right of second opinion, and thus did not need a new expert panel like the one proposed. The case was discussed several times in the Council, coupled with the discussion on the inequity for patients to take part in studies of emerging treatments. This resulted in 2015 in a public website for patients with information on ongoing clinical trials open for inclusion, but no solution regarding the expert panel. A journalist in a national newspaper published a series of articles in the summer of 2017 on the topic. This was close to the election for Parliament, and the politicians got interested; first the opposition, then the current Minister of Health and Care services. The decision was made in August 2017 to establish such an expert panel for renewed evaluation for patients with serious lifeshortening disease. Also, the information for patients on ongoing trials should be more complete and accessible. The Regional health authorities implemented the policy decision, and the expert panel was in place November 1st 2018.

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1. Introduction and background

Norway has a universal coverage, public healthcare system. Health care quality is considered good, as documented by the national quality indicator system [1,2]. Equity in access and quality is a political goal consistent across different government constellations. The hospitals are owned and run by the four regional health authorities (RHAs). Priority setting has been discussed widely, and the first white paper on priority setting was published in 1987 [3]. Since then, two more white papers have proposed national principles for priority setting [4,5]. In order to facilitate thoroughly anchored and knowledge based advice for the Government, the Council on Priority setting was established in 2007, reappointed in 2011 and in 2015, and was discontinued at the end of 2017 due to political decision. A system for formal decision making on which new and costly treatment methods to include in the basket

of services was established in 2013, as a means for implementing priorities and to ensure equal access to these treatments [6].

Patients in Norway have statutory patient's rights through the Patients' rights act of 1999 [7]. In this law, patients' right to second opinion is stated (§3-2). This right can only be used once for the same condition, and the patients' general practitioner is the one to seek such second opinion on the patient's behalf. There are no statistics showing how many patients actually make use of the right to second opinion, as it is not recorded anywhere.

Thus, we do not have information on Norwegian patients' second opinion seeking practice. From other countries we have some information. A systematic review comprising 9550 cancer patients, found that between 6,5% and 36% of patients sought second opinion, and for various reasons [9]. Five of the 13 included studies were from the US, three from Australia, the rest were from the Netherlands, France and Belgium. In 12%–69% of the cases, the original diagnosis, treatment or prognosis was modified. Patient satisfaction was high, but outcome related data were missing. In a study from the US, it was documented that over 50% of cancer survivors have sought at least one second opinion [10]. In an Australian cancer centre, 6,5% of new referrals were seeking second opinion [11]. These studies indicate that patients with higher education, younger persons and women, are more likely to seek second opinion.

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From 2013 the current conservative Minister of health and care services has had as his political mantra, that he will create the patients' health care system. Patient centeredness is the core of several white papers, is central in the yearly letters of instruction for Directorate of health and the four regional health authorities owning and running the public hospitals, and is mentioned in most talks he gives, such as the yearly hospital-talk, opening of conferences etc.

2. The new policy: a panel for renewed evaluation and increased equity in access to clinical trials and emerging treatment for patients with life-shortening disease

The policy described in this paper is two-tiered; Firstly it imposes on the RHAs to establish an expert panel where patients with serious and life shortening disease may seek renewed review on his or her treatment. This expert panel is also to give advice on treatment options or clinical trials nationally or internationally, given that regular treatment options are exhausted. Secondly, it imposes on both the regional health authorities and on the Directorate for health, to give more complete and understandable information for patients about ongoing clinical trials open for inclusion in Norway. If patients themselves identify possible studies or experimental treatment they think may be beneficial for them, they can get expert opinion from the panel as a help for deciding to take part or not.

3. Political and economical background

In Norway there is a political goal that healthcare should be fairly distributed and with the same access and quality for all inhabitants. This is stated in several white papers as well as in several health care laws, including the Patients' rights act [6]. The focus on patients' rights has been increasing, and patients' experiences of the healthcare system has been included in the national quality indicator system [2]. A system for formal, national decision making of which new treatment options should be offered to Norwegian patients was established from 2013, as a means for priority setting and to ensure equal access to treatments [6]. This National system for introducing of new methods, is based on Health Technology Assessments, and the Decision forum, which makes the formal decisions, consists of the four Chief executive officers of the RHAs. Until recently, the Directorate of health held the secretariat for the system. However, varying and delayed access to medications not yet accepted for general use, has been focused on in several newspaper articles, as well as varying access to participate in clinical trials of new treatments [12,13].

The process of developing the new policy had been going on for several years since 2009. It gained new speed when a national newspaper in a series of articles in May and June of 2017 focused on patients and relatives telling their stories of how their desperate search for knowledge about possible treatment options were not met by their treating doctor or by other parts of the healthcare system. The portrayed feeling of these patients and relatives of being left alone with life threatening disease without getting any guidance, was perceived as a threat to confidence and trust in the Norwegian health care system. Also, the stories of highly skilled and/or well connected patients being included in clinical trials of new drugs, and through this gaining years of life or even cure, added to the need for the politicians to act [14].

The policy was thus aimed at two goals; the first was to ensure that patients with serious, life shortening disease had the possibility of a highly qualified expert advice as a type of second opinion and guidance on treatment options. The second was to ensure all Norwegian patients equal access to being evaluated for participation in

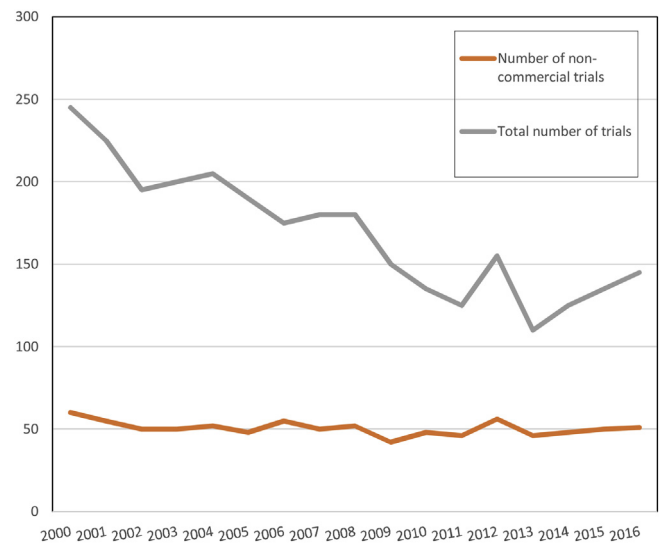


Fig. 1. Decline in number of clinical trials in Norway. Based on information from the Norwegian Medicines Agency.

clinical trials of emerging treatments, when all regular treatment options were exhausted.

Another probably important background for the policy proposal was that the number of clinical studies in Norway seemed to decline; particularly commercially financed studies (Fig. 1) [15]. As a response to this, two programs for publicly financed clinical studies were established in 2016, one through the Norwegian Research Council and one through the Regional Health Authorities, to address important questions not addressed by commercially financed studies [16,17]. The publicly available information through the website publication of the studies, should ensure equity in access. However, during the discussions leading to the reform, voices were raised concerning the inequity regarding costs, as most of the clinical trials are organized at the University Hospitals in Norway, or even abroad, and participation in trials may induce high costs for travelling for patients, especially those living far away from the study sites.

4. The stakeholders and policy processes

In 2007 a Council for priority setting was established in Norway, with a professional secretariat and members from all levels of healthcare, from the medical and nursing association and from patient organizations. All healthcare personnel, and later also the public, could propose topics for discussion, and the secretariat prepared documents for the meetings. All documents, agendas and proceedings were public (www.prioritering.no). The Council was discontinued by the end of 2017, the decision explained to be because of the newly established Forum for emerging treatments, which was given some of the same assignments (see below).

A member of the Council on Priority setting, an oncologist heading a unit at the Oslo University Hospital working with clinical trials, raised the issue already in 2009. He proposed for the Council on Priority Setting, to establish an expert panel to guide cancer patients regarding further treatment when their hospital tells them their treatment options have been exhausted [18]. The proposal was based on a similar Danish model, which established an expert second opinion panel in 2003 [19]. The council debated the issue and was in favor, supported among others, by the Norwegian Cancer Association. The details of such a system was left to the Directorate of health to sort out. However, the Directorate of health did not come back to the council with a detailed proposition. Thus, the issue was raised again in 2014 in the Council by the Norwegian

Table 1
Timeline of events leading to the decision to establish an expert second opinion panel.

2003	Second opinion panel established in Denmark
2007	Norwegian council for priority setting established
2009	First proposal of second opinion panel, by leading oncologist and Norwegian Cancer Association. Council recommends establishing a second opinion panel.
2009	Norwegian directorate of health is given the task to detail the organization of the panel, concluded it was too difficult legally and financially
2011	2 nd reappointment of Norwegian council for priority setting
2013	Norwegian national system for new and costly treatment prioritization established
2014	Evaluation of the Danish second opinion panel published
2014	New proposal for second opinion panel in the Norwegian council for priority setting debated and recommended by the council. Directorate of health opposed, same arguments as in 2009.
2015	3 rd reappointment of Norwegian council for priority setting
2015	public website for patients on ongoing open clinical trials established (at helsenorge.no)
May–July 2017	Several newspaper articles highlight patient stories, argues panel will reduce number of patients seeking undocumented treatments
July 2017	Opposition in Norwegian Parliament announces support for second opinion panel
August 2017	Decision by Minister of Health to establish second opinion panel
September 2017	Election for parliament (government reelected)
November 2017	Outline for system provided by the regional health authorities
31.12.17	Council on priority setting dissolved
January 2018	Letter of instruction for the regional health authorities from Minister of health, to establish a second opinion panel.
April 2018	Leader of expert panel appointed, suggests 6 appointed members, plus expert opinion in each case
November 1st 2018	The second opinion panel called the Expert group is operable [27]

Cancer Association since little progress had been made. The Directorate concluded that such an arrangement would be confusing and unnecessary, as patients already had a right to second opinion. In the meantime, stories of desperate patients and families seeking treatment options on their own, spent fortunes and precious time at end of life, chasing more or less documented treatments at clinics abroad, were published in local newspapers as single cases.

It was a journalist in the national newspaper *Aftenposten* who started the case up again in the summer of 2017, after having worked on the matter for almost a year. Through her network within healthcare, and through colleagues and friends, she became aware that many patients found, through aggressive internet marketing via a firm in Stavanger, a possible treatment option at a clinic in Germany. After digging through the material, and talking to relatives, a few surviving patients and oncologists all over the country, she portrayed in a series of newspaper articles how the patients felt absolutely left alone when regular treatment options were exhausted and they wanted to see whether emergent treatments, even if experimental, would help them. The journalist documented that Norwegian health care did not meet the need of these patients, and that they were left to seek treatment for themselves [20]. They easily became victims of aggressive marketing of undocumented and expensive treatment options, which also had serious side effects. The journalists researched more than 37 patient cases of patients going to the same clinic in Germany, only to discover that most of these patients died either during treatment abroad, or right after return home [21]. This series of newspaper articles, propelled the politicians. There was an election for Parliament coming up in September of 2017, and the current opposition stated that they wanted to establish such a new system for second opinion [22]. The political editor of the newspaper *Aftenposten* also supported this in an editorial [13]. This was in May 2017, and the newspaper kept the storyline warm through a series of articles also documenting that the Norwegian website with available clinical studies that had been established, contained less than half of the studies registered in the *clinicaltrials.gov*-site, where studies need to be registered in order to be published in scientific journals [23]. Also, the Stavanger firm marketing of the German clinic was found to be illegal by the Consumer ombudsman [24]. They also identified how some patients googled and found studies to participate in, while other patients did not get this option, and that patients with connections and resources were able to pay for treatment other patients could not get access to [12,14]. In the beginning of August, the Minister of Health and Care Services, stated in a newspaper interview, that his political platform at the election would include a system for

renewed evaluation by an expert panel for all patients with serious, life shortening disease. In the article he was cited as saying he would, with an addition to the yearly letter of instruction to the four Regional Health Authorities, ask them to propose how this system should be implemented. This letter was sent to the Regional Health Authorities August 22nd 2017, and a report with details on possible implementation of such a system was sent by the RHAs to the Ministry of Health and Care Services in November 2017 [25]

The reform that the Minister of Health and Care services proclaimed through the newspapers in August 2017, was put into action through the yearly letter of instruction to the regional health authorities and the Directorate for health in January 2018 [26]. The Western Norway Regional Health Authority was given the task to establish the expert panel, as outlined by the report the RHAs sent the Ministry of health and care services in November 2017, in close collaboration with the other regional health authorities as well as with consultation of the Directorate for health. The establishment of the second opinion panel, and the possibility to have their case reviewed by it, is not considered a new patient right, but is considered to be part of treatment. For the patients it is funded and free of charge, and if further treatment or clinical trials are recommended abroad or within the country, the patients' travel expenses will be covered. The system was in place by November 1st 2018, with and the Expert panel is led by an oncologist as the panel's administrator. The timeline of the process is outlined in [Table 1](#).

5. Expected or preliminary outcomes

The Danish system of second opinion, on which the Norwegian system is based, was evaluated in 2014 [16]. The evaluation found that of the 7000 patients referred, the panel agreed on the current treatment strategy for 43%, and 28% had no further treatment available. 7% were advised on further treatment in Denmark, while 18% got advice on clinical trials or explorative treatments to take part in. However, the evaluation did not include information about effects on patients' survival or quality of life. It is of interest to note that neither of the two other Nordic health care systems, in Sweden and in Finland, have had this debate about access to clinical trials.

Since the system has just started operating, we do not know what the outcomes will be. It is to be expected that the patient composition of the Norwegian system will be much the same as in the Danish system, where more than 95% of patients seeking renewed evaluation have cancer. It is to be expected that the number of patients participating in clinical trials will increase, as availability increases for more patients. A renewed interest in funding clinical

trials through the Norwegian Research Council and the Regional Health Authorities may be an intended and welcomed outcome, one hoped for by the oncologist who firstly proposed this policy, and for the Norwegian Cancer Association. It is also a hope that fewer patients will receive undocumented treatments at clinics in other countries. It will be interesting to see whether the patients seeking council by the Expert panel will have similar characteristics as reported from second opinion seeking cancer patients in other countries; a majority being female with higher education [9–11]. The system is designed to increase availability and equity, so these are important parameters to follow.

Neither the report by the RHAs nor the letter of instruction from the Minister of health and care services imposing the RHAs to establish such a system, outline how or when it should be evaluated. That is an obvious weakness, which hopefully will be corrected, in order to gain knowledge, which may advise other countries debating whether to introduce a similar policy.

As we know little about Norwegian patients' behavior concerning seeking second opinion, one might expect them to have the same characteristics as in other countries, where studies have shown that more female patients seek second opinion than men [8–10]. Whether educational level will be a factor in this new system, one can only speculate. In an American study 51% had lower level of education, but the awareness of the possibility of seeking second opinion, and the possibility to actually get an independent second opinion, may be greater in other countries than in Norway.

6. Conclusion

The new policy was decided rather suddenly by the Minister of health, after a yearlong debate in the National Council on Priority Setting. The main aim was to ensure expert evaluation on treatment options and equity for patients regarding access to be evaluated for clinical trials or experimental treatment, when all regular treatment options were exhausted. The decision to introduce the policy at the exact time it was done, was probably partly due to the upcoming election, but may also have been propelled by the political aim of creating the patients' health care service, and the voices of patients and relatives telling about an increasing lack of trust in help from Norwegian health care. The seemingly disagreement between the Directorate of Health and the Norwegian Cancer Association in the Council for Priority Setting may have influenced the decision of discontinuation of the Council of Priority Setting. The lack of planned evaluation of the new policy is a weakness, and should be corrected, in order to obtain a sound baseline from which to follow the effect of the policy. If such evaluation is performed, this may inform other countries considering a similar policy.

Conflict of interest

None.

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