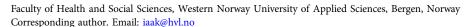




ARTICLE

Successfully changing the mode of regulation in clinical priority setting: how organisational factors contributed to establishing the Norwegian priority guidelines for specialist health care services

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Abstract

This article investigates factors that contributed to the successful introduction of 33 priority guidelines for Norwegian specialist health care from 2008 to 2012. The guidelines constituted an important step in changing the regulation of clinical priority setting from largely self-regulation by medical professionals to a more centralised and hierarchical form, and therefore, resistance from the medical profession was expected. My focus is on organisational factors within the project that developed the guidelines, using policy documents and project documents as the main source of data. I find that the project was characterised by a high level of autonomy in terms of how it was organised and the actors included, with significant capacity for action in terms of both structure and personnel, and a broad inclusion of affected actors. The priority guideline project was dominated by medical professionals, and its organisation did not represent a radical break with established traditions of medical professional self-regulation. Although organisational autonomy, action capacity and broad inclusion were clearly of importance, the project's compliance with historical traditions and norms of medical governance stands out as the key factor in understanding the successful establishment of the priority guidelines.

Key words: guidelines; hospital care; Norway; prioritisation; public reform

1. Introduction

Between 2008 and 2012, the Norwegian health authorities launched 33 national clinical priority guidelines for specialist health care. The guidelines constituted an important step in changing the regulation of clinical priority setting from mainly medical professional self-regulation to more centralised and hierarchical forms of regulation. The priority guidelines were formed as part of the project 'Better prioritisation in the hospital sector'. The project was initiated by the health authorities in the context of documented significant variations in how the legal regulations concerning priority setting were applied in clinical practice (Helsedirektoratet, 2018). Developed to support more uniform priority setting across hospitals and regions, the guidelines operationalise the Norwegian Patients' and Users' Rights Act and the Prioritisation Regulation. The guidelines are designed to be used by hospital doctors when evaluating whether patients have a legal right to elective specialised health care services and, although not binding, they are a central form of legal authority (Syse, 2015; Riska and Aasen, 2018). The priority guidelines have been successfully established and implemented. They were revised in 2015 and studies show that they are well known and used in clinical practice (Bjorvatn and Nilssen, 2018; Aase-Kvåle *et al.*, 2019).

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Although regional variations continue to exist, the variations in allocation practices have decreased since their introduction (Helsedirektoratet, 2012), and it has been suggested that priority guidelines should also be developed for municipal health care (Norges offentlige utredning, 2018).

In a field characterised by a strong tradition of medical professional autonomy and selfregulation, it is somewhat puzzling how the health authorities managed to establish and introduce priority guidelines that represent a new mode of regulation oriented against more hierarchical steering and control. The guidelines curtail the medical professional discretion in making decisions regarding access to specialised health care by imposing a more detailed hierarchical regulation. In general, attempts to weaken professional autonomy and discretions are likely to be met with resistance from the professionals affected (Evetts, 2002, 2018). In this article, I elucidate key factors that contributed to making this shift in regulation of clinical priority setting possible. My approach draws on insights concerning how public sector reforms succeed. The literature on public reforms in general (e.g. Brunsson and Olsen, 1993; Christensen et al., 2020) and reforms in health care in particular (e.g. Roberts et al., 2003) offers a range of explanations for why and how some reforms fail, whereas others succeed. Explanatory factors can be related to the different stages of a reform, from the driving forces through to the political decision-making processes and the administrative implementation stage (Pollitt and Bouckaert, 2017). Acknowledging that the implementation stage, where reform ideas and political decisions are put into practice, constitutes a particularly important part of the reform process (Pressman and Wildavsky, 1984; Hill and Hupe, 2002; Pollitt and Bouckaert, 2017), I focus on the process of formulating and developing the priority guidelines. How the implementation process is organised is key for new policies to succeed (Vrangbaek, 2009; Egeberg and Trondal, 2018) and organisational factors found to enhance reform success are the involvement of affected actors (Compton et al., 2019), sufficient action capacity (Christensen et al., 2020), organisational autonomy (Meier et al., 2019) as well as compliance with historical norms and traditions (Brunsson and Olsen, 1993; Christensen et al., 2020). The main research question asked in the article is: How did organisational factors in the project of developing the Norwegian priority guidelines for specialised health care services contribute to the successful establishment of the guidelines?

To answer this question, I study organisational factors associated with successful reform implementation through the following sub-questions: What was the project's level of organisational autonomy? What was the project's capacity for action? To what degree were affected actors involved in the project? And finally, was the project organised in accordance with established norms and traditions for medical governance?

These questions are investigated by conducting a retrospective single-case study (Thomas, 2011) of the project that developed the 30 first priority guidelines from 2005 to 2008.¹

This article presents knowledge of how specific factors in the implementation phase can contribute to a successful change in the mode of regulation for clinical priority setting. I seek to make an empirical contribution to the research field of medical governance (see e.g. Burau and Vrangbæk, 2008; Kuhlman and Saks, 2008) by focusing on conditions for successfully implementing legal regulation to steer clinical priority setting. The article moves beyond studies focusing on how legal regulations of clinical priority setting are interpreted and applied in clinical practice (see e.g. Magnussen and Brandt, 2014; Aase-Kvåle *et al.*, 2019) and the implications of the legal regulations (e.g. Bjorvatn *et al.*, 2020) by offering empirical evidence of the organisational conditions in forming a new and successful regulating tool. By focusing on how specific factors in implementing reforms can contribute to reform success, the findings have implications for the design of governance processes and are likely to be of interest to decision-makers as well as

¹Guidelines for adult habilitation, child habilitation and interdisciplinary treatment for substance dependence were developed and introduced from 2008 to 2012, but this article focuses on the first 30 guidelines developed.

implementers. This article also addresses the call for a stronger emphasis on and empirical insights into public policies that have worked well (Compton *et al.*, 2022).

2. Context

2.1 Norwegian priority setting and the priority guidelines

Norway has a relatively long tradition of government-initiated efforts and public debates in priority setting. In 1985, the Norwegian government established the world's first public committee on health care prioritisation. Since then, the priority-setting process in Norway has passed through different phases, and a total of four national public committees have assessed and discussed health care prioritisation. Since the 1980s, Norway has moved from a core focus on outlining principles to a stronger emphasis on establishing reasonable and accountable decision-making processes for priority setting (Holm, 1998; Hofmann, 2013). From the late 1990s and early 2000s, individual legal rights to health care were emphasised and the established set of priority-setting principles – severity of disease, cost-efficiency and expected benefit – were codified into the Patients' and Users' Rights Act established in 1999 and the Prioritisation Regulation of 2001 (Norges offentlige utredning, 1997; Feiring, 2003; Hofmann, 2013; Aasen et al., 2018). It is argued that after 2006, Norway entered into a new phase, marked by open public negotiation in priority-setting issues (Hofmann, 2013).

The priority guidelines formed in the project 'Better prioritisation in the hospital sector' consist of two parts. There is a general part that is similar for all the guidelines that states how the legal regulation should be interpreted and how the guidelines should be used. The second part applies to each specific health care specialty, which varies for each guideline. The specialty-specific parts contain tables listing the most common conditions for the relevant specialty, with recommendations concerning when patients have or do not have rights to specialist health care, and recommended deadlines for when health care should start at the latest. The guidelines give recommendations on a group level, and clearly state that individual assessments are necessary (Helsedirektoratet, 2018).

The priority guidelines are not legally binding as law or regulations. However, they serve a legal function as authoritative recommendations endorsed by the authority of the Directorate of Health (hereafter, the Directorate) to set norms and standards through clinical guidelines. Therefore, deviations from the guidelines' recommendations would need to be based on a concrete and justified assessment (Syse, 2015; Riska and Aasen, 2018). To be allowed to assess referrals to specialist health care, hospital doctors are required to attend a course in the use of the priority guidelines developed by the health authorities (Helsedirektoratet, 2015).

2.2 The Norwegian health care system: governance context

Norway offers a specific context for the study of priority-setting processes. The health care system, in common with the Nordic welfare system in general, is characterised by the dominant position of the state and an extensive public sector. At the core of this welfare model lie the principles of universalism and broad public participation in various areas of economic and social life (Magnussen *et al.*, 2009). Traditionally, the central feature of the health care system has been an egalitarian model promoting equal access to health care services that are predominantly tax financed (Kristiansen and Pedersen, 2000). In 2017, Norway (along with Switzerland) had the highest per capita health expenditure in the world, estimated at over USD 6500 purchasing power parity. Public sources account for 85.5% of the current health expenditure in Norway (Saunes *et al.*, 2020).

From the 1990s, the government ideology in Norwegian welfare politics has been influenced by the private sector and market models (Lian, 2007). This trend was especially evident in an extensive hospital reform in 2002. In the reform, the ownership and responsibility for specialised

health care services were transferred from 19 counties to five regional enterprises (later, in 2007, to four), known as Regional Health Authorities (RHAs), which were subordinate to the Ministry of Health (hereafter, the Ministry) (Martinussen and Magnussen, 2009). Today, Norwegian specialised health care is semi-decentralised. The Ministry determines national health policy, prepares and oversees legislation and decides on the allocation of funds within the health sector. The Ministry steers the activities of the four RHAs (Western Norway RHA, South Eastern Norway RHA, Central Norway RHA and Northern Norway RHA) through legislation and ownership arrangements via budgets and governing letters (Saunes *et al.*, 2020). The Directorate serves as an executive agency and professional authority under the Ministry and has regulatory and implementing authority in areas of health policy (Directorate of Health, 2021).

Norway follows a general international trend (Coburn, 2006) in facing a decline in the autonomy of the medical profession as well as in their dominance in health care (Syse, 2012; Berg, 2013). This trend is related to a shift in the instruments used for medical governance as the request for public accountability has oriented these instruments towards hierarchical control rather than professional autonomy (Evetts, 2002; Burau *et al.*, 2009; Berg, 2013).

3. Analytical approach

I analyse the shift in regulation of clinical priority setting represented by the establishment of the priority guidelines as a reform. A reform is constituted by an active and deliberate attempt initiated by political or administrative actors to alter structural and/or cultural traits in organisations or current policy in a policy field (Christensen *et al.*, 2020). Different perspectives exist on reform processes and why some reforms fail while others succeed (Brunsson and Olsen, 1993; Christensen *et al.*, 2020). In this article, I will apply a so-called transformative perspective on public reforms (Christensen and Lægreid, 2018; Christensen *et al.*, 2020) to shed light over organisational factors that contributed to the success of the priority guidelines. This perspective combines insights from both an institutional and an instrumental perspective, emphasising that different factors in the process need to be considered and combined.

According to the so-called instrumental perspective, public reforms are carried out as planned changes initiated by leaders and superiors and are based on rational calculation and means-end thinking (Christensen et al., 2020). The reform process can be deliberately designed to reach the stated goals (Egeberg and Trondal, 2018). Within this view, autonomy for the organisations carrying out and implementing reforms is considered an important organisational factor for successful reform. The significance of autonomy is related to the notion that it leads to the best use of bureaucratic expertise and maximises bureaucratic effectiveness in executing and implementing policy (Meier et al., 2019). A further organisational factor related to successful implementation of reforms is sufficient action capacity. Action capacity encompasses the ability of the reforms to achieve their intended mission, and is indicated by the size of the reform organisation and the skills, expertise and competencies of the personnel, as well as the division of tasks, specialisation and co-ordination in implementing the reform (Christensen et al., 2020). The involvement of affected actors is another key organisational factor within an instrumental perspective affecting successful implementation of a reform. The inclusion of affected actors constitutes a key part of a fair decision-making processes, and procedural fairness contributes to trust in the decisionmaking process and to the legitimacy of the eventual decision. Inclusion can lead to better tailored solutions, lessen disagreement and improve adherence to policies, making them more effective (Compton et al., 2019; Norheim et al., 2021).

Institutional perspectives challenge the instrumental view of tight coupling between the organisation of the reform and its course and outcome (Brunsson and Olsen, 1993). According to institutional perspectives, established cultural traditions will influence the reform and the possibility for success. Existing informal norms and values will affect what procedures and solutions are considered appropriate in the reform process (Christensen *et al.*, 2020), and reform goals can only be

achieved to the extent that they are in accordance with the historical traditions, cultural norms and values of those involved (Askim *et al.*, 2010). Therefore, according to an institutional perspective, for reforms to be successful they must pass a compatibility test (Brunsson and Olsen, 1993).

The transformative perspective on public reforms applied in this article is based on the notion that no single factor, nor institutional or instrumental will explain the course and outcome of a reform, and different factors therefore need to be studied (Christensen and Lægreid, 2018; Christensen *et al.*, 2020). Thus, the project's autonomy, its capacity for action, the involvement of affected actors (instrumental factors) and the project's compliance with historical norms and traditions (institutional factor) are all significant factors to elucidate the successful establishment of the guidelines. To study these factors, the empirical analysis has focused on three dimensions of the priority guideline project; initial instructions given from higher-level organisations or agencies that may have influenced the project's autonomy, the project's organisational structure and the actors involved.

Following Verhoest *et al.* (2004), agencies' organisational autonomy is determined by the scope and extent of their decision-making competencies. These decision-making competencies can be constrained by instructions and regulations given *ex ante* by higher-level agencies as well as by structural, legal, financial or interventional means that limit the actual use of these competencies. In this article, I have mainly focused the investigation of the organisational autonomy of the priority guideline project on its scope of decision-making competencies and how initial instructions given by higher-level agencies as the Ministry, the RHAs and the Directorate, may have influenced the project's space for decision-making. Organisational autonomy encompasses autonomy in managerial and policy issues (Verhoest *et al.*, 2004). The level of managerial autonomy in the project can be related to eventual instructions given to the project in how to organise and who to recruit. The project's level of policy autonomy will depend on eventual instructions given to the project regarding the processes to carry out, and the policy instruments applied to implement the externally set policies.

A reform's capacity for action is related to its organisational structure. I have focused my empirical investigation on the priority guidelines project's size and the division and co-ordination of tasks. An extensive project organisation indicates plentiful resources but requires strong co-ordination and specialisation to have the capacity for action. Conversely, a small organisation might have less resources to implement the reform but be more effective in terms of co-ordination (Christensen *et al.*, 2010, 2020; Egeberg and Trondal, 2018).

The actors involved constitute the last element of the priority guideline project that I have investigated. The actors are of interest because of the action capacity that they possess in terms of their skills, knowledge and competencies. Further, a focus on the actors also sheds light on how affected actors were involved as well as the project's compliance with historical norms and traditions of medical governance. Therefore, I have investigated the actors involved by focusing on their background characteristics, including their primary organisational affiliation and position within this organisation and their educational background.

4. Methods and materials

The research questions raised in this article are investigated by analysing documents related to the project of developing the priority guidelines. This analysis is supplemented by an interview with one of the project's leaders from 2006 to 2009. The documents constituting the dataset analysed in this article were retrieved from an extensive data corpus, consisting of both policy documents and project documents mostly from the period from 2005 up to 2008, when the first 30 (of 33) guidelines were developed. The policy documents consist of official documents related to the project and were retrieved from the web pages of the Ministry and the Directorate or requested from the Ministry for the study. The policy documents included in the study are:

- 30 priority guidelines.
- The project directive for the project 'Better prioritisation in the hospital sector'.
- Governing documents from the Ministry to the Directorate and the RHAs and from the Directorate to the RHAs in 2005 and 2006.
- A report by the Directorate on developing priority guidelines (Helsedirektoratet, 2018).

The project documents consist of approximately 9000 documents that were either written or compiled by the project organisation, mostly by the secretariat, during the period in which the guidelines were developed. The documents were made available as electronic documents for the study by the project's former secretariat. They include several different types of documents, e.g., preparatory notes and reports from board group meetings, drafts for project directives, suggestions/drafts for priority guidelines, schedules for workshops, lists of participants and the log of the secretariat's work.

All 9000 project documents were initially studied briefly by the author. This was done by opening all documents and make a quick overview over the content by studying the document's name and headlines. All unique documents that contained information of relevance for the three analytical dimensions established in the analytical approach section (initial instructions placed on the project from higher-ranking organisations or agencies, the project's organisational structure and who participated in it) were extracted from the data corpus, and sorted into named files. These approximately 500 documents were studied more thoroughly and reduced to about 100 project documents that provided information on:

- Initial instructions from the Ministry, RHAs and the Directorate that may have influenced the project's space for decision-making in managerial and policy issues,
- The organisational structure in terms of size, division of task and coordination, and
- The actors involved in term of background characteristics, including their primary organisational affiliation and position within this organisation and their educational background.

These documents constituted, together with the policy documents, the dataset of the study and consisted of the following:

- Agendas, preparatory documents, suggestions for decisions and meeting reports related to eight project board group meetings from January 2006 to January 2007.²
- Drafts for the project directive.
- Notes from the secretariat to the Directorate's management and the project's board group in 2006
- Lists of participants in the priority guideline project.
- An instruction manual for developing specialty-specific priority guidelines.

Information related to the three analytical dimensions established in the study were marked and extracted from the original policy and project documents. This information formed the basis for a description of the autonomy of the priority guideline project, its organisational structure and the actors involved.

The data from the interview are largely used to support the findings from the documents or to seek for inconsistency between the documents and the interview. The interview was conducted before the documents were analysed. Internet-based searches were used to map most of the project participants' educational backgrounds, as this information was not evident generally in the project documents. For some participants, work positions at the time of developing the priority guidelines were also obtained in this manner.

²By January 2007, the decisions regarding organisation and what actors to include had largely been made. Only small adjustments were carried out regarding the actors involved.

5. Findings

In this section, the empirical findings are organised along three dimensions; the project's organisational autonomy, the organisational structure of the project and the actors involved.

5.1 Organisational autonomy in the project of developing the priority guidelines

The annual assignment letters from the Ministry to the Directorate and the RHAs in 2005 were the starting point for the priority guideline project, and constituted its principal mandate. The letters circumscribed the project's decision-making competencies in relation to some managerial and policy issues, but simultaneously left significant scope for discretion and freedom in others.

In relation to policy issues, the Ministry constrained the project's discretion regarding its strategic goals and course, as the assignment letter to the Directorate established that the objective of the project was 'to create a comprehensive strategy that can provide greater assurance that the specialist health service conducts its activities in accordance with current norms for prioritisation and, within the framework of strategy, measures are identified that can contribute to more correct priorities' (2005, part 1, page 17). Later in this letter, the development of guidelines as part of this strategy was explicitly mentioned. Further, the letter established that the Directorate and the RHAs were the project owners and were to hold decision-making authority regarding the eventual measures to be carried out in the project. The letter specified that these decisions 'should be made within existing competence structures of the different institutions' (2005, part 1, page 17). However, in accordance with the overarching objective, the priority guideline project board group later formulated their own goals for the project.

The assignment letters circumscribed the project's decision – making competencies in some managerial issues. In the 2005 assignment letter to the Directorate (part 1, page 4), the Ministry assigned the Directorate with the task of establishing and heading the project as a collaborative project with the RHAs. Some local projects were already established between the Directorate and the RHAs to translate the Prioritisation Regulation into recommendations for clinical practice, and the letters emphasised the importance of interacting with these projects. Apart from these instructions, the letters gave no formal indication of any other actors, organisations or institutions to be included in the project beyond the RHAs and the Directorate.

The Ministry initiated the development of the priority guidelines as a project outside already established organisations, but the Directorate and the RHAs were assigned as the project's owners. To evaluate the project's autonomy, its relation to the superior project owners is of importance. From February to June 2006, a newly established board group for the project headed by a person from the Directorate made several key decisions that influenced the project's organisational autonomy in both managerial and policy issues. These decisions were made with the approval of the project owners in the RHAs and Directorate. First, they decided that the board group would operate the project partly independently from the project owners, as the board group was to hold the decision-making authority in questions regarding the project. However, the board group had to ensure support from the project owners on principal issues, e.g. the project's budget. Second, the board group was to hold an extensive mandate, which included the authority to decide on the project's organisational structure, as well as holding the key decisionmaking authority regarding the operation of the project and approval of the guidelines. They were to decide who would have access to the process of developing the guidelines and to determine the roles, tasks, rights and duties of the participants. Third, they decided that the priority guideline project was to be carried out as a fully centralised project. The alternative was that the project was centrally co-ordinated, with each of the four RHAs responsible for forming specific priority guidelines. These initial decisions were key in granting the project independence from the RHAs and the Directorate. Although the project was headed by a representative of one of the project owners, and the project was to report and secure approval in key decisions, it was nevertheless characterised by significant organisational autonomy, especially in managerial issues.

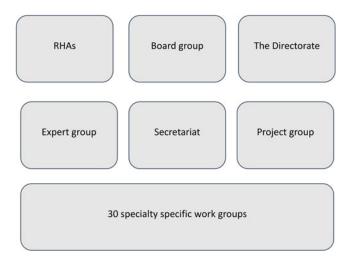


Figure 1. Project owners and project organisation.

5.2 The project's organisational structure

In spring 2006, the board group began to develop the project organisation together with a secretariat. The project organisation eventually established was comprehensive and consisted of approximately 240 participants. Several different groups were established as part of the project organisation. Figure 1 provides a simple overview of the different units established, in addition to the project owners.

The project organisation assigned each group specialised tasks and stands out as well organised. There were differences in how formal authority was distributed, and the project clearly had a hierarchy structure. As Figure 1 illustrates, the project's organisation consisted of several vertical levels, with the board group and the project owners at the top. The lowest vertical level consisted of different specialty-specific work groups.

The board group's key tasks were as outlined above. The secretariat and the project group were assigned a key co-ordinating role and the responsibility for operating and administering the project. The project's leaders (from 2007–2009 two persons did share this role) were members of the secretariat and were employed full time to administer the project. Further, both the secretariat and the project group were assigned to support the specialty-specific work groups and present suggestions for priority guidelines to the board group. Thus, the project group and secretariat had little formal decision-making authority but, given the tasks that they carried out, they had the capacity to influence both agenda-setting and the day-to-day work in the project. This was particularly the case for the secretariat, as it headed the project group and participated in preparing and commissioning the board group meetings. According to the interview informant, the secretariat prepared a comprehensive instruction manual for the specialty-specific work groups. This document, together with the project directive, played a key role in steering and co-ordinating the project.

The expert group was largely assigned an advisory role. It was to advise the other groups and assist in clarifying issues of a professional nature or those concerning principles. The expert group was assigned to formulate rules and an appeal system if the specialty-specific work groups were unable to reach consensus. The expert group held the authority to decide on these issues. Further, the expert group formulated templates for the specialty-specific priority guidelines and evaluated the work groups' suggestions for guidelines on behalf of the board group.

The task of developing specialty-specific guidelines was assigned to the work groups. Each medical specialty work group included in the project was to form a guideline for its particular specialty. Ten speciality-specific guidelines were developed in parallel, and the work groups

met for two days workshops two or three times. The work groups' suggestions for the specialty-specific guidelines were to be evaluated by the expert group, sent for a formal national hearing and finally approved by the board group. The work group had no formal influence on the final evaluation or approval of these suggestions. In addition to the project directive, the work groups were guided by an instruction manual describing a systematic method to apply when forming the specialty-specific part of the guidelines. The work groups were expected to follow the formal instructions in the process but had otherwise considerable leeway in assessing the conditions to be included in the guidelines, their legal status and eventual deadlines for treatments.

5.3 Actors involved in developing the priority guidelines

The priority guideline project consisted of several different units and there were a large number of positions to be filled with actors. Table 1 provides an overview of the actors who were included in the project's board group, secretariat, expert group and project group from 2006 to 2008, and their primary organisational affiliations, positions in the primary organisations and educational backgrounds.³ The fields of expertise that the expert group were assigned to cover in the project are listed in the figure. For the specialty-specific work groups, these variables are summarised in the text.

In establishing the board group in winter/spring 2006, conversations regarding which actors to include were held first between the project's secretariat and management in the Directorate, and then in the first board group meetings. Before establishing the board group, the Directorate decided that it and the RHAs were to be equally represented in this group. The secretariat formally suggested that representatives for municipal health care and patients should be included as members of the board group. The board group decided not to give these actors access, but to include them in specialty-specific work groups to be established later. The board group decided to admit the National Medical Association, a professional association and trade union organising 95% of Norwegian doctors (Legeforeningen, 2018), into the board group as an observer from June 2006.

The board group established consisted of five members, all of whom held leading management positions in their primary organisations. The National Medical Association was represented by its president. All board group members were educated as medical doctors. The RHA representatives were all key persons involved in local and regional prioritisation work.

The project's secretariat was employed by the Directorate and had various backgrounds. In the first phase of establishing the project, the secretariat consisted of only two persons, but more actors were recruited as the project grew and became more complex.

Once the board group was constituted, attention turned to establishing the expert group. The composition of the expert group was discussed and revised, and more areas of expertise were added to the group as the planning proceeded. A professor in medical ethics with experience in prioritisation issues and in developing priority guidelines in Western Norway RHA headed the expert group. Three members of the expert group were also members of an already established priority setting institution; the Norwegian National Council for Priority Setting in Health Care. The expert group eventually established had a broader composition than the other groups regarding educational backgrounds and primary organisations. Nevertheless, as Table 1 illustrates, four out of seven expert group members were educated as medical doctors.

The project group was established in late autumn 2006. Originally, it was suggested by the secretariat that the project group should consist of representatives from each of the five RHAs and a representative from the National Medical Association. In the preparatory work in summer 2006,

³In winter/spring 2008, there were some changes in the groups that are not evident in the figure. In the board group, the participant from South Eastern Norway RHA left and was replaced by a director of Central Norway RHA (also a medical doctor). In the expert group, the expert from South Eastern Norway RHA was replaced by a department director (again, also a medical doctor) from the same RHA. In spring 2008, the secretariat was supplemented with four new members.

Table 1. Primary organisational affiliation, position in primary organisation and educational background

Board group	
	• Directorate, deputy dir. general, MD (leader of the board group)
	Directorate, dir., MD
	• RHA West, dir., MD
	• RHA South, dir., MD
	National Medical Ass., president, MD
Secretariat	
From Jan 06 - Autumn 06	
	• Directorate, Master in nursing science (project leader, returned July 2007)
	Directorate, department director, MD
From Autumn 06	
	Directorate, economist (project leader)
	Directorate, sociologist (until Aug. 07)
	Directorate, MD
Expert group	
Prioritisation:	
	University of Bergen, professor, MD (leader of the expert group)
Ethics:	
	University of Oslo/Oslo University Hospital, professor/head of clinic, MD
Municipality health care:	
	Stord municipality, GP, MD
Systematic reviews:	
	Norwegian research centre for health service, researcher, MD (until March 07)
Law:	
	Directorate, legal advisor, legal scholar.
Process:	
	RHA South/East, chief management advisor, economist
Health economy:	
	University of Bergen, professor, economist
Project group	
	RHA North, head of clinic, MD
	RHA Central Norway, head of clinic, MD
	RHA West, senior consultant, MD
	RHA East, legal advisor, legal scholar

- Norwegian GP Ass./Bergen municipality, vice president/GP, MD
- · National Medical Association, head of section, philosopher

MD, medical doctor; GP, general practitioner. Board group, secretariat, expert group and project group.

the board group decided to include a representative for general practitioners (GPs) as well. The project group eventually established had six participants, but only four RHAs were represented. Most members in the group were educated as medical doctors (four of the six members) and were engaged in clinical work at the time of guideline development. It is worth noting that three of the medical doctors in this group moved into leading positions as senior advisors in the RHAs a few years later. The fourth medical doctor later headed the Norwegian Association of General Practitioners and was vice-president of the National Medical Association.

The work groups established consisted mostly of one or two participants from each RHA, and a representative from a university hospital, a GP and a representative for patients. The numbers of actors in the work groups established varied between five and 11. All the representatives for users in the work groups represented organisations, such as the Norwegian Diabetes Association and the National Association for Heart and Lung Diseases. The board group decided that the work groups could be supplemented with a representative from another medical specialty, other relevant professional groups or disciplines, and could include an RHA representative with responsibility for management and budgeting. In practice, this proved to be difficult to fulfil and was rarely carried out.

6. Discussion

The main object of this study is to provide insight into factors that made it possible to successfully establish and introduce a new tool for governing clinical priority setting, namely the Norwegian priority guidelines for specialist health care. The findings demonstrate that the project was characterised by significant autonomy in managerial issues as few constrains were placed *ex ante* on the project by the Ministry or the project owners concerning how to organise the project and what actors to include. However, the project's autonomy was more restricted in relation to policy issues, e.g. as the Ministry set the overarching goals to be pursued (developing priority guidelines). The findings show that even though structural, financial and interventional means as reporting could have circumscribed the project's space for the use of its decision-making competencies, the project enjoyed considerable organisational autonomy in relation to its higher-level agencies.

In terms of action capacity, I find that an extensive and well-organised project organisation was established that included a broad range of skills, knowledge and competencies. An extensive organisation, with several specialised units, as was the situation for the project, requires strong co-ordination to succeed. Two factors stand out as key for successful co-ordination in the guideline project: a secretariat that secured persistent attention for the project and the use of formalised instructions and plans.

The project of developing the guidelines included multiple actors in the field of health care. But were these affected actors? As priority setting involves 'decisions about the allocation of resources between the competing claims of different services, different patient groups or different elements of care' (Klein, 2010: 389), a broad range of actors can be considered as affected by the establishment of the priority setting guidelines. Many actors clearly affected by the priority

⁴Southern Norway RHA was unrepresented in the project group until it merged with Eastern Norway RHA in July 2007, forming South Eastern Norway RHA.

guidelines were included, such as hospital owners, representatives for patients, bureaucrats and clinical doctors. However, the guidelines first and foremost were aimed at steering medical doctors' clinical decisions. Thus, medical doctors can be regarded as the actors mostly affected by the establishment of the priority guidelines. Medical doctors were very well represented in the project, both in terms of numbers and rank. The importance of involving affected actors in developing the guidelines goes beyond including relevant views and technical expertise in the project, and encompasses matters of trust and legitimacy. The broad inclusion of affected actors in the project is likely to have strengthened the procedural legitimacy of the project. If actors affected by the establishment of the priority guidelines considered the process of developing them to be fair, it is likely that this would have improved acceptance of the guidelines by actors who may have initially opposed the establishment of the guidelines or substantially disagreed with the content (Norheim et al., 2021).

The findings demonstrate that medical doctors dominated the project in terms of both numbers and rank. This finding is supported by Syse (2012), who argued that the priority guideline project was more of a medical professional project than a juridical/legal project. In this sense, the development of the priority guidelines did not represent a radical break with the tradition of medical self-regulation. As the project organisation distributed tasks in accordance with the actors' positions in their primary structure, the project represented a well-known distribution of tasks and authority in the field of health care. By demonstrating that the project did not challenge the existing hierarchy in health care, and that it allowed for medical dominance in the process, I clearly show that the project of developing the priority guidelines was organised in compliance with historical traditions and norms for medical governance.

In conclusion, answers to the sub-questions raised initially are that the priority guideline project had significant autonomy in managerial issues, but less in policy issues. Further, the project had high levels of action capacity, broad involvement of affected actors and was organised in compliance with historical norms and traditions. These organisational factors are likely to have contributed to the success of the priority guidelines. However, to answer the main research question raised in this study key questions are as follows: What were the relationships between these factors, and are some factors more significant than others to understanding why the priority guidelines were successfully established? It is probable that there were interconnections between some of the factors. For example, the project's organisational autonomy in managerial issues could be important in allowing for medical dominance in the project. Locating decisions regarding how to organise the project and who to include outside the political realm, and therefore closer to the actors and organisations that were to implement the guidelines, is likely to have contributed to the project being organised in compliance with historical traditions and norms for medical governance. Although the successful implementation of reforms depends on multiple institutional and instrumental factors, compliance with established norms for medical governance stands out as a key factor in understanding how it was possible to successfully establish the priority guidelines as a new mode of regulation. As the medical doctors could be considered to have the strongest potential to veto the process, securing the support and commitment of the medical community was essential for the priority guideline project to succeed. The organisation of the project gave representatives from the medical profession positions that allowed them to influence the content of the guidelines. To what degree the actual content of the guidelines represented a break with established medical professional practice is another relevant factor in the success of the project. Although investigating this factor is beyond the scope of this article, I highlight the organisational arrangements that would enable this type of influence.

My finding of the existence of path-dependent elements in organising the project to develop the priority guidelines is in line with other studies on medical governance reforms, which emphasise the importance of existing institutions and pre-reform policy pathways to understand how reforms unfold (Wilsford, 2007; Burau *et al.*, 2009). However, by complying with existing traditions and norms for medical governance, the priority guidelines run the risk of codifying existing

practices and power relations in priority setting and the support from key actors in reform processes needs to be balanced against the risk of excluding other relevant actors.

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