Governance models in healthcare – draft of a model for ethical analysis

The Swedish National Council on Medical Ethics

Stockholm 2019

Smer report 2019:2

This is an unofficial translation of the report Governance models in healthcare – draft of a model for ethical analysis, published in April 2019.

Smer report 2019:2. Governance models in healthcare
– draft of a model for ethical analysis

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Layout: Committee Service, the Government Offices of Sweden

Foreword

Healthcare governance and management is and has been subject to intense debate in recent years in Sweden. New governance models for healthcare are launched at regular intervals. The Swedish Government has recently appointed several commissions to submit proposals for the future management of healthcare.

The question of how publicly-funded healthcare institutions such as hospitals are governed and the consequences of this are of great importance for patients, relatives and citizens, for professionals and staff, and ultimately for society as a whole.

The Swedish National Council on Medical Ethics (Smer) is an advisory board to the Swedish Government and Parliament on bioethical issues. The Council shall encourage an exchange of knowledge and opinions and serve as a link between science, citizens and political decision-makers, and shall also encourage public debate on bioethics. The Council decided to publish this draft of an ethical analysis model as decision-making support when choosing governance models for healthcare.

This report aims to highlight the relevance of organisational ethics issues in terms of managing and organising healthcare. A concrete proposal is also presented as a tool for the ethical analysis of governance models in care. We hope that the report can contribute towards a broad discussion at different levels on where, when and how ethical analysis should be used when making decisions on the governance of healthcare.

This report has been written by a working party consisting of Göran Hermerén, professor emeritus and expert member, Ingemar Engström, adjunct professor and expert member and Lotta Eriksson, general secretary. The decision of this report have been made by the following members of the Council: Chatrine Pålsson Ahlgren, Finn Bengtsson, Sven-Olov Edvinsson, Åsa Gyberg-Karlsson, Anna-Lena Sörenson and

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Stockholm, April 2019

On behalf of the Council,

Chatrine Pålsson Ahlgren

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Summary

The question of how the provision of healthcare services is organised and managed as well as the consequences of this are of great importance for patients, relatives and citizens, for professionals and staff, and ultimately for society as a whole.

Healthcare management has been subject to intense debate in Sweden in recent years. On the one hand there are demands for changed working methods and governance models in order to improve the effectiveness of healthcare. One the other hand various models have been criticised for not having the intended effects and potentially coming into conflict with the objectives of healthcare in Sweden.

How can and should management best take place at different levels in order to meet the objectives of healthcare – including to provide good health and care on equal terms for the entire population – while at the same time being cost-effective?

Healthcare should be managed on the basis of established objectives and aims

Healthcare in Sweden is publicly financed in all essential respects, which involves demands for its governance to be based on politically established objectives and aims. The overall frameworks for leading and organising publicly-funded healthcare are set by the Government and the Riksdag (Swedish Parliament). In accordance with the Instrument of Government (1974:152) public power shall be exercised with respect for the equal value of all people and for the freedom and dignity of the individual. There is a framework law for healthcare – the Health and Medical Services Act – containing many objectives. Management of the economy is not an objective in itself but a means to achieve the objectives or the required results.

Ethical analysis is needed before governance models are introduced

The term 'governance model' is used in this report in a broad sense to describe different models for how healthcare services should be managed and organised at different levels.

Governance models for healthcare are not value-neutral, which is why the Council emphasises in this report that a detailed ethical impact analysis of changes to the management systems should be carried out before current models are changed or new ones are introduced. This means that an analysis should be conducted of the values that are explicitly or implicitly included in the governance model, the consequences the model is likely to lead to and how these values and the model's anticipated consequences relate to the objectives that healthcare should achieve according to the Health and Medical Services Act and other objectives and requirements contained in the legislation.

An analysis that is carried out before a new governance model is introduced at some level should involve a comparison between different alternatives, where one alternative is to continue as before.

This is a starting point for the Council's report on ethical aspects when choosing governance models within healthcare.

A proposed model for ethical analysis of governance models in healthcare

Ethical analysis can be a valuable tool in the process of designing and improving the management of healthcare. This can constitute a tool – which decision-makers, officials and the profession as a whole can use when they cooperate – in order to adapt, assess or draw up governance models. The ethical analysis can then be a point of departure, supporting both quality and cost-effectiveness in ways that are in accordance with set values and objectives for healthcare. These governance models should build upon the leadership system for quality and patient safety (SOSFS 2005:12), which allows for continuous improvements and for risk and impact assessments.

Within the context of this work, the Council has not identified any framework for ethical analysis with a focus on management and organisation models in healthcare either among other national ethics

councils or in the literature. The Council has therefore drawn up a proposed model for a structured ethical analysis of governance models in healthcare. A concrete tool in the form of questions that may support such an analysis is also presented. The hope is that the tool may be useful when management and organisational changes are considered at various levels, such as national, regional, hospital or care unit level. The model can be used both when introducing new models and when analysing systems or models that have already been introduced. The ethical tool is a proposal and is intended to be used in the continued discussion and development of the management, leadership and organisation of healthcare.

A tool for ethical analysis

The presented analysis model focuses on goals and obstacles for the provision of healthcare. This approach is particularly suitable when the operation or activity under discussion has reasonably clear objectives. The model is based on four basic concepts – the current situation, goals (objectives), obstacles (barriers) and strategies – and the questions raised under these headings: Where are we now? Where do we want to be? What barriers are there along the way and how can we overcome them? This report presents instructions for using the model and questions that operationalise the model.

The aim of this ethical analysis is to demonstrate a way of thinking when the intention is to make well-founded decisions on governance models. It suggests a number of questions under the above headings and certain quality demands are placed on the answers given to these questions. It must be possible to provide evidence for these answers; the answers must not be based on poor research.

A critical review of the reasons or evidence for assertions about a governance model and its anticipated effects is therefore essential. The important thing is that relevant questions are asked, serious attempts are made to answer them and the need for ethical competence is emphasised. It is particularly important to highlight and clarify those values that come into play and any conflicts of values that arise.

The Council's general conclusions and recommendations based on the proposed model are as follows: 1) Take the questions raised by the goals and obstacles analysis as a point of departure, (2) compare

the answers to these questions with what is asserted in or about the proposed changes to the governance instruments, tools or model, and 3) review the evidence or reasons given for these assertions.

Target group

The primary target group for this report is decision-makers at various levels (national, regional and municipal), officials and healthcare professionals. The text may also be of interest to patients, their relatives and their organisations, as it is ultimately they who are affected by the choice of governance models.

Recommendations

There is a need for continuous monitoring and evaluation of management and governance models for the provision of healthcare services of different kinds. Several central government agencies analyse the governmental management of municipal operations, including healthcare. However, neither the National Financial Management Authority (ESV), the Swedish Agency for Public Management, the National Board of Health and Welfare nor any other agency has been tasked with guiding municipalities and regions when it comes to how they should manage their activities. This may have contributed towards the significant interest in new governance models for healthcare that are often marketed intensively by various companies. Central government should play a greater role in supporting knowledge in relation to management and governance models in healthcare.

There is a need for more research into the management of publicly-funded healthcare and ethical analyses of this field.

The Council is of the opinion that:

– Ethical analysis is a tool that should be used at different levels before introducing management and organisation models (and in the analysis of existing models) in healthcare.
– Ethical competence among decision-makers at different management levels is essential and must therefore be provided and developed.

– New models should be developed and improved in collaboration between professionals and decision-makers, taking value issues and the ethical analysis as a starting point.

1 Introduction

Healthcare in Sweden should be designed on the basis of politically established objectives and operational aims. Swedish healthcare is publicly financed in all essential respects. Responsibility for healthcare is shared between the Government, regions and municipalities. The overall goal of healthcare is to provide good health and care on equal terms for the entire population. The provision of healthcare services is complex. It relies on highly qualified personnel and is governed by a framework law with many objectives.

There are different types of governance models in which economic, legal, organisational and other incentives are used, either individually or in various combinations. The question of how healthcare operations are managed and the consequences of this are of great importance for patients, relatives and citizens, for professionals, for related operations and ultimately for society as a whole. Many questions are raised.

Specific requirements are also placed on the management of publicly-funded operations.[1] The overall frameworks for leading and organising publicly-funded institutions are set by the Government and the Parliament (Riksdag). In accordance with the Instrument of Government (1974:152) public power shall be exercised with respect for the equal value of all people and for the freedom and dignity of the individual. Effective use of economic – resources – is not an objective in itself but a means to achieve the objectives or the required results.[2]

Decisions on governance models can be made at different levels within healthcare: nationally, regionally, at hospital level and at clinic level. The choices and the distribution of responsibility at these levels are not the same. Nor are the objectives always the same at different levels. They are more generally formulated at a higher level and more

[1] The National Financial Management Authority 2014.
[2] Ibid, p. 37.

specific at a lower level. The choices made at a higher level involve certain restrictions in the options at lower levels.[3] Regardless of the level, this can involve completely different types of management. Different governance models may be needed depending on the level and the objectives of the activities carried out.

In recent years the choice of governance models in healthcare has been subject to extensive discussions. A number of central questions with ethical relevance have been discussed in this context. Examples of such questions include: On what grounds are models for managing and organising healthcare at different levels selected? Which considerations should form the basis for choosing such models? Which ethical issues are relevant in this context? What consequences with ethical implications can different governance models involve? Who are the actors and the parties affected, and what competences should those who make decisions on governance models have?

The background to the Council's report is the intense debate on value-based care in 2017. In August 2017 the Government commissioned the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) to review the knowledge base regarding the value-based care governance model. Smer was then asked by SBU to assist with an ethical analysis of value-based care within the framework of SBU's work. During the course of this work, it was decided that Smer would report on its work separately. SBU submitted its report in May 2018. Smer's work has since developed into a general discussion on governance and organisation models, with a focus on the ethical aspects and consequences of choosing governance models generally within healthcare.

Questions about the management and organisation of healthcare relate to value issues and potential conflicts of values. Governance models for healthcare are not value-neutral. It is therefore important to clarify how the values that are explicitly or implicitly included in the governance model relate to the objectives that healthcare should achieve according to the Health and Medical Services Act and other objectives and requirements contained in the legislation. This is a central starting point for this text. As far as the Council is aware, no ethical analyses of new or existing governance models are currently carried out.

[3] On the other hand, regional and municipal autonomy can involve certain restrictions in management from national level.

The term *organisational ethics* is often used within bioethics to describe this field of knowledge. Smer has previously worked with issues that touch upon organisational ethics, e.g. in projects on priorities within healthcare and most recently in the ethical analysis of proposals to introduce co-payment models to healthcare.[4]

The aim of this report is to propose a model for an ethical analysis to be used before choosing governance and organisational models in healthcare. It should also be suitable to use when assessing management systems that are currently used or in situations where there is no clear model for how the activities of an institution are managed and organised. The present report includes suggested questions that are relevant to take into account in this context as well as ways of thinking when a new governance model is proposed internally or when decision-makers are faced with external proposals to choose a new governance model. The aim of this report is that it should lead to more in-depth critical, probing questions being asked when deciding on new governance models in healthcare. The report also emphasises the relevance of ethical analysis within this field.

The primary target group for this text is political decision-makers at various levels of healthcare (national, regional and local), as well as non-political officials and healthcare professionals. The text may also be of interest to patients, their relatives and their organisations, as it is ultimately they who are affected by the choice of governance models.

The report begins with a description and definition of the governance model concept followed by a short section on organisational ethics within the field of healthcare. Then follows a brief description of the background to healthcare management. A model for ethical analysis is then described. It provides a structure for thinking before introducing a new governance model in healthcare. The ethical model is operationalised through a set of questions which can be used as a concrete tool in such an analysis. The report concludes with considerations and recommendations.

[4] The Swedish National Council on Medical Ethics 2014.

1.1 What is a governance model?

The National Financial Management Authority defines a governance model as an overall idea that determines how governance and its components shall be designed.[5] The term 'governance model' is used in this report in a broad sense to describe different models relating to how the work of a healthcare institution, department or unit will be managed and organised at different levels. 'Governance model' is thus used in this report as a collective term for different types of initiatives for managing and organising healthcare.

The structural level relates to how operations shall be organised and managed, while the individual level guides the actions of the individual employee. One requirement for a successful governance model is that management at organisation and individual levels cooperates and creates a culture where employees feel motivated and involved. A requirement for effective governance is a well-thought-out governance model that influences the organisation's decisions and behaviour in the desired direction.[6]

Relevant questions include keeping in mind the objectives of the healthcare institution or unit. What must be governed, at which level, how can the results be achieved and how do different means of governance relate to each other and to the whole?[7] In situations where a new model will be introduced, the starting point also includes an analysis of the shortcomings and limitations of the model(s) currently used.

A governance model consists of *governance structure*, *governance instruments* and *governance tools*. *Governance structure* specifies the structure and direction of the management. Performance management, regulatory intervention, management by values and financial governance are different governance structures that can be combined.[8] The task and character of operations, internal strategic choices and desired direction determine the most suitable *governance structure(s)*. The combination of governance structures interacts with management at both organisational and individual level.

Governance instruments are the relatively fixed structures designed based on what needs to be managed. The structure – the design of the organisation – consists of both common organisational factors such

[5] The National Financial Management Authority, p. 44.
[6] Ibid.
[7] Ibid.
[8] Ibid.

as task, strategy, organisation and allocation of resources, and the organisation's culture in the form of common attitudes and values. These structural factors set the framework for the organisation's culture, distribution of responsibility and tools for governance.[9]

Examples of *organisational governance instruments* include organisational structure, rules of procedure and distribution of decision-making processes and responsibilities. Governance instruments can relate to *rules*, such as guidelines, rules and procedures. *Employer policy instruments* may be salary and career paths, competence strategies, leadership and employeeship, organisational culture or communication. *Planning and monitoring* are instruments for obtaining the desired direction of the healthcare institution and its activities. The choice of governance instruments depends on what this governance should focus on. It is important that the governance instruments pull in the same direction and thus reinforce each other.[10]

Governance tools provide the organisation with the information needed for management. This is the most practical level of governance that impacts on an employee's day-to-day work. Governance tools can be e.g. system support, process control, indicators and internal reporting such as analysis results.[11] Governance tools should be chosen based on the task and character of operations, its focus and form, and its governance structure. They should also be linked to governance instruments for the focus of operations.[12]

[9] Ibid.
[10] Ibid.
[11] Other examples include remuneration models, assignment descriptions, agreements for procured operations, books of requirements for care choices, etc.
[12] The National Financial Management Authority 2014, p. 44 ff.

2 Organisational ethics within healthcare

Issues of organisational ethics are becoming increasingly relevant in a changing healthcare landscape. Healthcare has undergone far-reaching changes in recent decades and there will be more changes in the future. We are currently seeing rapid technological developments with medical advances alongside new ideas and research findings on managing care. The direction of healthcare has also shifted towards an organisation that is increasingly adapted in line with the market. The inner logic and interests of the various domains[1] are affected, and new and old conflicts of goals have been sharpened and may be sharpened further. Other goals may also come into conflict with healthcare goals. Emerging research and literature analyse these issues.[2]

Organisational ethics is the field within bioethics that analyses ethical aspects of issues raised by the structure and organisation of care, such as different remuneration systems,[3] care choices and prioritisation ethics, in contrast to clinical ethics which focuses on the individual and the patient-doctor relationship.[4] It is pointed out in the literature that organisational ethics within bioethics is and has

[1] The literature describes healthcare's three domains with in-built conflicts of interest: politics, administration and the profession. The domains are built on different logics and have different tasks. See e.g. Berlin and Kastberg 2011.
[2] See e.g. Dahlgren 2018, Falkenström and Höglund 2018, Firth 2013, Firth 2018 and Feiler et al. 2018. The researcher Firth for example proposes – against the background of ongoing developments – that organisational ethics programmes should be introduced into the NHS to analyse the ethical issues and problems relating to management and organisation in the UK. In Canada there are examples of local ethics committees that have to take a position on organisational ethics issues alongside clinical ethics.
[3] There is however other research (not from an ethical perspective) that analyses e.g. the pros and cons of different remuneration systems, primarily within economics. See e.g. Anell 2010 and Lindgren 2014.
[4] Spencer et al. 2002.

been a natural development of bioethics towards a version of bioethics that studies "the moral sociology of organisations and the broader context of individuals as biosocial organisms."[5]

Current questions from a general organisational ethics perspective include: What are the organisation's objectives and values? What are the organisation's working models, guidelines and promotion criteria? How does the organisation deal with conflicts of interest? What responsibility does the organisation have to its clients? How do the organisation's actions affect society as a whole?[6]

Gibson et al. highlight three main types of organisational ethics issues: 1) ethical issues that arise in clinical care/everyday care as a result of decisions made elsewhere in the organisation, 2) ethical issues in clinical care with extensive organisational implications and 3) ethical aspects related to business aspects of the healthcare organisation.[7]

Organisational ethics has largely been developed in North America, but there is also an emerging discussion in Europe.[8] Ethical issues relating to resource allocation, i.e. prioritisation ethics have long been analysed in e.g. Sweden and Norway. These issues have also been repeatedly analysed by the Swedish National Council on Medical Ethics.

When it comes to other areas of organisational ethics that analyse ethical aspects of different forms of governance models (remuneration models and other organisational models), there is currently little research in Sweden even if the ethical implications of changes within the management and organisation of healthcare are discussed and analysed extensively in different contexts.[9] Current examples that touch upon governance models from an ethical perspective include Falkenström and Höglund's study (2018)[10] and Ljungblom (2014)[11] who studied whether ethical care is taken into account in the implementation of LEAN. There are also more articles in the international literature.[12]

[5] Potter 1996. Bishop et al. 1999. Gibson et al. 2008. Firth 2018. Wolpe et al. 2000.
[6] Firth 2018.
[7] Gibson et al. 2008.
[8] "Organizational Ethics in Healthcare." Encyclopedia of Bioethics. Encyclopedia.com. Retrieved: 2 January 2019 <https://www.encyclopedia.com>
[9] There is however other literature from e.g. an economic perspective that analyses e.g. the consequences of different types of remuneration models, e.g. Anell 2010 and Lindgren 2014. This report highlights the analyses from an ethical perspective.
[10] Falkenström and Höglund 2018.
[11] Ljungblom 2014.
[12] See e.g. the following articles which problematise value-based care from ethical perspectives: Bailes et al. 2014, Bircher and Hahn 2017, Bozic and Wright 2012, Dainty et al. 2016, Enthoven, Crosson, Shortell et al. 2007, Enthoven and Tollen 2015. Faith 2013, Goldstein 2016, Oprea et al. 2010, Putera 2017, Simpson 2012, Indrakanti et al. 2012.

The starting point for the Council's work in this report is to analyse ethical problems in the provision of healthcare services of different kinds with stated objectives. The aim is to direct attention to the fact that a number of value questions are raised in connection with changed leadership and management of healthcare. Against this background the assignment was to draw up decision-making support in the form of a set of questions that can be asked when comparing and analysing governance structure, governance tools and governance instruments that have been used to date, and before considering new models, in order to investigate which of these suits the organisation.

Within the framework of this work the working party has searched the organisational ethics literature to see if others have developed decision-making support or questions for the ethical analysis of new governance models to be used before making a decision in healthcare. We have identified one article of interest for our work which formulates questions to support the assessment of new policies and which also corresponds to a certain extent with the set of questions we have drawn up. Based on their experiences as members of the Canadian ethics council at IWK Health Centre, the authors describe the experiences and challenges they encountered when making the transition from theory to practice and including organisational ethics questions in their work. The committee has formulated a number of questions to support its ethical analysis of different policies.[13] The questions developed to support the assessment of different types of guidelines include the following:[14]

- What are the values (explicit or implicit) at issue in the policy?
- Are these values clearly articulated or should they be?
- Are the values congruent with the health centre's values?
- What are the relevant ethical principles or theories operating in this situation?
- What is the potential 'good' or the potential 'harm' inherent in this policy (including the potential for moral distress)?
- Does the policy restrict or limit treatment options?
- Does the policy treat all those who are affected by it equally?

[13] McDonald, Simpson and O'Brien 2008.
[14] A full list is presented in Appendix 1.

– Were the 'right people' (those who might be impacted, those who have to apply the protocol or guidelines, etc.) included in the process of policy development?

3 Swedish healthcare governance

The provision of healthcare has to consider many objectives expressed in a framework law and a number of other steering documents of various types.[1] Several groups of actors may also be discerned who have or may have competing objectives and interests.[2] Healthcare is therefore particularly challenging to manage. There are no obvious solutions to how it should best be organised and managed.

Researchers have identified three different phases in the development of national healthcare systems from a historical perspective. The first phase focuses on care on equal terms, the second imposes cost control requirements and the third features increased demands for results and value for money.[3] These phases can also be identified in the development of Swedish healthcare. There are clear links between each phase and method of managing care and how the remuneration principles have been designed.[4]

According to the literature in this field there have been "four dominant organisational ideas within the county councils' healthcare planning:[5] decentralisation, market emulation, cooperation and coordination" since the 1970s.[6] These ideas have succeeded one another, but have also existed simultaneously within the organisations.[7] Several organisational ideas compete for influence over the continued development of care. A number of governance models have been tried and retried in recent decades, primarily to achieve greater cost control,

[1] See Appendix 2.
[2] Hallin and Siverbo 2003.
[3] Cutler 2002.
[4] Anell 2010, p. 28.
[5] Hallin and Siverbo mean by 'planning' that the dominant idea within the county councils during the 1970s and the early 1980s was long-term planning. Spri (the Institute of Healthcare Planning and Rationalisation), the National Board of Health and Welfare and the Ministry of Health and Social Affairs were central players in this process.
[6] Hallin and Siverbo 2003, pp. 51–52.
[7] Berlin and Kastberg 2011, p. 30 ff. Hallin and Siverbo 2003.

enhanced effectiveness and deeper democracy. Care on equal terms has also been an objective.[8]

Since the 1990s the most widespread governance models in healthcare have been models inspired by NPM (New Public Management)[9], such as management by objectives: total quality management (TQM); quality: quality, development and leadership (QUL); balanced operational management; lean production and value-based healthcare.[10] Different concepts tend not to survive for long in healthcare. International experience suggests survival periods of three to five years. A couple of the models live on for a few more years in different variants but with limited practical significance.[11]

The term 'pseudoinnovation' has been used in scholarly literature to describe this phenomenon. This means that concepts replace each other but are essentially based on similar ideas and methods despite using different terminology.[12] There is a high degree of contagious effect when new governance models and solutions are disseminated. Ideas and solutions for Sweden often come from the Anglo-Saxon world – particularly the US and the UK.[13] However, many problems can arise when governance models are transferred between countries with different healthcare insurance systems and different ways of providing healthcare services.

3.1 The difficulties of managing healthcare

Healthcare in Sweden is difficult to manage. There is sometimes a discrepancy between different governance models based on the administrative level, the objectives in practice (e.g. the professionals' work ethics) and the official objectives for healthcare derived from legislation, guidelines and international agreements that Sweden has committed to following.

This does not rule out comparing the objectives that different governance models claim they will achieve with the objectives for

[8] Hallin and Silverbo 2010, p. 187 ff.
[9] NPM stands for New Public Management. It relates to the collection of market-inspired solutions in public organisations that have gradually been introduced within the public sector since the 1980s.
[10] Öhrming 2017.
[11] Walche 2009. Fredriksson et al. 2015. SBU 2018.
[12] SBU 2018.
[13] Anell 2010, p. 27.

the healthcare organisation on different levels that the model will be applied to. In certain respects the difference can be entirely clear.

The literature highlights various explanations why healthcare is hard to manage including the following:

- Healthcare includes many different decisions and activities, and a change in one area can have consequences in other areas. This places demands on cooperation and coordination.[14]
- The political, administrative and professional players compete with each other for control of decisions and activities and the values to be created.[15]
- The administrative governance models find it difficult to break through as most people in healthcare work according to a professional logic. Even if a governance model is used, it often does not have the intended effect.[16]
- The profession's decision-making mandate and role. Politicians have a mandate to make decisions on resources and the direction in which decisions and organisations should be developed, but they are also heavily dependent on the profession's decision-making when assessing individual cases. Doctors have great opportunities to make decisions with considerable significance for the content and resource consumption.
- Healthcare is managed by elected politicians who must decide during their mandate period on the objectives, direction and financing of operations. (The length of the political mandate periods may for instance have an impact on whether decisions are made quickly and without being preceded by in-depth analysis.)
- It can be hard for the decision-makers to get an overview of the extensive regulation of healthcare activities.

[14] Hallin and Siverbo 2003. Lindberg and Blomgren 2009.
[15] Hallin and Siverbo 2003.
[16] Broström et al. 2000.

3.2 A lack of impact analyses and ethical analysis?

The question is then if, and if so how, analyses of the consequences of the likely effects of various proposed models of governance are made by decision-makers at different levels within healthcare before various reforms and changes to the management and organisation of healthcare in Sweden. Within the framework of this work, the Council has not carried out any in-depth analysis of these questions. Against the background of the debate, newly published studies and the dialogue organised by the working party and the Council with various experts, however, there is reason to maintain that impact analyses[17] of governance models, which also include ethical analysis, are not currently carried out or are only carried out to a minor extent.

A recently published ESO[18] report states that there are in general significant deficiencies in terms of impact analyses ahead of major reform decisions in Sweden. Either no in-depth analyses are carried out or they are too late, too narrow in scope or substandard. In many cases it has subsequently seemed incomprehensible that certain consequences could not have been foreseen and counteracted in advance. The report recommends that unbiased socioeconomic impact analyses should be carried out at an early stage with a broad focus on consequences for central government, citizens and industry. The report also points out that the work involved with socioeconomic impact analyses should be strengthened in all parts of the civil service.[19] This analysis focuses on the lack of socioeconomic impact analyses before reforms are carried out and the fact that there is also no follow-up of the effects of various reforms.[20]

A study by Öhrming[21] notes with surprise that Stockholm County Council engages external management consultants to a large extent following decades of marketisation and privatising healthcare in

[17] In an impact analysis the likelihood of the consequences should be stated or estimated and then assessed on the basis of values and principles.
[18] ESO, the Expert Group on Public Economics.
[19] Forsstedt 2018.
[20] The EU carries out ongoing work in connection with improved regulatory impact assessments (RIAs). This is part of the EU's 'better regulation' work and is an agreement between the Commission, the Council and the Parliament in 2003 and 2016. The objective of an RIA is to produce proposals that lead to political objectives being achieved at the lowest cost and the greatest possible benefit for citizens, businesses and employees. It is a tool for structuring and making decision-making more transparent and for making considerations possible (cost-benefit, effectiveness). No RIAs are carried out in Sweden according to Forsstedt's 2018 study.
[21] Öhrming 2017, p. 122.

Stockholm.[22] His study highlights several examples of serious deficiencies in the knowledge base and impact analyses ahead of key decisions made by the studied county council.[23]

3.2.1 Lack of ethical competence in the leadership and management of healthcare

As far as the Council is aware, no systematic work is carried out regarding ethical analyses of issues affecting the implementation of new governance models in healthcare in Sweden or of existing models at either regional or local level. Where this does happen, it is only on a small scale and is not systematic.[24]

Discussion and analysis of ethical issues raised in healthcare are carried out in different ways in the different regions and at hospital level. There is currently an ethics council with a mandate from the region in nine of the 20 regions. There are also local ethics councils or groups at hospitals and university hospitals in most regions.[25]

There are several examples of ethical issues touching upon leadership and management issues being noted and discussed[26] but we have not found any systematic ethical analyses in the respective regions regarding questions relating to new governance models among either the ethics councils or the management of the regions. A current survey reveals that several of the ethics councils linked to the regions indicate that there is a lack of dialogue and that the ethics groups want more insight into decisions in order to boost the possibility of integrating ethical aspects into the regions' documentation and work.[27] Nor has it transpired in the Council's meetings with various county councils on ethics work and current ethical issues that ethical analyses are carried out before choosing governance models. Ethical issues relating to resource allocation and prioritisations are, however, addressed to a greater extent, and in some cases even systematically.[28]

[22] Öhrming 2017, p. 122.
[23] Ibid.
[24] The Council has not carried out any mapping of the issue within the framework of this work. This is an assessment based on literature, contact with various experts and the Council's previous dialogue with different county councils.
[25] Chenik 2019, Chenik 2015.
[26] Chenik 2019.
[27] Chenik 2019, p. 8.
[28] See e.g. Brinkmo 2007, Chenik 2019.

An empirical study by Falkenström and Höglund[29] shows that various decisions concerning the organisation and provision of healthcare services are made without ethical assessment and with inadequate impact analyses within a county council (region). The study reviews ethical competence based on different forms of decision-making within a county council – Stockholm County Council – when it comes to budget work, care agreements and reform work. The authors identify examples of haste, self-interest, power games and (with a few exceptions) an absence of ethical competence. Their results are summarised as follows:

"Our results indicate that there is a lack of ethical dialogue, communicative rationality and systematic ethical analyses where alternative courses of action are considered that could offer factually wellfounded arguments for the ethical legitimacy of political decisions on the leadership and governance of care."[30]

The study shows that both individual and collective ethical competence is called for within all key groups in the healthcare leadership organisation in the studied region. Also, joint inter-organisational collective ethical competence is required in order for management practice to be able to live up to the ethical requirements set out in the Health and Medical Services Act and other central steering documents. The authors also believe that this is required in order for politicians, officials and responsible managers to be able to take ethical responsibility for the conditions created for caregiver organisations so that good care on equal terms for the entire population can be achieved.[31]

3.3 The debate on the management and organisation of healthcare

The management of healthcare has long been debated in Sweden.[32] On the one hand there are demands for changed working methods and governance models in order to improve the effectiveness of care. One the other hand various models have been criticised for not having the intended effects and potentially coming into conflict with the objectives of publicly-funded healthcare.

[29] Falkengren and Höglund 2018.
[30] Ibid, p. 189.
[31] Ibid, p. 283.
[32] SOU 2017:56.

In recent years the debate has related mainly to governance models based on New Public Management (NPM) and the effects of commercialising care with private providers whose central motivation is profit. The debate on NPM gathered pace following a 2013 series of articles in the Swedish newspaper Dagens Nyheter, which attracted considerable attention and in which the introduction of governance models was highlighted as one of the main reasons for the problems experienced in healthcare.[33] It has also been pointed out that the debate and the criticism levelled against NPM has been one-sided and lacking in nuance.[34] In line with growing Swedish interest in value-based care and the introduction of the model at three large university hospitals – either throughout the hospital or within selected clinics – the debate surrounding this particular model has intensified in recent years.[35] The value-based care concept was first presented in 2006 by the American economists Michael Porter and Elizabeth Olmsted Teisberg.[36]

Research is currently being carried out in both Sweden and the UK with the aim of determining the effect of the 'marketisation' of public healthcare in the two countries. The ethical aspects of these issues are attracting ever greater attention.[37]

Several commissions have been appointed in Sweden in response to the extensive criticism directed against the effects of New Public Management (NPM) within the welfare sector. They have been tasked with drawing up alternative principles for managing publicly-funded operations. The Trust Delegation (a government inquiry) has recently submitted its proposals for trust-based management.[38] The Swedish Society of Medicine highlights important principles for healthcare management in its programme of ideas for Swedish healthcare.[39]

Attention has been called to the need for ethical analysis in connection with forms of governance and organisation within the framework of the debate. The Network Against Unsuitable Governance in

[33] Zaremba 2013.
[34] See e.g. Almqvist et al. 2014 and Andersson 2014.
[35] Articles in the daily press and trade magazines, news reporting and programmes on e.g. Radio Sweden Radio and various TV channels have criticised and argued in favour of value-based care.
[36] Porter Olmsted Teisberg 2006.
[37] Feiler et al. 2018.
[38] SOU 2017:56, SOU 2018:38, SOU 2018:47 and SOU 2018:39.
[39] The Swedish Society of Medicine's programme of ideas for improved healthcare, adopted 2018.

Care[40] has raised the question of the importance of ethical analysis and competence in several opinion articles.[41] Engström and Ågård also point out that structural changes in healthcare must be formed to a greater extent with regard to the ethical implications of organisational changes.[42]

[40] The Network Against Unsuitable Management in Care was founded in autumn 2016 by doctors Gunnar Akner, Niklas Ekerstad and Bengt Järhult. More than 150 doctors are now members. www.network-styrning.com
[41] Akner 2016, Löfmark et al. 2018, Akner et al. 2017a, Akner et al. 2017b.
[42] Engström and Ågård 2017.

4 A model for ethical analysis

4.1 Analysis models

We can differentiate between several models for ethical analysis. One is the so-called stakeholder model which is especially useful when there are conflicts of interest between – and within – actors and those affected.[1] Another is the goals and obstacles analysis which is particularly useful when the activities under discussion have reasonably clear goals. Both include analyses of consequences and alternatives and are described in the literature.[2]

In this context, where objectives for the provision of healthcare services are stated in a number of texts, it is convenient to apply the goals and obstacles analysis. Its basic concepts are *the current situation*, *the goal(s)*, *obstacles* along the way towards the goals and *strategies* for overcoming these obstacles. Value questions and ethical problems are raised when each of these concepts is applied to a particular problem or situation. Empirical questions about the effects of the choices made are also raised.

It may be easier for the reader if the questions that are relevant in connection with discussing any changes in the governance structure are related to an analysis model of the type that the goals and objectives analysis constitutes. It is therefore introduced by saying something about the four basic concepts – current situation, goals/objectives, obstacles and strategies for dealing with them – and the issues raised under these headings.

A comparison is then made between the governance model that is currently used and proposed changes to it. It will be particularly

[1] See e.g. Smer 2018.
[2] Hermerén 2007. Göran Hermerén has developed a method for an objectives and barriers analysis in several publications. Smer has used an adapted form of the objectives and barriers analysis in combination with the actor model e.g. in the report *Assisterad befruktning – etiska aspekter* ("*Assisted fertilisation – ethical aspects*") 2013:1.

important to note the differences that are then noted. They are part of what should be taken into consideration before decisions are made on introducing changes to Swedish healthcare.

The instructions for using the model are first presented followed by a set of questions that operationalises the model.

4.2 Instructions for using the model

4.2.1 The current situation

Different actors have different perspectives – they do not have the same mandate and opportunities. This can influence their description of the current situation and the problem. Perspectives, underlying values and conditions need to be made explicit in order to allow for constructive debates and cooperation and to facilitate a clear distribution of responsibility. Empathy, respect for different opinions and the ability to listen are, of course, important qualities in practical ethics work.

Particular attention should be drawn to two points here. Naturally, a description of the current situation should not include any false assertions. However, it is possible for every statement in a description to be true and for the description still to be grossly misleading. People can be deceived without using lies – as Erik Ryding has demonstrated with a number of examples[3] – often by making a selective choice of facts or processes. Hence ethical requirements are placed on the description of the current situation: it should not only be factually correct but also not be misleading.

A description of the current situation can also point with a greater or a lesser degree of clarity to problems that need to be rectified. It is then important to see that this requires an impact analysis and values, which should be made explicit. What poses a problem for one individual or group may be an opportunity for someone else, if their values differ.

Efforts to reduce waiting times for diagnostics and treatment are extremely important for those with cancer, whereas those who want to see the rapid expansion of maternity care may have different priorities. If there are insufficient resources for both of these then

[3] Ryding 1971.

the focus on cancer care will be an opportunity for some and a problem for others – and vice versa.

In order to pave the way for a constructive debate, the descriptions should be as value-free as possible. Current problems and difficulties within the organisation for the provision of healthcare services are reported under another heading that clearly presupposes and is based on values: problems and barriers.

The description of the current situation and possible alternatives should also include economic aspects. Every change involves a cost. This cost may be different for different alternative courses of action. Continuing as before also involves a cost.

The key question under this heading is thus: Is the description of the current situation to which the governance model is intended to be applied misleadingly selective?

Specific aspects to take into account:

- At which level is the model intended to work? National, regional, local?
- To which type of healthcare provision is the model intended to be applied? Urgent/non-urgent, out-patient/in-patient, etc.?
- To which patient groups?
- To which medical conditions?
- What does the model not include?
- Which effects should be achieved using the governance model in question and what scientific and/or empirical evidence is there that this is correct or likely?
- Is there support from pilot projects to suggest that the governance model will work in the environment where it is intended to be applied?
- What does it cost to introduce the model and to work in accordance with it?
- Are there other alternatives?

4.2.2 Goals and objectives

An important advantage of the goals and obstacles analysis is that it reminds us that individuals and groups have different objectives. These objectives therefore need to be clarified. The objectives sometimes relate to each other like overlapping circles, and sometimes not. The objectives sometimes pull in different directions. Behind the objectives there are of course valuations and ethical values. We strive to achieve certain objectives because we think that it would be valuable to achieve them. In the initial stage we do not need to go into these values and valuations in depth.

However, we do need to go into greater depth in relation to vagueness and ambiguity in the description of the objectives which can result in both apparent agreement (pseudo-agreement) and apparent disagreement (pseudo-disagreement). We believe that we agree because we use the same words for instance 'need', 'fairness', 'solidarity', 'effectiveness', 'availability', 'continuity' or 'security' without being aware that we use them in different senses. Or we may believe that we disagree because we describe our standpoints in different ways.

The underlying objectives of medicine and healthcare largely relate to the value conditions. They have a historic dimension.[4] On a general level these objectives involve fighting disease: restoring, maintaining and improving health and quality of life, and preventing ill-health. The concepts of health and quality of life can be defined in different ways, as is evident from the literature on this subject. The general objectives can therefore be replaced by a number of more precise objectives. These objectives can in turn be broken down into time-based and area-specific objectives where there are differences between, for instance, palliative care, orthopaedics and preventive public health work (infection control, healthy living conditions, hygiene, etc.).

When it comes to the objectives for healthcare in Sweden, regulations and guidelines state that it shall promote good health, prevent ill-health, promote a high degree of patient safety, protect against care-related injuries, be based on respect for the patient's right to self-determination and integrity, provide care with respect for all people's equal value and for the dignity of the individual, provide care on equal terms and give priority to those with the greatest need. Care shall be of good quality and shall meet the patient's need

[4] See e.g. Fleischhauer and Hermerén 2006 and the literature cited therein.

for security, continuity and safety. It shall also be carried out according to science and proven experience. The quality of the organisational activities shall be systematically and continuously developed and ensured. Publicly-funded care shall be organised so that it promotes cost-effectiveness. Cooperation shall take place in order to achieve more efficient use of resources. Care shall be easily accessible.

Such a description can be developed and deepened by clarifying the interpretation of key concepts in the documents that form the basis for the above description of the objectives. These documents include the Health and Medical Services Act, the Prioritisation Platform, the Patient Act, the Patient Data Act, the Patient Safety Act, the General Data Protection Regulation, the UN Convention on the Rights of the Child and a number of other conventions.

Greater depth can also be achieved by reviewing practice on application.

Relevant values include not only health and quality of life but also fairness, self-determination, co-influence, availability, continuity, patient benefit, a good and safe working environment for staff, and confidence in staff and in healthcare as a whole. These values can be ranked in hierarchies where certain values are means (e.g. availability and continuity) for achieving other more basic values or objectives, e.g. good health for the individual and the population. Trust and competence can correspondingly be means (or conditions) for achieving good care.

The values are dynamic, not static. Their relative importance is not constant. We have seen a clear increase in the focus on freedom of choice within healthcare in recent years. This value has been upgraded while the value of increasing collective benefit is no longer is emphasised as much as it was before. This is also an international trend in the Western world. The same can apply to the interpretation of the precise meaning of these values – it is not always constant over time.

Moreover, it is important to clarify which diseases and which processes in healthcare the formulated values relate to. For example, has the focus been mainly on hospital care and primarily on 'simple' healthcare processes such as treating hip and knee joints and cataracts? Are these taken as examples to demonstrate the potential of a proposed governance model while not taking patients with complex healthcare

needs into account as clearly? Or – conversely – has there been a focus on complex healthcare processes rather than simple processes?

How do the objectives to be achieved through proposed changes to the current governance model relate to the objectives and values to be promoted in healthcare according to the Health and Medical Services Act and similar documents? Which of these objectives are ranked and time-based?

What is the situation with objectives such as care on equal terms, respect for everyone's human rights, a fair distribution of care resources and care governed by demand? Here there may be a significant difference regarding which values are added to the governance models.

The application of statements of objectives and steering documents requires a high degree of ethical competence for the reasons stated by Falkenström and Höglund in their study:[5] the stated objectives and the values that lie behind them and justify them are often abstract. They are presented as being obvious, and arguments are rarely given for them. They sometimes pull in different directions. In order for the application to be as beneficial as possible, dialogue is required on the application where all actors and affected parties are ideally engaged and where questions of responsibility are clarified.

If a new governance model is proposed to be introduced it is relevant to ask: Which objectives does it achieve and what evidence (to be specified if possible) do we have for this? And how do these objectives relate to the objectives that the specific provision of healthcare services or healthcare in Sweden in general shall achieve? If these objectives can be represented as two partly overlapping circles, what lies within the individual fields? What can the proposed model improve in relation to the existing model(s)?

The relevant questions – which should be asked prior to the launch and introduction of a new model – will then be:

- Which explicit and implicit objectives will be achieved with the help of the governance model in question or the proposed changes to the currently used governance model?
- Which values and whose values lie behind and justify these objectives?

[5] See Falkenström and Höglund 2018, e.g. p. 279.

– What evidence is there for assuming that the governance model in question or the proposed changes to the governance model will achieve these objectives?
– How does the new model stand in relation to the existing model?
– What does it cost to introduce the model and to work in accordance with it? What do the alternatives cost?

Compare the objectives of the existing model with the objectives that the specific organisational model/policy/activity or healthcare in Sweden shall strive to achieve in accordance with applicable regulations and guidelines (the Health and Medical Services Act, the Patient Act, the Patient Safety Act, etc.).[6] Are there any differences between these objectives?

Specific ethical aspects to take into account include:

– Is Swedish legislation taken into account including the Prioritisation Platform adopted by the parliament (Riksdag)?
– How will the patient's involvement and right to self-determination be expressed and considered?
– Are there any elements in the governance model that could threaten patients' integrity?
– What consequences could the model have for patients with complex care needs?
– How are patients with reduced capacity for decision-making affected?
– What effects could the proposed changes to the governance structure have on the objective to even out differences in (ill-)health between different groups?
– Are the proposed changes to the governance structure compatible with the codes of professional ethics for the professions involved and with other ethical guidelines for the organisation?

[6] The Health and Medical Services Act (2017:30), the Patient Act (2014:821), the Patient Safety Act (2010:659), and part of the National Board of Health and Welfare's regulations and general advice on management systems for systematic quality work (SoSFS 2011:9).

4.2.3 Obstacles and problems in achieving set objectives

Obstacles and problems are related concepts but they are not identical. In order for a problem to become a barrier, it must involve a certain degree of difficulty. A shortage of nurses may be both a problem and a barrier to providing good care at a hospital or a clinic. All barriers are problems, but not all problems are barriers.

In other words we can differentiate between obstacles of different types: strong barriers which make it impossible to achieve the objectives being striven for, weak barriers that delay and impede achieving these objectives without making it impossible to do so, and medium barriers that are somewhere between the two. In reality the transitions between these barriers are not abrupt – they flow. The point is only to underline the obvious – that a problem can be a weak barrier without being a strong barrier. The terms 'obstacle' and 'problem' are therefore not synonymous.

Another important point regarding the goals and obstacles analysis is that it makes it easy to see that there can be many different types of problems and barriers along the way towards the goal(s). It is not just about a shortage of money. The barriers that arise can also be legal, organisational, attitudinal, due to knowledge gaps, or due to a lack of suitable equipment and/or competent staff.

These barriers must be tackled in different ways if we are to eliminate or reduce them. If the barriers are legal, new laws are required. If the barriers are organisational, a new or changed organisation is required. If there is a shortage of competent staff, competent employees must be recruited. If the working conditions are poor, they must be improved. If the barriers are attitudinal, people's attitudes must be influenced through information or incentives.

In their previously mentioned work, Falkenström and Höglund provide a number of examples of practical ethical employer problems such as those faced by healthcare (requiring ethical competence if they are to be dealt with in a responsible manner): "waiting lists, patient safety deficiencies, unequal care, working environment problems and long-term skills supply, etcetera."

Barriers to effective healthcare have been discussed in several investigations.[7] Patients with complex care needs, reduced capacity

[7] SOU 2016:2, SOU 2018:39, SOU 2018:55, Committee Directive 2017:128 on structure within care.

for decision-making and shortages of adequate equipment and competent staff can involve challenges and difficulties in Swedish healthcare. The same is true of the lack of continuity in healthcare – patients rarely meet the same healthcare staff.

Transferability may be a problem in this context. It is therefore important to investigate where and for what purpose the model has been developed, and the reasons for believing that it will solve the problems it is intended to be applied to within Swedish healthcare. Problems can arise when a governance model intended to be applied to certain circumstances, such as hip operations, are applied to others, such as chronic diseases, or when a governance model developed for application in a country with a certain healthcare system and type of healthcare insurance is applied in a country with a different healthcare system and insurance.

Just as with objectives, we can expect problems and barriers to be partly the same and party different when changes are proposed to the management system for an operation within healthcare in Sweden.

Relevant overall questions are then:

- Which problems and obstacles are identified in the (proposed) governance model in question?
- How do these problems and obstacles relate to the involved professions?
- How do these problems and obstacles relate to what patients or patient associations have perceived to be problems and obstacles?

4.2.4 Strategies to overcome the obstacles identified

Attempts can be made to circumvent, reduce or eliminate problems and obstacles on the way towards objectives in several different ways. The choice between these strategies is not ethically neutral. Some can be applied more quickly than others. Certain strategies may be cheaper than others. Some may be ethically problematic, and others undemocratic, politically inappropriate or (sometimes for other reasons) reprehensible.

Another example can be found in the debate on co-payment of care. One of the problems in Swedish healthcare relates to costs and

accessibility. It may then appear that some health economists' proposals on co-payment (and out-of-pocket payments) could be a useful strategy for resolving or in any case reducing these problems. However, one objection is that the proposal will come into conflict with the Prioritisation Platform adopted by the Swedish parliament (Riksdag) and the Health and Medical Services Act's paragraph on healthcare being provided on equal terms and on the basis of need.[8]

Hence a strategy can be advantageous from an economic opinion but comes at the expense of something else.

How should time, cost, ethics and political direction be valued when comparing different methods for approaching or achieving objectives? Choosing the fastest alternative is not always the best option. Nor is choosing the cheapest – particularly if a longer time perspective is applied. But how long a time perspective should be applied? Nor is this an ethically neutral issue. Which frameworks set legislation, directives and guidelines? What freedom of action do decision-makers have at different levels in Sweden?

Here there may be both cultural and legal differences that are worth observing in dialogues between actors and those affected. These dialogues require communicative competence if they are to be successful. The values behind the objectives are not too hard to identify. However, the values behind the choice of strategies for dealing with barriers are often less easy to perceive.

The effectiveness of the proposed or used strategies when it comes to eliminating or reducing barriers along the way is, of course, an important issue. Actors can make assertions about the effectiveness of strategies that favour their other (political or financial) interests. The quality of the evidence allegedly supporting the claims made about the effectiveness of the proposed changes therefore also has an ethical dimension.

Monitoring is an important component of management in order to see at an early stage what might work and what does not work. This monitoring often focuses on measurable indicators. This involves a risk that many have cited: focusing on what is easily measured, such as economic dimensions, while other aspects such as ethical values are disregarded or ignored.

Relevant questions under this heading are thus:

[8] Smer report 2014:2.

- Which methods or changes to the governance instruments are proposed in order to resolve the problems and bypass identified obstacles in this governance model?
- Are they compatible with the objectives for the organisation/activity in question or healthcare in Sweden, and with basic medical-ethical principles?
- What conditions are required in order for these methods or changes to have the intended effect?
- What evidence has been presented in support of the proposed methods or changes leading to the desired objectives?
- Who wins and who loses what if these strategies are used? How are aspects of fairness taken into consideration?
- Is it possible to test the governance model on a smaller scale before it is introduced more generally?
- Is any monitoring and evaluation planned? Which indicators are used in this context and which values are represented?

4.3 Conclusion

The Council's general conclusions and recommendations based on the proposed model are as follows: (1) Take as a starting point the questions raised by the objectives and obstacles analysis, which includes analysing alternatives and consequences; (2) compare the answers to these questions with what is asserted in or about the proposed changes to the governance instruments, tools or model; and (3) review the evidence or reasons given for these assertions. It is particularly important to pay attention to the values that are explicitly or implicitly included in the models and any shortcomings in the reasons for the assertions made.

A more detailed set of questions is presented in the following chapter.

5 Questions for ethical analysis

Questions that can and should be asked when carrying out an ethical assessment before taking a position on the introduction of new governance models in healthcare are collected and presented here. These questions can also be used when analysing current governance models at various levels within healthcare. It is particularly important to note any differences between (a) principles and objectives for Swedish healthcare and (b) principles and objectives that the proposed model advocates or is based on. This is especially important to bear in mind if the model has been developed in a country with a different healthcare system.

The questions do not claim to be exhaustive when carrying out an ethical assessment.

The current situation

Descriptions

1. Describe the current situation within the organisation.
2. Is the current situation within Swedish healthcare described accurately in the proposed governance model?
   a) Are all statements in the description correct?
   b) Is the description misleadingly selective?
3. Specific questions focusing on possible differences between these descriptions:
   a) At which level is the model intended to work? National, regional/local?

b) For what type of organisation is the model suited?

c) Urgent/non-urgent, out-patient/in-patient?

d) Which patient groups?

e) Which medical conditions?

f) What does the model include and not include?

Problems

1. What are the problems within healthcare in Sweden according to available evidence (knowledge and experience)?
2. What problems and whose problems are highlighted in the proposed governance model?
3. Which underlying values are taken as the starting point when certain problems in the current situation are noted in the proposed model?
4. What similarities and differences are there between these problem descriptions?

Evidence (knowledge and experience)

1. Which effects are likely to be achieved by using the governance model in question and what scientific and/or empirical evidence is there that this is correct?
2. Is there support from pilot projects to suggest that the governance model will work in the environment where it is intended to be applied?

Objectives (a) for healthcare in Sweden and (b) the objectives according to the governance model in question

Formulation of objectives

1. Which explicit and implicit objectives will be achieved with the help of the proposed governance model or the proposed changes to the currently used governance model(s)?
2. Which values and whose values lie behind and justify these objectives?
3. What evidence is there for assuming that the governance model in question or the proposed changes to the governance model will achieve these objectives?
4. Compare the objectives that the proposed governance model is asserted to achieve with the objectives and values that healthcare in Sweden shall strive to achieve according to relevant regulations and guidelines.

Differences between objectives

Specific questions focusing on possible differences:

1. Objectives and values in healthcare and the Prioritisation Platform: How does the proposed governance model relate to objectives and values in laws and guidelines for healthcare in Sweden and the prioritisation principles for healthcare adopted by the Swedish parliament?
2. Patient perspective. How will the changes in governance that are proposed affect the possibilities for patients to be involved in the decisions concerning their treatment (self-determination and shared decision-making)?
3. Integrity. Are there any elements in the governance model that could threaten patients' integrity?
4. Patients with complex care needs. What consequences can the model have for this group of patients?

5. Patients with reduced capacity for decision-making. How does the model affect this group of patients?
6. Equal care. What effects could the model be thought to have in relation to equal care and the objective of evening out differences in (ill-)health between different socioeconomic groups?
7. Are the proposed changes in the governance instruments compatible with the professionals' work ethics?
8. Is any monitoring planned?

Barriers to achieving the objectives (a) for healthcare in Sweden and (b) in accordance with the model

1. Which barriers and difficulties are identified in the currently used governance model?
2. How do these problems and obstacles relate to the professions within the identified organisation?
3. How do these problems and obstacles relate to what patients or patient associations have perceived to be problems and barriers?
4. Is it possible/reasonable to test the model on a smaller scale before it is introduced more generally?

Strategies for overcoming the obstacles identified to achieve (a) the objectives for healthcare in Sweden and (b) the objectives according to the governance model in question

Identifying strategies

1. Which methods are proposed in order to resolve the problems and bypass identified obstacles in the proposed governance model?

2. Are they compatible with the objectives for the organisation in question (healthcare in Sweden) and with basic medical-ethical principles?
3. What conditions are required in order for these methods or changes to have the intended effect?
4. What evidence has been presented to support the claim that the proposed methods or changes will lead to the desired objectives?
5. Who are the actors and the parties affected? Who wins and who loses what if these strategies are used?

   What does it cost to bypass the barriers? Are there (better: more effective and cheaper) alternatives?

   How are aspects of fairness taken into consideration?

6 Concluding considerations and recommendations

It is important that governance and organisation models in healthcare are designed so that they facilitate the realisation of the objectives for publicly-funded healthcare.

Smer believes that an ethical analysis model may be useful in the process of designing and improving the governance and management of healthcare. Such an analysis can constitute a tool through which decision-makers, officials and professionals can cooperate in order – using the ethical analysis as a starting point – to ensure that the devised models are economically effective while also being compatible with the objectives and values of healthcare. These models should build upon the leadership system for quality and patient safety (SOSFS 2005:12). This system allows for continuous improvements and for risk and impact assessments.

The described model for ethical analysis raises questions about objectives, barriers and strategies, and invites comparisons between how these are dealt with in the analysed governance model and in the reality to which this model is intended to be applied. The analysis model can also be used for considerations when comparing which model should work best, i.e. in comparison with the starting position and between different new models. The questions that are asked cannot be answered by ticking a box marked 'Yes' or 'No'. There is therefore little risk that the list of questions will be developed into a checklist. When the questions are applied, this should be based on knowledge, arguments and analytical ability.

The aim of this report is – as previously mentioned – to demonstrate a way of thinking if the intention is to take a well-founded position on proposed governance models or to analyse existing models.

The presented ethical framework raises a number of questions that should be asked and answered, divided up under four headings: current situation, objectives, barriers and strategies. Quality requirements are also applied to these answers: it must be possible to present the evidence for the answers, and the answers must not be based on inadequate research. The important thing is that relevant questions are asked, serious attempts are made to answer them and the need for ethical competence in decision-making is emphasised. It is particularly important to highlight and clarify those values that come into play and to shed light on and examine any conflicts of values. A clear distribution of responsibility is important when dealing with such conflicts.

With this report the Council aims to highlight the relevance of ethical analysis and ethical competence in developing healthcare. Governance models for healthcare are not value-neutral. A detailed ethical analysis should therefore be carried out before they are implemented. The ethical analysis of values and conflicts of values should complement other impact analyses before making changes to management, organisation and ways of working, as well as analyses of current management. This applies to all levels of decision-making, from national, county/region, municipal, hospital, out-patient care organisation or other organisational levels to clinical level within healthcare.

Carrying out this analysis requires ethical competence. Such competence is of the greatest importance in order for politicians, non-political officials and caregivers' senior management to be able to take responsibility for leading and managing healthcare.

This requires insight into and awareness of the fact that new models for management and organisation may have ethical consequences. The Council has previously stated in several consultation responses and reports that the organisation and management of healthcare has a particular responsibility to highlight ethical issues and to signal their importance downwards within the organisations. This ethical competence – and the ethical analysis – should thus also be strengthened at management level.

There is a real need for continuous monitoring and evaluation of governance models for the various organisations/provisions of healthcare at different levels. Several central government agencies analyse the governmental management of municipal operations including healthcare. However neither the National Financial Management

Authority (ESV), the Swedish Agency for Public Management, the National Board of Health and Welfare nor any other agency has been tasked with guiding municipalities and regions when it comes to how they should organise and govern their work. This may have contributed towards the significant interest in new governance models for healthcare that are often marketed by various management consulting companies. Central government should play a greater role in supporting knowledge in relation to management and governance models in healthcare.

In the Council's preparation of this report, we have found that it would be desirable to focus more on research into the governance of publicly-funded healthcare and ethical analyses in this area.

In summary, the Council believes that:

- Ethical analysis is a tool that should be used at different levels before introducing governance and organisation models in healthcare.
- Ethical competence among decision-makers at different management levels must be provided and developed.
- New models should be developed and improved in collaboration between professionals and decision-makers, taking value issues and the ethical analysis as a starting point.

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Extract from article. Questions as decision-making support before the assessment of various policies

Below follows an extract from the article "Including Organizational Ethics in Policy Review Processes in Healthcare Institutions: A View from Canada" by Macdonald et al. (2008). In this article the authors summarise their experiences from an ethics council linked to IWK Health Centre in Canada. The following is a presentation of the questions compiled as support for their analyses of new policies/organisational reforms.[1]

- What are the values (explicit or implicit) at issue in the policy?
- Are these values clearly articulated or should they be?
- Are the values congruent with the Health Centre's values?
- What are the relevant ethical principles or theories operating in this situation?
- What is the potential 'good' or the potential 'harm' inherent in this policy (including the potential for moral distress)?
- Does the policy restrict or limit treatment options?
- Does the policy treat all who are affected by it equally?
- Does the policy result in overriding the patient's or surrogate's wishes?
- Does the policy result in a restriction of liberty?
- Does the policy allow for disclosure of information when that person, or group of persons, might not consent to the disclosure?

[1] McDonald et al. 2008, p. 148.

- Does the policy impact on privacy? Does the policy impact on the exercise of autonomy?
- Does the policy impact on vulnerable groups (internal or external)?
- Does the policy impact on the civil rights of anyone in the Health Centre (including rights to natural justice)?
- Does the policy impact on the community?
- Were vulnerable people given a voice?
- Does the policy expect too much or too little from those expected to uphold it?
- Is the language used appropriate (for example is it family centred, culturally sensitive)?
- Is this a policy the Health Centre would be comfortable having the public know about?

The ethical review should also encompass reviewing whether the policy is or will be effective. Questions that they ask when conducting an effectiveness review include:

- Are the policy statement and procedures clear?
- Are key terms defined?
- Were the 'right people' (those who might be impacted, those who have to apply the protocol or guidelines, etc.) included in the process of policy development?
- Is there a process for 'enforcing' the policy or ensuring the policy will be upheld?
- Is there a process for ensuring the goals of the policy are achieved?
- Are there quality assurance processes within the policy?

– Are there specific issues relating to the hospital's ethical obligations to patients in respect of the implementation of the policy?[2]
– Are there specific issues relating to the hospital's ethical obligations to users in respect of the implementation of the policy?[3]

[2] Ibid p. 149.
[3] Ibid p. 149.

Objectives, ethical values and principles for Swedish healthcare

Healthcare is a value-related organisation. Treatments aim to promote health and quality of life, and this care is important for people. Ethical values and principles are expressed in healthcare legislation.[1] There are also objectives and requirements for care that are important from a patient perspective. Governance models for healthcare need to be chosen so that they help to meet the objectives and that provision of healthcare services is carried out in accordance with relevant principles, values and requirements.

Objectives and requirements

Publicly-funded healthcare shall contribute towards good health and preventing ill-health as well as promoting a high degree of patient safety. The requirements for good care shall be met. Care shall be knowledge-based and shall be carried out in agreement with science and proven experience. Care shall be of a good quality. The quality shall be systematically and continuously developed and ensured. Care shall promote good contact with patients. It shall be designed and implemented in consultation with the patient, and relatives shall have the opportunity to be involved. There shall be cooperation between different actors for different purposes. The table below summarises a selection of the objectives and requirements that exist for Swedish healthcare.

[1] In e.g. the Health and Medical Services Act (2017:30), the Patient Act (2014:821), the Patient Safety Act (2010:659), the National Board of Health and Welfare's regulations and general advice on management systems for systematic quality work (SoSFS 2011:9) and the Local Government Act (2017:725).

Ethical principles

All people have equal value. All people therefore have certain fundamental rights that must be respected. Important ethical principles involve self-determination, not causing injury, good and fair actions, and not treating people or groups differently if there are no differences that are significant from an ethical perspective. Integrity involves human dignity and every individual's right to have their dignity upheld regardless of external circumstances. A person has the right to have their values, wishes and opinions respected. The right to self-determination (autonomy) is linked to ability. Different people have different abilities to take care of their interests and convey their values, opinions and wishes. This affects both the ability and the opportunity for self-determination. Self-determination can be transferred to someone else, but the right to integrity is unconditional.

The ethical principles of legislation relate to the view of mankind in the form of all people's equal value, the right to self-determination and autonomy, fairness and other fundamental values. They involve respect for the patient's autonomy and integrity, as well as equality when it comes to who should be offered various types of care intervention.

The ethical platform for prioritisations

Prioritisation involves putting something before something else. If resources are allocated to one group or organisation another will go without. A comparison therefore needs to be made with what an alternative use of the resources can offer. The Health and Medical Services Act states that those with the greatest need for healthcare should be given priority. This provision is based on the Riksdag's decision on what is often referred to as the 'ethical platform'.[2] This contains guidelines for prioritisations within healthcare and guidance for those who decide on prioritisations in care.

The platform works to ensure respect for the individual's values, rights and dignity. It is based on three fundamental ethical principles. According to *the principle of human value* all people have equal value and the same rights regardless of their personal qualities and their

[2] Government Bill on Priorities within healthcare (Bill 1996/97:60).

functions in society. *The principle of need and solidarity* involves resources being allocated according to need. According to the Bill the principle has a strong link to both the underlying motivation for care (doing good, helping those who need help) and the ideal of justice and equality, which is strongly rooted in our culture. According to *the principle of cost-effectiveness* decision-makers in healthcare should strive for a reasonable relationship between cost and effect when choosing between different organisations/alternatives, measured in terms of improved health and quality of life. The principle of cost-effectiveness is subordinate to the other two principles and should only be applied after the principle of need has already been applied.

Other prioritisation aspects

There are also ethical aspects to consider in other resource prioritisations. The legislation includes demands for economic management and cost-effectiveness. County councils and municipalities have limited resources. The resources – staff, equipment and premises, money – are always limited. It is important that the prioritisations of care are carried out consciously and on the basis of ethical principles.

Tabell 1 **Objectives and requirements in legislation with significance for patients' health and wellbeing – a selection**

	Objective and purpose
The Health and Medical Services Act	Good health
The Health and Medical Services Act	Prevent ill-health
The Patient Safety Act	Promote a high degree of patient safety within healthcare
The Patient Safety Act	Protect against care-related injuries, suffering, bodily or mental harm or disease and undesirable death
	Ethical values
The Health and Medical Services Act	Be based on respect for the patient's self-determination and integrity (the Patient Safety Act – good care)
The Patient Act	Promote the patient's integrity, self-determination and involvement
The Patient Act	The patient's self-determination and integrity shall be respected
The Health and Medical Services Act	Care with respect for all people's equal value
The Health and Medical Services Act	Care with respect for the dignity of the individual

The Health and Medical Services Act	Care on equal terms
The Health and Medical Services Act	Priority for those with the greatest need for healthcare
	Care requirements
The Health and Medical Services Act	The requirements for good care shall be met
The Health and Medical Services Act/ The Patient Act	Good quality with a good standard of hygiene (the Patient Safety Act – good care; the Patient Act)
The Health and Medical Services Act	Meet the patient's need for security, continuity and safety (the Patient Safety Act – good care)
The Health and Medical Services Act	Be easily accessible (the Patient Safety Act – good care)
The Patient Act	Expert and caring
The National Board of Health and Welfare	Good care (safe, adapted according to the individual, knowledge-based, equal, accessible, effective and sustainable)
	Knowledge-based care
The Patient Act	In agreement with science and proven experience (the National Board of Health and Welfare – Good care: knowledge-based)
	Quality assurance
The Health and Medical Services Act	The quality of operations shall be systematically and continuously developed and ensured
	Patients and relatives
The Health and Medical Services Act	Promote good contact between patients and healthcare staff (the Patient Safety Act – good care)
The Patient Act	Healthcare services should be designed and implemented in consultation with the patient wherever possible
The Patient Act	Relatives have the opportunity to be involved in the design and implementation of care
	Circumstances, organisation and finances
The Health and Medical Services Act	The staff, premises and equipment needed for good care
The Health and Medical Services Act	Organised so that it promotes cost-effectiveness (for publicly-funded organisations)
The Local Government Act	County councils and municipalities shall carry out good economic management in their operations
	Cooperation shall take place
The Health and Medical Services Act	When planning and developing healthcare (with bodies within society, organisations and caregivers)
The Health and Medical Services Act	If the care involves multiple county councils (with other county councils)

The Health and Medical Services Act	In order to achieve more effective use of available resources (with municipalities, the Swedish Social Insurance Agency and the Swedish Public Employment Service)
The Health and Medical Services Act	When financing, planning and implementing public health science research work (county councils, municipalities, universities and university colleges)
The Health and Medical Services Act	When financing, planning and implementing clinical research work within the field of healthcare (county councils, municipalities, universities and university colleges)