

# National Model for Transparent Prioritisation in Swedish Health Care

Revised Version



2011:4

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**National Center for Priority Setting in Healthcare**

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## FOREWORD

*“Democratic discourse and citizen acceptance of necessary prioritisation requires knowledge about the grounds on which priorities are set, the opportunities that patients have to influence these, and the avenues to pursue when dissatisfied with the priorities set. Health services have an obligation to develop methods to make such information available to those who are patients today and those who may become patients in the future.”*

The above citation is from the government bill containing the guidelines for setting priorities in healthcare. Increasing the transparency of priority setting (prioritising is always part of health care) requires instruments both to communicate these priorities to citizens and to communicate the ethical considerations and different positions taken by those who set these priorities. In the late 1990s, Östergötland County Council recognised the need to develop a systematic and uniform process for prioritisation. In conjunction with work on the first national guidelines (for cardiac care), initiated by the National Board of Health and Welfare, the need to further define and clarify prioritisation methods became increasingly obvious. The general principles for priority setting described in the government bill were insufficient to direct the practical work, and a call arose for a concrete description of the process for ranking health conditions and needs for health care.

Over time, a need also arose among individual county councils and health service sectors to be able to use the prioritisation experience of the National Board of Health and Welfare in setting priorities at the local level.

In 2006, a working group comprised of representatives from the National Board of Health and Welfare, the National Center for Priority Setting in Health Care, and other organisations involved in priority setting, e.g. Östergötland County Council, Stockholm County Council, Västra Götaland, the Swedish Society of Medicine, the Swedish Society of Nursing, and the Swedish Association of Health Professionals developed the initial proposal for a national model for transparent vertical prioritisation.<sup>1</sup> The proposal was reviewed and accepted by agencies, professional associations, and individuals with specialised knowledge in the field.

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<sup>1</sup> Mari Broqvist & Per Carlsson, National Center for Priority Setting in Health Care; Kristina Eklund, Christina Kärvinge, & Anna Sohlberg, National Board of Health and Welfare; Bo Hallin, Västra Götaland Region; Catrine Jacobsson, Swedish Society of Nursing/Swedish Association of Health Professionals; Gunilla Jacobsson Ekman & Marion Lindh, Stockholm County Council; Christina Källgren Peterson, Östergötland County Council; Britt Nordlander, Swedish Society of Medicine; Urban Sjöblom & Per Rosén, South Sweden Healthcare Region.

Since its publication, the model has been used in several different contexts, and experiences from several projects have been documented. The model has received strong support as an important tool for implementing systematic prioritisation based on the guidelines from the Swedish Parliament (*Riksdag*). The model has also been tested in municipal health and social services (e.g. guidelines on dementia by the National Board of Health and Welfare), which have found it applicable, albeit with some modifications that we discuss in the report.

The health service sectors and county councils that have used the model have, however, reported certain weaknesses in its implementation. Some weaknesses are associated with internal work processes, insufficient evidence for decision making and care classification systems, and a lack of clarity in the guidelines from the Swedish parliament (*Riksdag*). The need to further refine the model itself is also a recurring topic – for instance, greater clarity regarding the linkage between the model and the parliament's (*Riksdag's*) guidelines and further specification on how to implement the different steps. Also, a more user-friendly handbook was requested.

Even as the first version was being published, the National Center for Priority Setting in Health Care and the National Board of Health and Welfare were planning to send out invitations to update the report. The first meeting was planned for no later than October 2007. In conjunction with that year's national conference on priority setting, a seminar was held to address implementation of the national model. Here it was argued that additional experience in applying the model must be acquired before there would be reason to consider revising the report. The prioritisation model has now been well-tested throughout the country and is shown to work. We propose minor changes in the work process and have made a substantial effort to better describe how the model should be used.

The revised version of the model presented in this report has been developed jointly by the National Center for Priority Setting in Health Care and the National Board for Health and Welfare. This report has been presented to the board of the National Center for Priority Setting in Health Care, which includes representatives of the Swedish Society of Medicine, the Swedish Medical Association, the Swedish Society of Nursing, the Swedish Federation of Occupational Therapists, the Swedish Association of Registered Physiotherapists, and the Swedish Association of Local Authorities and Regions (SALAR).

The board approved the publication of this new version of the model. Discussions have also taken place at a seminar attended by invited individuals with experience in implementing the model by working on the National Board of Health and Welfare's guidelines, in county-wide priority setting initiatives, and in different health service units across Sweden. The revised version was also sent to all directors of health services (or equivalent) in every county council and region, to the Dental and Pharmaceutical Benefits Agency, to a national coordinating group on knowledge management, to coordinators of general issues on leadership and management, and to SALAR (for wider distribution to municipal representatives for their review and comment).

Our hope is that everyone who is planning or already implementing a prioritisation process in health care and services arranged by the state, county councils, municipalities, clinics, professional groups, or similar organisations can benefit from this report by gaining a better understanding of how the National Model for Transparent Prioritisation in Swedish Health Care is intended to function.

We would like to extend our appreciation to everyone who contributed to the revised version of the model and, of course, to those who contributed to the first version.

*Linköping, June 2011*

*Per Carlsson, Director*

*National Center for Priority Setting in Health Care*

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## SUMMARY

The National Model for Transparent Prioritisation concerns a systematic method of interpreting and implementing the Riksdag's guidelines and ethical platforms in practice. The model may be used for prioritisation, primarily at group level, by all types of publicly funded health care providers, within county councils, municipalities and privately managed health care. The prioritisation model is applicable in both vertical and horizontal prioritisation.

The National Model for Transparent Prioritisation aims to increase the systematic application of the Riksdag's guidelines in order to ensure that a greater proportion of resources are allocated appropriately and efficiently to the care of those in greatest need of it, enabling and facilitating transparent prioritisation. The model does not, however, stipulate how the actual work of priority setting shall be organised.

The starting point for the national model is the Riksdag's decision on prioritisation and the ethical platform, consisting of: the *human dignity principle*, *needs-solidarity principle* and *cost-effectiveness principle*. When there is a lack of clarity regarding how the guidelines are to be applied in practice, the impact of these ambiguities on the formation of the prioritisation model is described. What may be strictly interpreted as deviations from the guidelines is presented.

- Decision-makers within health care who are faced with making complex choices may find it beneficial to rank conceivable options in order of priority. The prioritisation model denotes solely the ranking of different priorities. It does not specify or determine the consequences of ranking; neither does it establish parameters or thresholds for what constitutes an acceptable coverage of needs.
- The model consists of the following stages:
  - Determining purpose/aim and area of prioritisation
  - Identifying the prioritisation object
  - Compiling and assessing severity levels, benefits to patient and cost-effectiveness
  - Weighting and ranking
  - Presentation of ranking, its foundation/basis and consequences
- Each actor that applies the model must individually specify an aim or purpose for prioritisation. This aim affects the choice of area of prioritisation (organisation, disease groups etc) for priority setting.

A few examples of the aims stipulated include creating decision support and quality assurance for clinical care, a basis for redistribution or rationing, the organised introduction of new methods and the phasing out of ineffective methods.

- The term *prioritisation object* is given to that which is ranked. The prioritisation object is comprised of various combinations of health conditions (i.e. an established condition of poor health or illness, a suspicion of or risk of illness) and action to promote or enhance health (prevention, examination and analysis/diagnostics, treatment, self-care, follow-up or palliation). Choice of health condition and intervention as well as that of extent or magnitude and level of detail is dictated by the aim of priority setting.
- The human dignity principle, the overall principle of the model, means that all humans have equal value and equal rights, irrespective of their personal characteristics and functions in society. Personal characteristics such as, for example, age, gender, lifestyle or social function in a group may however signify special care needs or affect the usefulness of various types of intervention. In such cases, personal characteristics may also be considered when prioritising at the group level and be included when describing the health condition of the prioritisation object.
- The prioritisation model is solidly based on the needs-solidarity principle and the cost-effectiveness principle. The need for health care in this context concerns both the severity level of an individual's condition as well as the expected benefits to be gained by performing a certain action or intervention. With regard to the model, this means that the prioritisation objects identified are assessed according to the seriousness of the patient's condition, the benefit to the patient of various types of intervention and their cost-effectiveness.
- In the prioritisation model, assessment of severity level is based on the current health condition, risk of illness and duration of the health condition. The assessment of patient benefits incorporates both positive and negative effects, e.g. the risk of complications. The severity level and patient benefit are both indicated on a scale consisting of the values: very high, high, moderate and low. Cost-effectiveness is assessed based on the scale: a very high cost per effect, high cost per effect, moderate cost per effect and low cost per effect. The certainty of assessments of patient benefit and cost-effectiveness is then expressed, if possible, with an established evidence-grading system.

- Ranking in the national model involves qualitative weighting of severity level, patient benefit, cost-effectiveness and the quality of knowledge bases. Ten levels are used to indicate ranking. It is essential that the priority level may be logically understood according to the grading given to severity, patient benefit, cost-effectiveness and quality of knowledge bases. Overall low values for these factors may never result in a high priority level and vice versa; overall high values may not result in a low priority level. Absolute criteria for the different priority levels is very difficult to establish, which means that different ranking lists may not obviously be compared with each other without collective discussion.
- The highest priority (1) of health condition-intervention combinations means that the health services should allocate relatively more resources to these and secure that action is taken. Similarly, priority 10 for a health condition–intervention combination signifies that the specified action should be taken for these conditions only if sufficient resources exist for performing higher priority intervention. On appraising patient benefit, findings may show that certain interventions should be phased out of care regardless of the availability of resources, due to a lack of effect, a high level of risk or the incidence of adverse effects in relation to benefit. These should be presented separately and are therefore not included in the rankings 1-10.
- Results may be presented in the form of a ranking list. Detailed adjustments may be needed of language and appearance for pedagogical reasons, depending on the aim and target group for the work. The ranking list should be supplemented with various types of comments and descriptions of consequences.

## 1. INTRODUCTION

*The National Model for Transparent Prioritisation in Swedish Health Care encompasses a systematic method for implementing the guidelines established by the Swedish Parliament (Riksdag) to set priorities in health care. The Riksdag's guidelines refer primarily to the guidelines presented in the government bill "Priority Setting in Healthcare" 1996/97:60, where the cornerstones of the ethics platform coincide with the principles specified in the Health and Medical Services Act. The revised version of the prioritisation model presented in this report replaces the previous version presented in 2006. The National Model for Transparent Prioritisation in Swedish Health Care is largely unchanged in terms of its fundamental principles and steps. Any changes to the guidelines have been based on the broad experience that has been gained in implementing the prioritisation model and mainly involve clarification of various concepts and steps.*

This report presents the second version of the National Model for Transparent Prioritisation in Swedish Health Care and is intended primarily for those involved in implementing prioritisation processes in health services by state agencies, county councils, municipalities, clinical departments, professional groups, or similar organisations. Hopefully, this report will provide an understanding of how the national model is intended to function.

The National Model for Transparent Prioritisation in Swedish Health Care presents a systematic method to implement the ethics platform, the principals of which appear in the Health and Medical Services Act and but also some supporting governmental guidelines for prioritisation. "National" indicates that the model has been developed in collaboration with many different actors in the Swedish health services, but also that the model aims to:

- create a uniform national view concerning what should be included in transparent prioritisation
- create greater potential for communicating priorities and their basis among various professions, care levels, county councils, and municipalities and among different geographic areas, organisations, and agencies/authorities.

The revised national model for transparent prioritisation is largely unchanged as regards the fundamental principles that comprise the model's framework. It does, however, clarify certain concepts and steps in the prioritisation model and the structure of the process.

Prioritisation is the key concept in this report. Since health services encompass several activities that relate in different ways to the distribution of resources<sup>2</sup> the terminology is important in distinguishing the type of activity concerned (Liss, 2004). Below we clarify the concepts used in this report.

## **KEY CONCEPTS**

### **Prioritisation**

A decision to give preference to something or someone; a choice based on a ranking. Ranking identifies the options that should receive consideration and action ahead of the options that must stand aside, e.g. scheduled later or not acted upon at all. To consider a ranked item to be a priority, other options must be considered and relevant, i.e. they must be appropriate for consideration.

### **Transparent prioritisation**

Refers to a priority setting process where the decisions, the decision base, and the consequences are available to anyone interested. In this report, transparent prioritisation means that these conditions have been met. Prioritisation can be conducted with various degrees of transparency.

### **Rationing**

Limiting the possibilities to optimally<sup>3</sup> satisfy care and social service needs. Hence, rationing inherently involves some change for the worse affecting those in need of health and social services.

### **Efficiency**

A type of activity (e.g. changes in work methods) that yields either the same possibility to optimally satisfy health and social service needs while utilising fewer resources, or the possibility to more fully satisfy health and social service needs while utilising equal or fewer resources than the alternative. Efficiency, in this sense, never involves a change for the worse affecting those in need of health and social services.

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<sup>2</sup> In this report, resources refer to anything that affects the possibility to perform a healthcare intervention, e.g. financial and human resources (including qualifications).

<sup>3</sup> A healthcare need is optimally served if the intervention results in the greatest possible satisfaction of needs, given the scientific prerequisites at the time (Liss, 2004).

We are aware that the use of healthcare terminology can differ. This report uses the terms *patient* and *user* synonymously, and we use the concepts of *intervention*, *service*, and *programme* interchangeably. The term *Riksdag guidelines* refers primarily to the guidelines for priority setting presented in the government bill (Ministry of Health and Social Affairs 1996/97), which includes the ethics platform (Chapter 3).

## **1.1 Overview of the report**

The report begins with a description of the model's purpose, and Chapter 2 discusses *The National Model for Prioritisation: Applications and Limitations*. Chapter 3, *The Ethics Platform – Foundation of the National Model for Transparent Prioritisation*, describes the principle cornerstones of the national model for transparent priority setting. Chapter 4, *Steps in the National Model for Transparent Prioritisation*, describes and explains the various steps in the model for the purpose of clearly linking the steps to the *Riksdag's* guidelines. Each chapter begins with a brief summary.

## **1.2 Interactive handbook**

The report does not describe in detail how to use the model. To meet the need for a more specific guide to implement the model, an interactive handbook will be published on the website of the National Center for Priority Setting in Healthcare (2011). This website will present the steps in the process of applying the model, starting from a general introduction to more detailed sections that include frequently asked questions and concrete examples for implementing the model in different health service sectors and situations.

The contents of the report and the interactive handbook must be adapted to various organisations with the help of general and/or specific examples. The governing body or organisation intending to implement a prioritisation process is the most likely entity to develop the most situational and organisationally adapted versions and instructions for prioritisation. For instance, it is reasonable to assume that instructions addressing the level of ambition and the requirements for accuracy (e.g. evidence searches) vary considerably between the National Board of Health and Welfare's work on guidelines and the locally based prioritisation efforts.

### **1.3 A living tool**

Considerable experience has been gained in applying the National Model for Transparent Prioritisation in Swedish Health Care to individual organisations/services, entire county councils, and at the agency level (Ahlström et al, 2008; Engström et al, 2009; Andrén et al, 2010; Waldau, 2009; Broqvist et al, 2009; Garpenby et al, 2010; National Board of Health and Welfare, 2011).

Despite the experiences gained and the revised model produced as a result, we would like to emphasise that the model should not be considered as “finalised”. For instance, the government needs to further clarify several points concerning interpretation of the ethics platform and the *Riksdag*'s guidelines. Nevertheless, many potential benefits can be derived as those in health services continue to work uniformly with the model, driving the process forward. A process that is uniform across the different health service sectors is more important than considering the model to be “finished” in all sectors. Instead, the model should be perceived as a living tool that is revised as new experiences are gained and guidelines for prioritisation continue to develop.

### **1.4 Changes in the model – a summary**

As mentioned above, the model itself is basically unchanged as regards the fundamental principles and key steps. The most important changes can be summarised under the following points:

- The prioritisation model can be applied toward both vertical and horizontal priority setting. Application of the model thereby contributes toward implementing the *Riksdag*'s guidelines and ethics platform via all types of priority setting that involves health services.
- The model now includes an initial step to specify the purpose of the prioritisation process. This is an essential step in the model since a clearly specified purpose facilitates applying the priorities established.
- The scales used to appraise severity level and patient benefits/effects from interventions should be viewed from a wider health perspective, beyond that of the area of prioritisation in question. In other words, high levels of severity involve major impairment to health, and large patient benefits have substantial effects on a large health gap. This provides opportunities to compare rankings between different health service sectors, and thereby horizontal priorities.

- The scale for cost effectiveness is given a wider interpretation than simply using the threshold values of Swedish kronor (SEK) per QALY<sup>4</sup>. When estimates of QALY are available, this measure should be used.
- Previously recommended scales for reporting evidence concerning patient benefits and health economics have been replaced by a broader recommendation to use established checklists and evidence grading systems where possible. In the absence of such systems, the quality of the knowledge base should be described in the evaluator's own words.
- The rating scale from 1–10 is less relative within each area of prioritisation. Instead, emphasis has been placed on the importance of a logical association between the ranking allocated and the grading of severity level, patient benefit, cost effectiveness, and quality of the knowledge base. This also provides opportunities for comparisons between rankings from different health service sectors and horizontal prioritisation.

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<sup>4</sup> Quality adjusted life year (QALY).

## 2. NATIONAL MODEL FOR TRANSPARENT PRIORITISATION – APPLICATIONS AND LIMITATIONS

*The National Model for Transparent Prioritisation in Swedish Health Care can be applied at the group level throughout the publicly financed health services sector within county councils and municipalities. In principle the model can also be applied to other health care and social services, but some adaptation could be necessary since the legal prerequisites differ. Areas of application include both vertical and horizontal prioritisation, which can be done for different purposes. Primarily, the model aims to ensure that relatively more resources yielding the greatest benefit are allocated to those in greatest need of the interventions and that this is done in a systematic and transparent way. However, the prioritisation model does not cover the degree to which needs are met, nor does it address questions concerning when and how and other organisational matters.*

The *Riksdag*'s guidelines for priority setting apply to everyone involved in health services regardless of role and responsibility. Hence, the goal is that everyone associated with health services (e.g. clinical directors, administrators, politicians, and eventually the public) should understand and accept the National Model for Transparent Prioritisation in Swedish Health Care. The model aims to:

- ensure systematic application of the *Riksdag*'s guidelines for priority setting and that relatively more resources are allocated to appropriate and effective care of people with the greatest care needs
- improve the conditions for transparent reporting of priorities and their basis and consequences.

The National Model for Transparent Prioritisation should apply:

- to any type of publicly financed health service provided by county councils, municipalities, and privately managed organisations
- to medical treatment, nursing, rehabilitation, habilitation
- to all care recipients of services such as health promotion interventions, prevention, examination and analysis/diagnosis, treatment, self-care<sup>5</sup>, follow-up, or palliation
- to prioritisation decisions at the group level in particular
- as grounds for vertical and horizontal prioritisation.

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<sup>5</sup> In this context, self-care refers to health and medical interventions that licensed healthcare professionals have determined that a person can perform himself/herself. Self-care that patients provide for themselves, or with assistance from other non-professionals, is not considered a health service and consequently not covered by healthcare legislation. However, healthcare evaluation, planning, and follow-up are considered to be health services (Ministry of Health and Social Affairs 2009).

The model does not prescribe:

- the specific purpose of a prioritisation process and how to use the results at a detailed level
- how and when health services should be provided
- thresholds regarding acceptable coverage of needs
- how to organise a priority setting process.

Determining or assessing how, when, and by whom a particular intervention should be delivered (e.g. a specific surgical intervention) is most suitable in conjunction with complementary activities such as developing treatment guidelines, identifying appropriate waiting times, or discussing organisational aspects.

In general, the *Riksdag*'s guidelines indicate that coverage of needs should be greater for those receiving highest priority than for those receiving lower priority. Needs coverage can include, e.g. the quality level of care or thresholds for public involvement. The national model does not address the specific consequences that might result from prioritisation. Matters of this type must be addressed regionally or locally – for instance, how to deal concretely with high- and low-priority items.

## ***2.1 Implementation at the group level***

The National Model for Transparent Prioritisation in Swedish Health Care is primarily intended for use at a group level.

The *Riksdag*'s guidelines emphasise that although a standard list of priorities could be helpful in allocating resources at the group level, determining the needs of individual patients could deviate from the general ranking of priorities (Ministry of Health and Social Affairs 1996/97). Nevertheless, a list of priorities developed for groups of patients provides indirect guidance and support for making decisions about individual patients. This is a common approach when applying treatment guidelines from various types of clinical protocols, where general recommendations and treatment must always be adapted to each unique individual.

The ethics platform developed by the Swedish *Riksdag* applies, however, to priorities at all levels in health care, from the political level to priorities concerning individual patients.

Interest has been expressed in testing the applicability of the model in directly supporting prioritisation decisions at the individual level, e.g. in the area of assistive devices where the choice may concern the extent to which assistive devices may or may not be prescribed for a person. Although experience is too limited to offer guidance on the extent to which the model would apply in this context, projects have been initiated to investigate this issue (National Center for Priority Setting in Healthcare, 2011).

## **2.2 Vertical and horizontal prioritisation**

The National Model for Transparent Prioritisation in Swedish Health Care may be used to support decisions involving either vertical or horizontal priority setting.

The *Riksdag*'s guidelines apply to all prioritisation in health care regardless of level. Due to the lack of practical experience, the first version of the national model was limited to *vertical* prioritisation, i.e. traditionally defined as choices within a disease category, clinic, or professional group. But choices must also be made between different areas of activity, community health centres, and clinics within a county council that involve several different actors. This broader approach – involving more heterogeneous choices – is referred to as *horizontal* prioritisation.

Nevertheless, various situations occur in an organisation when different working groups, professions, and departments develop their respective priorities, which are then compiled into a common rank order (e.g. in primary care). This includes an element of horizontal decision-making among different patient groups and/or areas of activity, showing that the concepts of vertical and horizontal prioritisation are not always uniform.

Previously the concepts of vertical and horizontal prioritisation were also a way to attempt to determine the limits of responsibility in setting priorities. Horizontal prioritisation was described mainly as a responsibility for politicians. Vertical prioritisation was seen mainly as a responsibility of healthcare staff. However, the thresholds of responsibility are not sharply defined. As a rule, political prioritisation deals with allocating resources to different areas of activity rather than decisions on specific interventions. Nevertheless, political prioritisation can also be detailed and address specific interventions and methods, e.g. when politicians support health services based on specific indications for various interventions, determine out-of-pocket fees, or make decisions to ration health services.

Politicians are also involved in detailed decisions concerning the introduction of certain new methods in health care, e.g. screening programmes or interventions of interest to the media. The basic idea is that the political decisions on prioritisation should provide guidance for the large number of priorities set by healthcare staff. Today, greater emphasis is placed on the value of collective decision making (Waldau, 2009; Broqvist et al, 2010; Broqvist & Garpenby, 2007).

### **2.3 Applications in other health and social services**

The National Model for Transparent Prioritisation in Swedish Health Care is designed to be applied in health services, but despite certain limitations it can also be applied in principle to other health and social services not covered by the Health and Medical Services Act. Certain modifications may be necessary due to differences in legal prerequisites.

The Social Services Act, which together with the Health and Medical Services Act steers municipal health and social services, is not accompanied by a *Riksdag* resolution on prioritisation. Likewise, prioritising according the severity level of different conditions has no legal support. Other legal conditions also distinguish the Social Services Act from the Health and Medical Services Act. In contrast to the Health and Medical Services Act, the Social Services Act is based in part on a bill of rights. This means that anyone who meets the requirements of the law is entitled to have their needs met. Hence, social services lack the latitude to prioritise among different needs, each of which should be met for the individual to achieve a reasonable living standard. This is mentioned, e.g. in the introductory provisions of the Social Services Act (Ministry of Health and Social Affairs 2000/01:80, p.90) which states:

*“Everyone should be entitled to services according to need. The needs of one group shall not be more strongly protected than the needs of another.”*

Nevertheless, the Social Services Act offers some possibility to prioritise between different methods and work processes, each of which can meet the needs of those entitled to assistance. In choosing alternative interventions, the intervention that best promotes the goals specified in the Social Services Act receives the highest priority. A ranking of alternative methods to serve people with similar needs, based on evidence of the costs and effects of the methods, can support municipal decisions. Developing information for these decisions and attempts to steer activities towards greater efficiency are said to receive support from both the Social Services Act and the Local Government Act. Decision-

making support can also be viewed as part of the work to develop social services by promoting evidence-based practices.

Examples of areas where the National Model for Transparent Prioritisation has been applied in municipal health services include the dementia and the schizophrenia guidelines from the National Board of Health and Welfare (National Board of Health and Welfare, 2011; Lund, 2010).

### **3. THE ETHICS PLATFORM – FOUNDATION OF THE NATIONAL MODEL FOR TRANSPARENT PRIORITISATION**

*For priorities to be considered reasonable and just, the government bill emphasises, e.g. the importance of the process being transparent and based on generally accepted principles. The National Model for Transparent Prioritisation in Swedish Health Care is based on the three principles of ethics (the human dignity principle, the needs-solidarity principle, and the cost-effectiveness principle) that the Riksdag decided should apply to priority setting in health care. The model builds on the assumption that transparent reporting can promote understanding of the priorities applied. The four priority groups are not included in the prioritisation model.*

#### **3.1 Transparency and accepted principles**

To view prioritisation as being reasonable and just, the government bill emphasises, e.g. that prioritisation must be transparent and based on generally accepted principles. Both of these considerations have guided the creation of the National Model for Transparent Prioritisation in Swedish Health Care.

##### **3.1.1 Transparent prioritisation**

Different types of choices and priorities can develop more or less transparently and systematically. When it is not possible to meet every care need, the government believes it is reasonable to have an open discussion to clarify the grounds on which priorities are set. According to the government bill on priority setting, transparent prioritisation (i.e. reporting on prioritisation and its principles and consequences) aims to create acceptance among the population for the priorities and limitations that are unavoidable in health care, but also to give people the opportunity to react to and act upon the priorities set:

*“Democratic discourse and citizen acceptance of necessary prioritisation requires knowledge about the grounds on which priorities are set, the opportunities that patients have to influence these, and the avenues to pursue when dissatisfied with the priorities set. Health services have an obligation to develop methods to make such information available to those who are patients today and those who may become patients in the future.”*

(Ministry of Health and Social Affairs 1996/97, p.13)

This, however, should not be interpreted to mean that all aspects of the work with prioritisation must be open to the public. Although the government's focus is on public transparency, when correctly applied the model can also promote greater transparency between different actors within the health services.

### **3.1.2 Generally accepted principles**

Another condition that the government believes will facilitate understanding of the need to set priorities in health care is to base priorities on generally accepted principles. The choices made in health care are always based on values of some type. The government, in principle, believes that the values underlying access to health services and the priorities set must be perceived to be fair by most of the population – in part to maintain the confidence and the will to publicly finance health care. In Sweden, the ethical platform establishes the principles for prioritisation in health care:

*“...if these [priorities] develop from a clear and generally accepted ethics platform this can promote understanding by the public and healthcare staff for the priorities that must be set and can thereby contribute towards maintaining confidence in publicly financed health care even when resources are insufficient to fulfil all needs.”* (Ministry of Health and Social Affairs 1995, p.115)

### **3.2 The ethics platform**

In 1992, the government at that time initiated an investigation, i.e. the Priorities Commission, to consider the role of health care in Sweden as a welfare state. The Commission was also tasked with identifying fundamental ethical principles to provide guidance and a foundation for open discussions concerning prioritisation in healthcare. The ethics platform developed by the commission is presented in the Commission's report (Ministry of Health and Social Affairs 1995), the government bill (Ministry of Health and Social Affairs 1996/97), the Committee on Health and Welfare's report (Committee on Health and Welfare 1996/97), and the Health and Medical Services Act, 1982: 763 sections 2<sup>6</sup> and 28<sup>7</sup> respectively (Ministry of Health and Social Affairs 1982).

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<sup>6</sup> Care shall be delivered respecting the equality of all people and the dignity of the individual. Those with the greatest care needs should receive priority to health services. Act (1997:142).

<sup>7</sup> Management of health services shall be organised to assure a high level of patient safety and appropriate quality of care and to promote cost effectiveness. Act (1996:787).

### 3.2.1 Human dignity principle

The *human dignity principle* is the overriding ethical principle in the platform. It addresses factors that should *not* determine the priorities for care, e.g. personal characteristics and functions in society (e.g., talent, social position, income, age, gender):

*“The relevant issue in prioritisation is that human dignity is not tied to a person’s personal characteristics or functions in society, but to existence itself. It is important to establish that talent, social position, income, age, etc should not determine who should receive care, or the quality of care received.”*  
(Ministry of Health and Social Affairs 1996/97)

Since resources are limited, the human dignity principle must be supplemented by other guiding principles.

### 3.2.2 Needs-solidarity principle

The *needs-solidarity principle* means that – when it is necessary to prioritise among effective interventions – more of health care’s resources should be given to those in greatest need, those with the most severe conditions, and those with the lowest quality of life. This applies even if it means that everyone cannot have their needs met in part or at all.

Although the *Riksdag’s* resolution on prioritisation gives major consideration to the severity level of disease, it cannot be the only grounds for prioritisation. Substantial importance is also given to patient benefit. Both the Priorities Commission and the *Riksdag’s* resolution on prioritisation established that the patient’s ability to benefit from an intervention is integral to the needs concept.

*“According to the Commission, the medical benefit aspect is integral to the needs concept. As defined earlier, one needs only that from which one can derive benefit, or conversely, one does not need that from which one derives no benefit.”* (Ministry of Health and Social Affairs 1996/97, p.18)

According to the government bill, *solidarity* in the needs-solidarity principle not only implies that care outcomes should be as equitable as possible (i.e. the best possible health and quality of life), but it also implies a special responsibility towards people who are unable to exercise their own rights:

*“... also to pay particular attention to the needs of the weakest. This includes children, the elderly with dementia, the unconscious, and others who for various reasons have difficulty in communicating with their surroundings.”*

*People who are unable to exercise their rights have the same right as others to receive care.*” (Ministry of Health and Social Affairs 1996/97, p. 20)

Health services have a special responsibility to appraise the needs of these groups in order to determine whether or not their needs are being met. In other words, the appraisal itself should be given high priority. Thereafter, further prioritisation activities are guided by the need for healthcare interventions, not impaired autonomy *per se*.

### **3.2.3 Cost-effectiveness principle**

The third ethical principle is the *cost-effectiveness principle*. In choosing between different services or interventions one needs to strive for a reasonable relationship between costs and effects, measured in terms of improved health and quality of life. According to the government bill, the cost-effectiveness principle should be applied only in comparing methods for treating the same disease; otherwise it is not possible to compare their effects fairly. Concurrently, the government emphasises the importance of generally pursuing cost effectiveness in care:

*“...it is essential to differentiate between the cost effectiveness of a treatment for a particular individual and that for health care at large. A cost-effectiveness principle that concerns choices between different interventions for the individual patient must be applied as proposed by the inquiry, and is subordinate to the principles of human dignity and needs and solitary. Nevertheless, it is essential for health services to strive for high cost effectiveness as regards health care services in general.”* (Ministry of Health and Social Affairs 1996/97, p. 21)

A later amendment concerning the situation of the patient in health care also relates to this principle. Section 3a states that consideration must be given to whether *“the costs of treatment are justified”* in relation to the disease or injury and whether the intervention is consistent with scientific evidence and standard practice.

The relationship between the needs principle and the cost-effectiveness principle is such that patients with severe diseases and substantially impaired quality of life should take precedence over milder cases, even if this care involves “substantially” greater costs for a given health benefit, assuming that the relationship between cost and health benefit is reasonable.

### 3.2.4 Proposed changes to the ethics platform and implications for the model

A follow-up of the *Riksdag*'s guidelines in 2007 (National Center for Priority Setting in Health Care, 2007) prompted the National Board of Health and Welfare to propose to the government several changes in the ethics platform and the guidelines generally (National Board of Health and Welfare, 2007). These suggestions have influenced the design of the National Model for Transparent Prioritisation in Swedish Health Care.

For instance, the National Board proposes refining the cost-effectiveness principle and broadening the area of application so that in addition to choosing between methods for the same disease it also encompasses choosing between different types of care needs. This approach is also applied in the national model.

The government bill includes four priority groups,<sup>8</sup> intended to exemplify the ethics platform. In its follow-up, the National Board proposes eliminating or substantially revising these groups, a proposal that the Swedish National Council on Medical Ethics (2011) also accepts.

Priority setting that considers only the condition (e.g. chronic disease) but not the patient benefit or cost effectiveness of various interventions does not live up to the ethics platform as a whole. For instance, a disease that is classified as a serious chronic disease can present with different degrees of severity in different stages, just as interventions/service areas (e.g. habilitation/rehabilitation) can probably offer both major and minor patient benefits and/or cost effectiveness. Hence, generally they cannot be given a particular level of priority. The priority groups can possibly play a role as a rough measure for rating the severity of different conditions. Even regarding this point there are obvious limitations. Hence, groupings (patient groups, interventions, type of care, etc.) that combine the various dimensions generate confusion.

The government bill emphasises that the priority groups serve only as examples, and that the priority levels can vary:

*“We want to emphasise that these are only examples, and that the need for care in each individual case must be determined based on the conditions of that particular case.”*

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<sup>8</sup> Priority group 1 (care for acute life-threatening diseases, care for diseases that untreated lead to permanent disability or premature death, care for severe chronic illnesses, palliative care and care during the final phase of life, care for people with impaired autonomy)

Priority group 2 (prevention, habilitation/rehabilitation)

Priority group 3 (care for less severe acute and chronic diseases)

Priority group 4 (care for reasons other than disease or injury)

(Ministry of Health and Social Affairs 1996/97, p. 32)

The Committee on Health and Welfare made the same determination: generally what is important in prioritisation is not the diagnosis or disease in question. Rather, what is decisive is the condition and care need at each particular point in time when a priority is set (Committee on Health and Welfare 1996/97).

In addition to the above proposal concerning the cost-effectiveness principle and priority groups, the National Board of Health and Welfare informed the government that an investigation and clarification of the prioritisation guidelines would be of substantial value even as regards other matters. For instance, this applies to questions concerning which *costs* are relevant to consider in calculating cost effectiveness where the principle is considered to be too vague. The same applies to the concept of *effects*, e.g. questioning whether effects should be limited to patients only, or if other individuals or social phenomena (external effects) are reasonable to consider (National Board of Health and Welfare, 2007). The national model gives some consideration to indirect costs and external effects, which strictly interpreted can be seen to deviate from the guidelines (Chapter 4.3). The extent to which this is allowed to affect prioritising must be clearly reported in all types of prioritisation activities.

### ***3.3 Association between the ethics platform and the National Model for Transparent Prioritisation in Swedish Health Care***

The National Model for Transparent Prioritisation in Swedish Health Care is based on all three ethical principles in the ethics platform.

Here, the human dignity principle serves as an overriding principle that is not an explicit step in the national model for transparent prioritisation, but must be considered in all types of priority setting. The principle provides general guidance on what should *not* determine priorities in health care.

The model concretely establishes the needs-solidarity principle and the cost-effectiveness principle in several *components* (Figure 1). These are taken from the description and explanation of the principles that appear in the government bill. The needs-solidarity principle is expressed both via the severity level of the health condition and the patient benefit/effect from the intervention. The national model uses the patient benefit concept to summarise the benefits of interventions, i.e. including interventions aimed at users or healthy individuals (in preventive interventions). The cost-effectiveness principle is expressed in terms of the effect of intervening and the estimated cost of intervening.

Chapter 4 further describes these components and presents the different steps included in the National Model for Transparent Prioritisation (Figure 1).

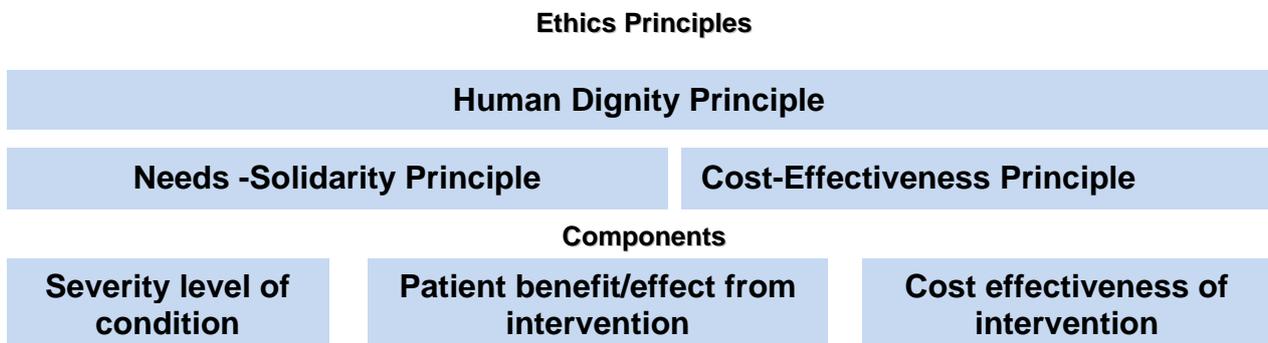


Figure 1. Diagram of ethical principles and key components forming the foundation of the National Model for Transparent Prioritisation in Swedish Health Care.

### **3.4 Other Riksdag guidelines for prioritisation**

In addition to the ethics platform, which forms the core of the *Riksdag's* guidelines, there are also guidelines addressing the applicability of the ethical principles and other notations concerning what the governing bodies should consider in setting priorities. The report, *Resolving Health Care's Difficult Choices* (National Center for Priority Setting in Health Care, 2007) summarises these guidelines under several points taken from the Priorities Commission's report (SOU, 1995:5), the government bill (1996/97:60), and the Committee on Health and Welfare report (1996/97 SOU14). The following points have implications regarding the National Model for Transparent Prioritisation in Swedish Health Care and will be addressed in conjunction with presenting the different steps in the model:

- That needs coverage should be greater for those with high priority than for those with lower priority.
- That all effective care interventions should be given high priority when a disease or diagnostic group is given high priority.<sup>9</sup>
- That care interventions with no benefits should not be used and should not be included in the options for prioritisation.

<sup>9</sup> According to the model, conditions *per se* cannot receive high priority, but the guidelines should be interpreted to mean that a high severity level in combination with effective care interventions point towards a high priority (assuming that the cost of intervening does not appear to be unreasonable).

- That in disease and injury, quality-of-life-related needs (e.g. symptom alleviation) should, in principle, carry equal weight as health-related needs (i.e. curative interventions).
- That all prioritisation should consider the opportunities for the promotion, teaching, and support of self-care options.
- That health and medical services regulated by law should be considered guaranteed resources, e.g. forensic psychiatric care.
- That although a standard list of priorities could be helpful in allocating resources at the group level, determining the needs of individual patients could deviate from the general ranking of priorities

## 4. STEPS IN THE NATIONAL MODEL FOR TRANSPARENT PRIORITISATION

*The National Model for Transparent Prioritisation in Swedish Health Care involves the following steps:*

- *Defining the purpose and area of prioritisation*
- *Identifying the prioritisation objects*
- *Compiling and appraising severity levels, patient benefits, and cost effectiveness*
- *Weighing and ranking*
- *Reporting the ranking, reasoning, and consequences*

The following diagram illustrates model:

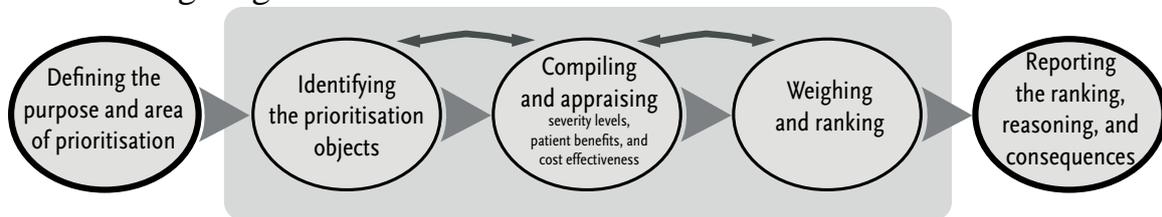


Figure 2. Illustration of the National Model for Transparent Prioritisation in Swedish Health Care.

The different steps do not necessarily follow a linear process, but some steps might need to be addressed repeatedly. It is usual for the process to move forward and backward (e.g. between appraising patient benefits and revising the prioritisation object) before the priorities can be ranked.

To approach the prioritisation process systematically, a worksheet covering the different steps in the model can be used to document the appraisals used as a basis for the final ranking (Figure 3). This chapter presents an example of a worksheet in conjunction with describing the steps in the model. The placement of the different columns can vary (Figure 3).

Condition	Intervention	Condition's severity level	Patient benefits	Quality of knowledge base	Costs/ effects	Quality of knowledge base	Ranking	Comments/ consequences

Figure 3. Worksheet for documenting the steps in the National Model for Transparent Prioritisation in Swedish Health Care.

## **4.1 Defining the purpose and area of prioritisation**

*The first step in the National Model for Transparent Prioritisation in Swedish Health Care involves defining the purpose of priority setting – How will we use the ranking? The purpose of prioritisation determines the area in health care to be subject to prioritisation.*

### **4.1.1 Defining the purpose of prioritisation**

The first step in the National Model for Transparent Prioritisation is to establish the purpose of the prioritisation effort. This involves deciding in advance how the prioritisation ranking will be used. According to the *Riksdag's* guidelines, the overriding purpose of using the model to support resource allocation in health care is to ensure that relatively more resources are assigned to the person(s) with the greatest need compared to the person(s) with low priority. Beyond this, the model does not specify any other purposes since every actor must define the purposes based on the situation where the model is applied.

#### *Examples of specific purposes in priority setting*

Since the definition of purpose in priority setting is so central to the process, some examples are used to describe *possible* operational aims of a prioritisation process:

- to create support for decisions and assure quality in clinical care (How do staff know that they are doing the right things?)
- to create a basis for introducing new methods and/or patient groups
- to create a basis for redistributing resources
- to create a basis for rationing
- to create a basis for improving efficiency by phasing out ineffective interventions
- to create a basis for phasing out interventions where the risk for complications exceeds the benefits to patients.

In situations involving a surplus of resources, the issue might involve prioritising how decision makers want to distribute the surplus. Hence, ranking might be aimed at creating a basis for decisions to give the surplus to areas/interventions with the highest rank. Another purpose might be to *redistribute* available resources among different health service sectors (e.g. from those with the lowest priority to those with higher priority) or to rank *new methods* in relation to interventions that are already being offered by the health service.

In times of austerity, the prioritisation process might be aimed at identifying targets for *rationing*, i.e. consciously limiting care or social services with some degree of efficiency. Rationing can be done in several different ways (increasing waiting times, reducing quality, changing the indications for care, eliminating certain options, etc.). According to the *Riksdag's* guidelines, rationing should begin with items having the lowest priority.

Prioritisation can also aim to provide a basis for phasing out methods that the health services should no longer offer. Here, the reason is not a shortage in resources, but involves interventions that are ineffective or have major risks or side effects in relation to their benefits. Phasing out ineffective interventions is not rationing, but an *efficiency* measure, i.e. better resource utilisation in relation to health gained. Identifying other types of efficiency measures (e.g. alternative work methods or caregivers) could be a valuable 'by-product' of priority setting.

#### 4.1.2 Defining the area of prioritisation

The *area of prioritisation* refers to the area in which the order of priority or ranking is established. The area could include, for example:

- different groups of needs or diseases, e.g. overweight risk group, stroke
- different service sectors e.g. habilitation, residential care for the elderly
- different professional groups, e.g. dieticians, speech therapists, physicians, nurses.

Priorities can be set both within and between different areas. In other words, an area for prioritisation can vary in scope. At its most limited, it can cover interventions by a single profession for a specific patient group within a specific service area (e.g. nursing interventions for diabetes patients in primary care). An area for prioritisation could also cover all health services in a county council and involve different patient groups, professions, and services.

The national model does not suggest how to best define the areas for prioritisation, i.e. what the priority setting process should include. Rather, it is the purpose of the prioritisation process that must determine which areas in health care should be subject to priority setting.

## 4.2 Identifying prioritisation objects

*Prioritisation always involves ranking something, i.e. an individual or group makes a choice between two or more alternatives, which results in a rank order. The National Model for Transparent Prioritisation in Swedish Health Care refers to that which is ranked as the “prioritisation object”. This always consists of a condition-intervention pair. A condition is defined as a state of ill health or the suspicion/risk of ill health widely interpreted. Interventions refer to all activities in health and medical services that are targeted at patients, users, or in some cases population groups (e.g. prevention programmes).*

To establish a rank order, we must identify and describe that which is to be ranked, i.e. the *prioritisation object*.

In the National Model for Transparent Prioritisation, a *prioritisation object* always consists of a combination of a *condition* and an *intervention*, i.e. a *condition-intervention pair*.

Both the conditions (disease, health risks, etc) and the interventions must be present in a prioritisation object for the ethics platform to be fully implemented. Simply ranking different conditions means that consideration is given to the condition’s severity level (which is an important part of the needs-solidarity principle), but not to the patient’s benefits from different interventions (which is part of the needs-solidarity principle and the cost-effectiveness principle). Simply ranking different interventions is also insufficient. Since interventions have different effects under different conditions, the same intervention can be given different priorities depending on the conditions at which it is targeted.

Determining which and how many condition-intervention pairs should be chosen, and their level of detail, is guided by the purpose of the prioritisation effort.

The worksheet begins with two columns that present the prioritisation object, *condition-intervention pair* (Figure 4).

Condition	Intervention	Condition's severity level	Patient benefits	Quality of knowledge base	Costs/effects	Quality of knowledge base	Ranking	Comments/consequences

Figure 4. Worksheet for documenting the steps in the National Model for Transparent Prioritisation in Swedish Health Care.

#### 4.2.1 Conditions

In identifying and describing health conditions these should reflect the broad perspective on health that, according to the government bill, should characterise health services:

*“... health does not consist of medical factors alone, but also social, psychological, and other factors.”* (Ministry of Health and Social Affairs 1996/97, p. 16)

The concept of *condition* has a broad meaning in the national model for transparent prioritisation, but it always involves a description related to a dimension or combination of different dimensions of ill health. This can apply to *confirmed* ill health, *suspected* ill health, or a *risk* for ill health, regarding:

- impairments of body structures (influence on organs and body parts, e.g. dementia, suspected brain inflammation). Often described in diagnoses
- impairment of body functions (including psychological functions) (e.g. pain, anxiety, hypertension)
- activity limitations (e.g. impaired mobility or communication capacity)
- participation restriction (e.g. related to work or social contexts)<sup>10</sup>
- obstacles involving environmental factors or living conditions that influence health (e.g. deficiencies in personal relationships or social support measures)
- personal factors (e.g. age, gender, lifestyle).<sup>11</sup>

<sup>10</sup> Limited participation can also include impaired co-determination regarding how an activity, e.g. personal care, should be carried out if one is unable to do it oneself.

<sup>11</sup> Section 4.3 presents a more detailed description concerning personal characteristics and human dignity principles.

The concept of health is taken from the International Classification of Functioning, Disability, and Health (ICF) (National Board of Health and Welfare, 2004).

Conditions can be described with varying degrees of detail depending on the purpose and context of the prioritisation effort. In some cases, the primary diagnosis, according to ICD 10 or other established classification system, can be appropriate to use in describing conditions concerning a prioritisation object. Often, more comprehensive descriptions are needed with several different health dimensions to capture more complex needs, e.g. in elderly people with multiple disorders.

The government bill recognises that the severity level of conditions can vary over time.

In other words, conditions may need to be defined with respect to different severity levels (e.g. severe or less pronounced aphasia) and different phases (e.g. new onset or chronic conditions or different developmental phases/age groups among children).

#### *Interpretation and perspectives concerning the national model*

Interpretation problems may arise in relation to the human dignity principle when it comes to using *personal factors* as prioritisation objects. In the bill, the government viewed it as a type of discrimination that is inconsistent with the ethical principle to generally allow needs to be subordinate to gender, age, birth weight, lifestyle, or economic and social conditions alone. Concurrently, the government bill states that characteristics or functions of a group could be justifiably considered since they may be indicators of:

- the presence of special care needs
- the scope of need and/or cost effectiveness.

In such cases, personal factors could be considered in setting priorities at the group level and included in describing the conditions in the prioritisation object. However, it should be clear that there is a connection to special care needs, the magnitude of these needs, and/or cost effectiveness.

*Age* is an example in this context. The government bill distinguishes between chronological *age* (based on date of birth) and biological age (based on medical judgement). Special treatment given solely on the basis of chronological age deviates from the human dignity principle. However, the potential to benefit from a treatment and the risk for injury must be taken into consideration.

“It is the total assessment of the patient’s need and how the patient can benefit from care that should determine the interventions.” (Ministry of Health and Social Affairs 1996/97, p. 25)

For instance, 35 years of age is used as the threshold in amniocentesis screening for Down syndrome. At this age, the risk of congenital disorders is so great that the benefit to patients from the test outweighs its disadvantages. Another example would be influenza vaccination in an age group that runs a greater risk for complications than other age groups, and where the level of the risk justifies a higher priority. Here, age should be included in describing the prioritisation object.

As a *gender*-related example, different principles are used to screen men and women for abdominal aortic aneurysm, where benefits in survival can be shown for men but not for women.

Expected *future lifestyle* may also be of importance in determining whether patients can benefit from a given treatment. This could involve, e.g. the effectiveness of certain types of surgery for those who are expected to continue smoking, or liver transplantation for those who are expected to continue abusing drugs. However, this should not be interpreted to mean that health services have no responsibility to influence a person’s ability to benefit from a treatment when possible. If, for example, patients have poor dietary habits that impair the effects of insulin, and they find it difficult to change, this could justify giving high priority to lifestyle interventions (e.g. dietary education) that are found to be effective. However, the Priorities Commission rejected consideration of *previous lifestyle* in setting priorities (Ministry of Health and Social Affairs 1995).

#### 4.2.2 Interventions

In addition to a condition, a prioritisation object must also include an intervention.

The concept of *intervention* encompasses the following actions in medical treatment, nursing, rehabilitation, and habilitation:

- preventive interventions
- investigation, analysis, and diagnostics
- treatment
- self-care
- follow-up
- palliation.

An intervention may involve a specific intervention, or a combination or chain of interventions (clinical protocols or types of care). The purpose of the prioritisation effort determines which interventions, and level of detail, are relevant to describe for each condition.

The *Riksdag*'s guidelines indicate that priority setting should always consider self-care as an intervention. However, the government bill states that legally regulated health services should be viewed as guaranteed resources (e.g. forensic psychiatric care). According to the government, such services should not be involved in prioritisation.

*Interpretation and perspectives concerning the national model*

The Health and Medical Services Act states that all patients have a right to a medical assessment of their health unless manifestly unnecessary (Health and Medical Services Act, Section 2a). According to the government bill, a medical assessment of individual health also comprises the most important grounds for prioritisation and can be viewed as an obvious priority at the individual level.

Nevertheless, medical assessments (e.g. for suspected heart disease in children) might need to be included as prioritisation objects in ranking at the group level since some medical assessments could be considered to have higher priority than others, e.g. due to the suspected severity of the condition, the speed of intervention necessary to be effective, the scope of examinations needed if different alternatives are available, and/or the extent to which interventions can benefit patients in meeting the medical needs being assessed<sup>12</sup>:

*“The conditions in the individual case determine the scope of the investigation that needs to be conducted.”* (Ministry of Health and Social Affairs 1996/97, p. 26)

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<sup>12</sup> Neither the *Riksdag*'s guidelines nor the Health and Medical Services Act define “medical assessment”.

### **4.3 Compiling and appraising severity levels, patient benefits, and cost effectiveness**

*Guided by the ethics platform, the National Model for Transparent Prioritisation involves appraising the severity level of the condition, the patient benefit of the intervention, and the cost effectiveness of the intervention. The severity level is appraised based on the actual health status, the risk of ill health, and the duration of the condition, while appraisal of patient benefit encompasses the intervention's effects on these parameters. The scale rates the appraisals as: very high, high, moderate, and low. As regards cost effectiveness, the scale uses the following ratings: very high cost per effect, high cost per effect, moderate cost per effect, and low cost per effect. Finally, the certainty of the appraised ratings is evaluated, if possible using established checklists and evidence grading systems. In the absence of such systems, the evaluators describe the quality of the knowledge base in their own words.*

Guided by the ethics platform, the National Model for Transparent Prioritisation in Swedish Health Care bases appraisals on:

- the severity level of the condition
- the patient benefits of the intervention
- the cost effectiveness of the intervention.

Severity levels, patient benefits, and cost effectiveness should, to the extent possible, be viewed from a wider perspective of ill health rather than in relation to only a limited area of prioritisation (e.g. orthopaedics or elder care). This promotes a shared view and the ability to communicate about priorities across different services (different care levels) within a region or nationally.

Severity level, patient benefit, and cost effectiveness should not be viewed as isolated phenomena, but as relating to each other in different ways and ultimately interwoven into rankings or priority levels. It is only the severity level that is assessed independently of patient benefit and cost effectiveness. The severity level influences the appraisal of patient benefits since the grade of ill health limits the amount of patient benefit that can be attained. However, a low amount of patient benefit (efficiency) is always appraised as low, regardless of severity level of the health condition. The amount of patient benefit is then included, along with the cost of an intervention, in appraising cost effectiveness.

### 4.3.1 Appraising a condition's severity level

In accordance with the *Riksdag's* guidelines, the appraisal of a condition's severity level in the prioritisation model encompasses the actual health condition (as regards suffering, functional impairment, and quality of life), the risk of future ill health (premature death, continued suffering, disability, and impaired health related quality of life), and the duration of the condition (Figure 5).

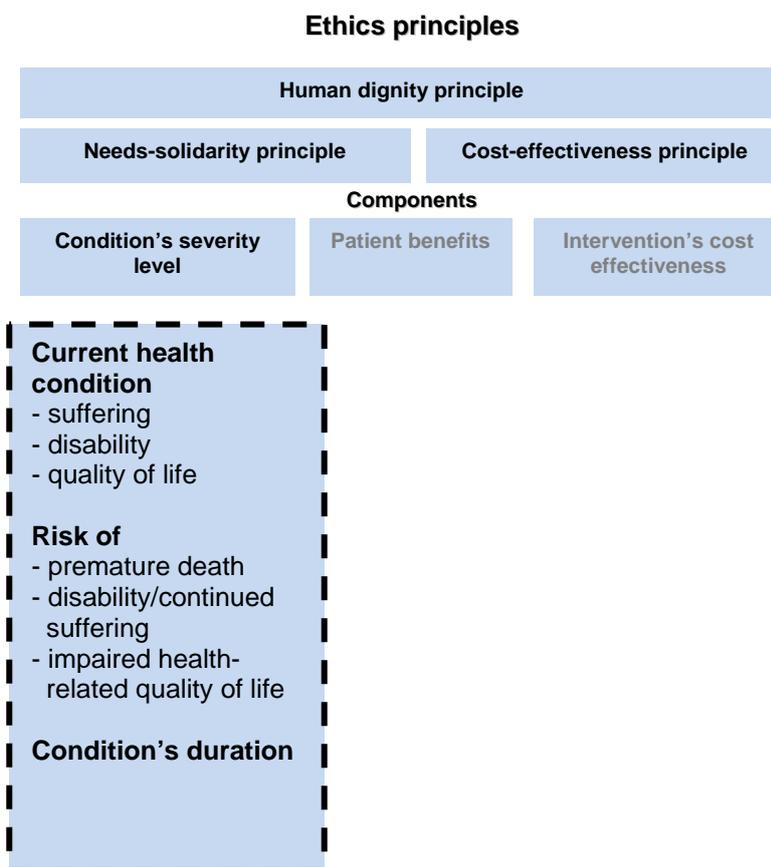


Figure 5. Components relevant for appraising a condition's severity level in the National Model for Transparent Prioritisation in Swedish Health Care.

#### *Appraisal in a specific situation*

Severity levels are appraised in the context of *the situation* where the interventions (which will be paired with the condition in the prioritisation object) are intended for use. The situation in which the severity level is appraised can vary. It might involve appraising the severity level of an untreated condition during the acute phase, e.g. an untreated femur fracture. The severity level relating the immediate health condition, risk, and duration should then be appraised based on the untreated fracture, i.e. the condition. Or, the situation might involve appraising the severity level after the intervention has been used. Then the condition in our example could be, e.g. a newly operated femur fracture. Health conditions can vary over time, so the severity level can differ in

different situations. For instance, screening programmes for aortic aneurisms are conducted in situations where the individual is healthy (i.e. current health condition), but is potentially at risk of illness. Hence, the current health condition shows no level of severity. But since there is a low risk of future ill health, the severity level is higher than if one considers only the current condition. However, if the current condition is a ruptured aneurism, then the severity level of the current condition is very high.

#### *Appraising duration*

As regards the *duration* of a condition, one must make a rough estimate since both the condition of ill health and the associated risks often vary over time. Only future duration should be considered. Although some discussion has focused on the extent to which previous suffering should be considered in prioritisation, the *Riksdag*'s guidelines provide no support for such considerations.

#### *Rating severity level*

The overall severity level (current condition, risk for future ill health, and duration) is rated on the following scale:

- very high
- high
- moderate
- low

The prioritisation model does not yet include a uniform definition of the levels used in the rating scale. Instead, it is recommended that those working with prioritisation should develop and present their own criteria for categorisation. One example of such a structure is the matrix developed by the rehabilitation sector in Kalmar County Council and which is based on ICF (Appendix 1).

Grading should aim to consider ill health more in absolute terms, rather than relative to other conditions in a particular area of prioritisation. A *very high* severity level indicates substantial impairments to health and/or long-term impairments and/or high risk for premature death/substantial reduction in quality of life. This can mean that within some services the entire severity-level scale, from *low* to *very high*, will be represented while in others the severity levels will show less variation.

*Weighing current condition, risk, and duration*

The model does not assign specific weights to the different parameters, i.e. current condition, risk, and duration. Hence, one can neither say they are equal, nor that any parameter weighs more than any other. Determining that a condition involving moderate suffering (which continues for 6 months with moderate pain, disability, etc, but a low risk for future complications and mortality) is more severe than an asymptomatic condition (but with some percentage of risk for premature death) is only possible by assigning values that are transparently reported by those responsible for the appraisals in the prioritisation process. The worksheet below includes a column for the *condition's severity level* (Figure 6).

Condition	Intervention	Condition's severity level	Patient benefits	Quality of knowledge base	Costs/effects	Quality of knowledge base	Ranking	Comments/consequences

Figure 6. Worksheet for documenting steps in the National Model for Transparent Prioritisation in Swedish Health Care.

*Interpretation and perspectives concerning the national model*

Deciding what should be included in appraising severity level is not without problems. The government bill offers no guidance for interpreting concepts such as suffering or quality of life. Hence, there is room for different interpretations of what can reasonably be considered in the appraisal. As regards children and adolescents, for example, a reasonable perspective might involve weighing not only the risk that a condition might deteriorate, but also the risk that development might be delayed or inhibited.

In appraising the severity level, there is also the question of how much weight can be given to *external effects of a condition* without conflicting with the human dignity principle. In this context, external effects refer to:

- consequences for the health of other people
- influence of environmental factors on the care needs of patients.

The first situation can be exemplified by the risk of transmitting an infectious disease. Can the inclusion of such external effects justify a higher severity level than simply considering how the condition affects patients themselves?

The second situation deals with the degree to which environmental factors (e.g. social networks) might influence, although not determine, severity levels. The government bill clearly establishes that social functions such as responsibilities, economic situation, and social position shall not be grounds for prioritisation. The bill also states that generally allowing social conditions to *determine* who should receive care, or the quality of care received, is inconsistent with the ethics principles. If a wider perspective of ill health is applied (as recommended in the government bill) then limitations in activities (e.g. problems related to eating or mobility due to disease or injury) can have different consequences and problems depending on whether or not the patient has a functioning social network.

Certain general statements in the government bill could be interpreted to mean that such considerations must be included in prioritisation:

*“That which should primarily guide the practical application of prioritisation in the individual case involves consideration of a particular patient’s overall situation, i.e. both the disease panorama and life situation.”* (Ministry of Health and Social Affairs 1996/97, p. 29)

In the absence of clear guidance, one cannot reject the premise that directly apparent external effects on the health of others and/or the influence of environmental factors on a patient’s health *can* be considered in appraising severity levels in the National Model for Transparent Prioritisation in Swedish Health Care.

In cases where these types of effect are allowed to influence priorities, it is essential to clearly report this and be aware that this can deviate from the ethics platform (strictly interpreted).

#### **4.3.2 Appraising patient benefit**

In appraising the expected patient benefits/effects of intervention, an overall evaluation considers the effects on a current health condition (in terms of suffering, disability, and quality of life), the effects on risk (premature death, continued suffering, functional impairment, and reduced health-related quality of life), and risks for side effects and serious complications from the intervention. (Figure 7)

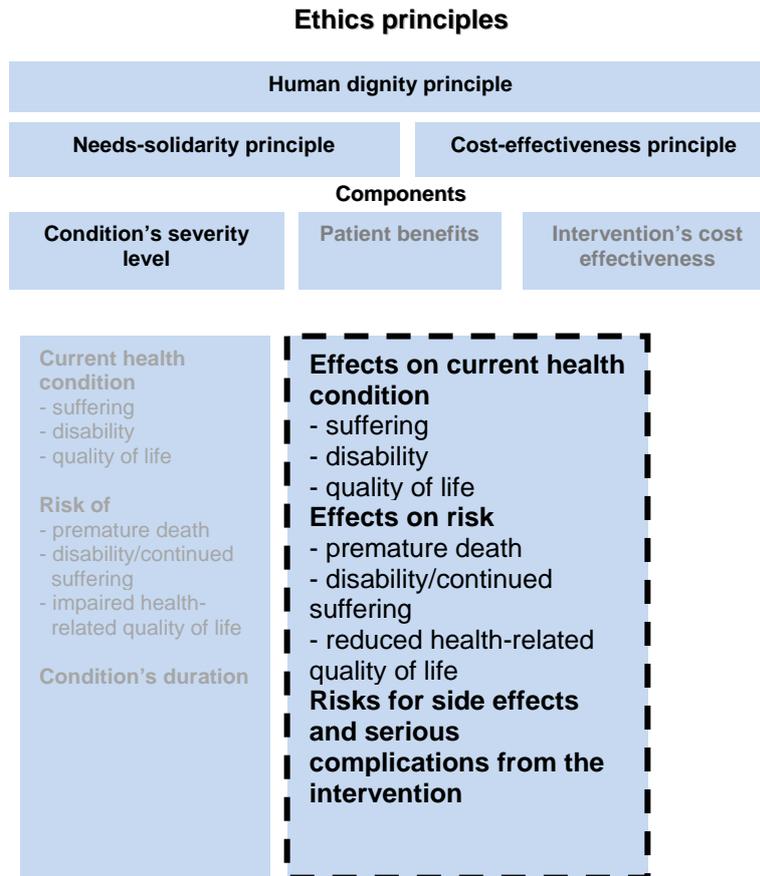


Figure 7. Components relevant for appraising patient benefit in the National Model for Transparent Prioritisation in Swedish Health Care.

Several reasons favour reporting patient benefits separately in the national model, even though this is also included in the appraisal of cost effectiveness. One reason is that the data for the appraisal would be easier to monitor, and another is the frequent lack of health economic data.

#### *Appraising a specific situation*

Patient benefits from an intervention are always appraised in relation to a specific condition in a specific situation that is defined in the prioritisation object (the condition-intervention pair).

The situation in which patient benefits are appraised can vary. For instance, the situation might involve the introduction of a new intervention (e.g. drug) in health care. Patient benefits are then appraised in relation to a condition where other interventions have already been applied, and the severity level has probably been reduced already. Hence, the patient benefits from the new intervention might be appraised as low – only a small amount of health is gained in relation to the benefits of the previous intervention.

Another prioritisation situation could involve studying an entire service sector for the purpose of assuring quality. In this case, the condition might be described as more of a fundamental condition without mentioning alternative interventions (e.g. the elderly person with anxiety). The patient benefits derived from different types of interventions are then appraised based on the option of not doing anything.

#### *Outcome measures in the model*

The effects of interventions are measured with the help of various outcome measures that can be categorised as decisive, important, and unimportant.<sup>13</sup> The decisive outcome measures carry the greatest weight in appraising patient benefit.

Decisive outcome measures are usually *patient-related*, i.e. measures of direct effects on the individual, such as mortality, current morbidity, health-related quality of life (e.g. activity limitations and participation restrictions), or risks of similar phenomena. According to the *Riksdag's* guidelines, interventions that provide relief and improve quality of life should, in principle, be given the same weight as interventions that focus on cure. Other decisive outcome measures can address the degree to which interventions cause serious side effects or complications.

Important, but not decisive outcome measures can be process- or surrogate-outcome measures. These measure something at the bodily or functional level that leads to, or can be assumed to lead to, cure or relief. These might include different laboratory values or test results, e.g. changes in blood pressure or increased joint mobility in rheumatic diseases. At times, surrogate outcome measures are the only measures available. However, they must be used with caution; on occasion a positive effect from a surrogate outcome measure might not have any effect on patient-related outcome measures, or it could even have a negative effect. An example is fluoride in treating osteoporosis, which leads to increased bone density (surrogate outcome measure), but increases the percentage of fractures (decisive outcome measure) (Rothwell, 2005). Other important, but not decisive, outcome measures include less serious side effects or complications.

Values determine what constitutes decisive and important outcome measures. To the extent possible, this determination should consider the values of the patient group in question (Atkins et al, 2004; Schunemann, 2006; Guyatt, 2008).

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<sup>13</sup> This means of categorising outcome measures relates to the most widespread evidence grading system, i.e. GRADE (Grading of Recommendations, Assessment, Development and Evaluation).

### *Patient benefit scale*

Overall patient benefit (i.e. effects on current condition and risk of future ill health and complications) is rated on the following scale:

- very high
- high
- moderate
- low or none

The National Model for Transparent Prioritisation in Swedish Health Care appraises patient benefits as absolute effects rather than in relation to the other interventions in a limited area of prioritisation. According to the model, it is the *expected average benefit* for the entire patient/target group receiving the intervention that should be evaluated.

The steps in the patient benefit scale have yet to be uniformly defined. Those working with prioritisation should create and report their criteria for defining the categories, e.g. very high patient benefit, high patient benefit, etc. (See Appendix 2 for an example of a conceptual structure for categorisation, based on ICF, developed by Kalmar County Council).<sup>14</sup>

In the National Model for Transparent Prioritisation in Swedish Health Care, patient benefit should reflect the degree to which a defined intervention for a specific condition actually affects ill health or impaired quality of life. Hence, the degree of patient benefit relates to the size of the health gap and how the intervention affects this gap. In this way, patient benefit relates both to the effectiveness of the intervention and to the severity level of the condition. This means that for conditions appraised with a high/very high severity level it is possible to achieve a very large change in health. Changes in conditions with a low severity level (small health gap) can, however, never be large – despite achieving ideal health and quality of life. It also means that a small change in health or quality of life (regardless of whether it involves a condition with a very high severity level) can never yield a very high level of patient benefit.

*Very high* patient benefit signifies a major effect on ill health/quality of life and/or a very long duration of a good effects and/or very large impact on premature death/major impairment in quality of life.

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<sup>14</sup> Originally it was developed to assess how an intervention affects a specific condition rather than the broader health perspective advocated in this revised model. Even though new categorisation is needed, the structure can still be helpful in clarifying different dimensions used in appraising patient benefits.

The grading of patient benefits – very high to low/none – is based on a rough scale. At times (depending on the purpose of the prioritisation effort) interventions with the same grade, e.g. low level of patient benefit, must be considered in relation to each other to determine which intervention should be the first choice, etc. This might need to be done when comparing new methods to established methods. The appraisal might show that the new intervention *per se* offers a low level of patient benefit, but the knowledge that patient benefit is higher, the same, or lower than benefits achieved from alternative interventions could be important in a selection process and needs to be reported on the worksheet.

#### *Expected average benefit*

In the model, the *expected average benefit* is appraised for the entire patient group receiving an intervention.

The benefits of an intervention often vary in a treatment group, and it is not always possible to know which interventions have the greatest effect. A few people in a group might benefit greatly from an intervention while others benefit less, and some could even experience a loss in health due to intervention-related side effects and complications. This could involve, for instance, treatment for moderately elevated blood pressure, where some people have no risk for mortality from stroke or other cardiovascular-related causes, others have a moderate risk, and some are at high risk, even though these subgroups cannot be identified in advance. The benefits for patient groups will therefore vary and should be presented as an expected average benefit instead of focusing on the exceptions.

If it is possible to identify those receiving high and low levels of benefit from an intervention, the prioritisation object should be divided into these groups so that prioritisation will offer better guidance (e.g. a group comprised of people with genetic risk for cardiovascular disease and a group without any known risk factors).

#### *Weighing effects on current conditions, risks, and duration*

The model gives no specific weight to the impact of different parameters on the conditions, risks, and duration of effects. Hence, one can neither say they are equal, nor that any parameter weighs more than any other. The extent to which an intervention that reduces suffering, but not the risk for future complications and death, offers greater patient benefit than an intervention that has less effect on suffering, but eliminates future risk for major ill health or death, must be determined through discourse and processes that are openly reported.

The worksheet includes a column for *patient benefits* (Figure 8).

Condition	Intervention	Condition's severity level	Patient benefits	Quality of knowledge base	Costs/ effects	Quality of knowledge base	Ranking	Comments/ consequences

Figure 8. Worksheet for documenting steps in the National Model for Transparent Prioritisation in Swedish Health Care.

### *Interpretation and perspectives concerning the national model*

In the national model, the effects of interventions are appraised primarily on patient benefit, but external effects on the health of other people cannot be disregarded.

In this context, external effects of interventions refer to consequences concerning the *health* of individuals other than those directly targeted by the intervention. These consequences could involve health gains or negative health effects for next of kin (e.g. home care or consequences for children with sick parents), or directly influence other people in society (e.g. vaccinations or compulsory care) or indirect influence (e.g. antibiotic resistance through environmental effects).

The *Riksdag*'s guidelines are unclear about the external effects regarding how the health of others is affected, but the Priorities Commission suggests that although individual benefit receives major focus, it cannot be completely isolated from external benefit:

*"...benefit in a care context should be viewed from the individual's perspective and not from a socioeconomic perspective. Rehabilitation is beneficial if it leads to improvement in quality of life for the individual, even if returning to gainful employment is not possible. However, the benefits for society and the individual often overlap."* (Ministry of Health and Social Affairs 1995, p.111)

Based on the human dignity principle and because the Priorities Commission avoids taking a stand on a benefit principle (i.e. that collective benefit should not outweigh patient benefit), our conclusion is that external effects should be considered with caution, and how they influence prioritisation should be clearly and openly reported. An important standpoint in the national model is that if conflicts arise between collective benefit and individual benefit, the collective benefit should never be given greater weight.

### **4.3.3 Appraising cost effectiveness**

The National Model for Transparent Prioritisation in Swedish Health Care also includes appraisal of cost effectiveness, i.e. appraising patient benefit/effects of intervention in relation to the cost of the intervention.

If costs are the same, interventions targeted at groups where the expected patient benefit is high are more cost effective than interventions where the expected patient benefit is low. An expensive intervention can be cost effective if it has good health effects in relation to alternative interventions. If costs are equal or lower for the intervention that provides the best effects/most patient benefit, it is easy to determine which intervention is most cost effective. When the cost of the intervention that provides the best effect is higher, then it becomes more difficult to determine when the cost per health benefit is reasonable or unreasonable.

Appraisal of an intervention's cost effectiveness is included in the national model, addressing primarily the direct costs, but even indirect costs (Figure 9):

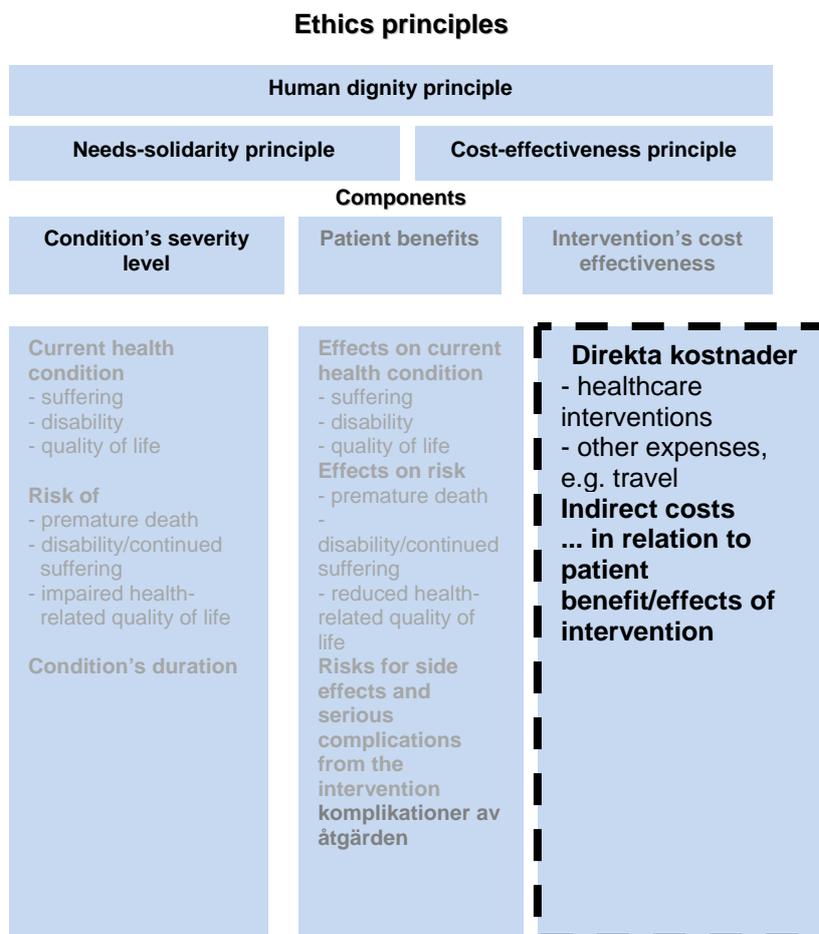


Figure 9. Components relevant for appraising an intervention's cost effectiveness in the National Model for Transparent Prioritisation in Swedish Health Care.

According to the national model, cost effectiveness should be considered when prioritising within a patient group and in horizontal prioritisation, i.e. prioritisation of different types of interventions for different health conditions at the group level.

The direct costs, and possibly the indirect costs, on which the appraisal of cost effectiveness is based are openly reported. Situations that potentially conflict with the human dignity principle must always be recognised and openly reported.

### *Cost-effectiveness scale*

Cost effectiveness is expressed in terms of cost per effect and reported using the scale:

- very high (cost per effect)
- high (cost per effect)
- moderate (cost per effect)
- low (cost per effect).

*Very high* cost per effect means that the cost in relation to the patient benefit gained is very high, which in turn means that cost effectiveness is low. *Low* cost per effect in this context indicates that cost effectiveness is high. The model does not include any threshold values for the steps on the scale, so these values must be reported in each individual project.

When health economic data are available, analyses primarily use cost per life-year gained and cost per quality adjusted life-year (QALY).<sup>15</sup> When health economic studies are not available then it is necessary to report on the other factors used to define the steps in the scale. For instance, cost effectiveness can be reported by a simple quantitative appraisal relating the estimated cost to the outcome measures that are most important for the patient group (e.g. increased participation). Local projects with few resources, or with difficulty in capturing consistent information on cost effectiveness, should at least include the rationale for cost effectiveness in those cases where the order of priority is decisively influenced by the cost.

The National Model for Transparent Prioritisation in Swedish Health Care does not provide threshold values indicating acceptable cost effectiveness.<sup>16</sup>

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<sup>15</sup> See the National Board of Health and Welfare website [www.socialstyrelsen.se](http://www.socialstyrelsen.se) for further information on scale thresholds related to SEK per QALY gained. The advantage of using SEK per QALY instead of measures based on cost per life-year gained is that treatments that mainly affect survival can be more easily compared with treatments that mainly improve the health-related quality of life.

<sup>16</sup> For a more detailed discussion concerning threshold values for cost effectiveness see the report, "National Model for Transparent Prioritisation in Swedish Health Care" (2007).

The worksheet includes a column for *cost effectiveness* (Figure 10):

Condition	Intervention	Condition's severity level	Patient benefits	Quality of knowledge base	Costs/ effects	Quality of knowledge base	Ranking	Comments/ consequences

Figure 10. Worksheet for documenting steps in the National Model for Transparent Prioritisation in Swedish Health Care.

### *Interpretation and perspectives concerning the national model*

The concepts of cost and effectiveness are far from problem-free in a principle or technical sense. As mentioned above, the National Board of Health and Welfare suggested that the government clarify several points in the cost-effectiveness principle (National Board of Health and Welfare 2007).

One question concerns the *situations* in which the cost-effectiveness principle should be applied. The Prioritisation Commission suggests that the cost-effectiveness principle should be applied only in comparing treatment methods for the same disease since otherwise the effect cannot be compared in a fair way. The motive for using the national model to choose between interventions for different conditions is that in its bill the government established that health services must always consider cost effectiveness. Healthcare resources must be used in the best way and used so they can serve many:

*“... it is essential to differentiate between cost effectiveness concerning the treatment of individual patients and concerning the delivery of health services in general. A cost-effectiveness principle that involves choosing between different interventions for an individual patient can be applied as proposed by the Commission and should be secondary to the human dignity and needs-solidarity principles. Moreover, it is essential that health services strive for a high degree of cost effectiveness concerning healthcare delivery in general.”* (Ministry of Health and Social Affairs 1996/97, p. 21)

*“... that resources are used in the best way and that they serve many.”* (Ministry of Health and Social Affairs 1996/7, p.21)

Another question concerns *which costs* should be included in the analysis. When including indirect costs/revenues in the analysis it is important to know the composition of the patient group in question as regards personal factors and social position (gender, level of employment, age, etc.).

Internationally, most of the guidelines for health economic assessment recommend using a socioeconomic perspective, which considers all relevant consequences (costs and revenues) that arise in society. But if one uses such a starting point, a consequence could be that a rehabilitation programme aimed at people on sick leave might be more cost effective than a programme aimed only at patients who are not gainfully employed, which can be said to conflict with the human dignity principle.

In the *Riksdag's* guidelines, the cost-effectiveness principle (applied to individual patients) is too limited to guide prioritisation at the group level. The National Board of Health and Welfare recommends that this is one of the points that the government should investigate and clarify. Awaiting this, we base our position on the guidelines that the *Riksdag* set for the Dental and Pharmaceutical Benefits Agency (TLV) in 2002<sup>17</sup> stating that even indirect costs must be considered in setting priorities. The legislation on pharmaceutical benefits (Ministry of Health and Social Affairs, 2002) emphasises that in deciding to subsidise (prioritise) a drug, the agency should determine, e.g. if it is cost effective from a societal perspective. The decisions weigh cost effectiveness along with the needs-solidarity principle and the human dignity principle to achieve a reasonable balance among medical, humanitarian, and health economic perspectives (Erntoft, 2010). It is reasonable to assume that TLV's actions should not be based on prioritisation principles that differ from those for health care in general. To the extent possible, the national guidelines published by the National Board of Health and Welfare also apply a socioeconomic perspective (Department of Health and Welfare, 2007).

In those instances where indirect costs are included in applying the national model, and are allowed to influence prioritisation, caution must be exercised so that the human dignity principle is not violated. Arguments and standpoints must be openly reported to enable review.

#### **4.3.4 Assessing the quality of the knowledge base**

The National Model for Transparent Prioritisation in Swedish Health Care includes a requirement to report and evaluate the quality of scientific evidence and/or experienced-based knowledge used to appraise the severity level, patient benefit, and cost effectiveness.

The introductory provisions of the Health and Medical Services Act emphasise the quality of care (Health and Medical Services Act, Section 2a) and the importance of basing care on scientific evidence and standard practice.

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<sup>17</sup> TLV was previously named the Pharmaceutical Benefits Board.

Hence, the best possible evidence, supported if possible by systematic reviews, should be used in setting priorities.

The requirement for systematic and comprehensive searches for evidence to determine severity level, patient benefit, and cost effectiveness must be adapted to the purpose of each individual prioritisation effort and the resources (e.g. time) available.

#### *Reporting of scientific evidence*

When possible, and if the quality of scientific evidence allows, established checklists and evidence grading systems should be used to describe the certainty of the reported effects and cost effectiveness. In the absence of systematic evidence, evaluators should describe the quality of the knowledge base in their own words.

GRADE is an internationally accepted evidence grading system used by the Swedish Council on Health Technology Assessment (SBU) and the National Board of Health and Welfare. It is used to describe the level of certainty surrounding the effects of an intervention. Evidence with a high rating indicates high certainty about an intervention's effects, and it is very unlikely that further research would change this appraisal. A high rating says nothing about the effects *per se*, which can range from small to very large, but simply rates the certainty of the appraisal. Hence, evidence with a high rating can indicate a high level of certainty that the effects are small. Conversely, evidence with a low rating indicates a high probability that further research might substantially change the estimates regarding effects and even the size of effects – the intervention could have larger effects than expected, or the intervention might even be harmful (GRADE Working Group, 2011; National Board of Health and Welfare, 2011; SBU, 2011).

#### *Reporting of experience-based knowledge*

In cases where satisfactory scientific evidence is lacking, other methods may be applied to make use of experience-based knowledge (e.g. systematic expert opinion).<sup>18</sup> If priorities are based on the clinical experience of those responsible for developing the ranking, this should be reported. Currently, there is no well-established scale for reporting on clinical experience. It is most important to describe how the appraisals were done – the process must be transparent.

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<sup>18</sup> Applied, e.g. within the framework of the National Guidelines for Dementia [www.socialstyrelsen.se](http://www.socialstyrelsen.se)

### *Identifying research and development*

At times, evaluations target new methods and interventions that have yet to become established. If the evidence is insufficient to determine an intervention's benefits/effects for patients, then instead of ranking, one must decide whether or not further assessment is required before the intervention can be introduced into health services.

The worksheet includes columns for the *quality of the knowledge base* (Figure 11):

Condition	Intervention	Condition's severity level	Patient benefits	Quality of knowledge base	Costs/effects	Quality of knowledge base	Ranking	Comments/consequences

Figure 11. Worksheet for documenting steps in the National Model for Transparent Prioritisation in Swedish Health Care.

## **4.4 Weighing and ranking**

*In the National Model for Transparent Prioritisation in Swedish Health Care, establishing a rank order involves weighing the appraisals of severity level, patient benefit, cost effectiveness, and quality of the knowledge base. Items are ranked on a 10-level scale where 1 indicates the highest priority and 10 indicates the lowest. It is important to have a logical association between the priority level assigned and the appraisals of severity level, patient benefit, and cost effectiveness.*

In the National Model for Transparent Prioritisation in Swedish Health Care, the ranking process involves weighing the appraisals of severity level, patient benefit, cost effectiveness, and quality of the knowledge base. In setting priorities, the items are ranked on a 10-level scale:

- 1 indicates highest priority
- 10 indicates lowest priority

A ranking scale with 10 possible levels is widely supported despite a recurring debate about having fewer levels. The disadvantage with a 3-level prioritisation scale, for example, is that the groups become very large and heterogeneous. Within the same level there could be needs that are considered to be much more urgent than others.

As a rule, increases or reductions in resources for new services involve a small segment of the total organisation. Hence, if a third of the services are ranked as high priority, and a third are ranked as low priority, this information provides little guidance. Ten levels enable a wider distribution and thus offer better guidance in making decisions about priorities.

The National Model for Transparent Prioritisation in Swedish Health Care contains no threshold values for severity levels, patient benefits, or cost effectiveness. Hence, it is difficult to find a neutral method to mathematically/quantitatively calculate the priority level. A more quantitative approach would suggest greater objectivity and accuracy than could be justified by the model. Instead, the priority level should be viewed as a qualitative appraisal.

#### **4.4.1 Principles for ranking**

- Although the *Riksdag*'s resolution on priority setting in healthcare places major importance on the level of severity, this alone cannot determine the rank order.
- Severe health conditions and effective interventions receive higher ranking than less severe conditions and less effective interventions (according to the law, severity level cannot be used as a basis for ranking in a social services context).
- Interventions with a high level of benefit for the individual, in relation to cost, receive higher ranking than interventions with a low level of benefit in relation to cost.
- Interventions that are well documented and show good patient benefits /cost effectiveness have priority over those supported by little or no scientific evidence, assuming all else is equal. Likewise, interventions based on consistent, longstanding, experience-based knowledge and which demonstrate good patient benefit/cost effectiveness have priority over those supported by weak experience-based knowledge, assuming all else is equal.
- To be given high-level priority, interventions having major consequences (e.g. high cost or major organisational requirements or are associated with risks and side effects) must be based on highly accurate appraisal of effects/benefits.
- Accuracy in appraising the evidence underlying the priority level is important, but high accuracy *per se* does not ensure a high priority level for the intervention.

#### 4.4.2 Ranking scale

Severity level, patient benefit, and cost effectiveness should be appraised from a wider perspective, not just relatively within a limited area of prioritisation.

Likewise, the ranking scale should not be relative within an area of prioritisation. It is important that the ranking relates logically to the appraisal of severity level, patient benefit, cost effectiveness, and quality of the knowledge base; low overall values can never yield a high priority, and vice versa – high overall values cannot yield low priority.

There are no absolute criteria for determining the priority levels from 1 to 10. This means, e.g. that a ranking of 2 in a priority setting project for a particular prioritisation object is not necessarily equivalent to a 2 in another priority setting project for another prioritisation object. Consolidating different prioritisation lists requires new discussions to compare and value different priority rankings in relation to each other.

In certain areas of prioritisation the distribution among the prioritisation objects is wide – everything from low severity level and low patient benefit/cost effectiveness to prioritisation objects with a high severity level and high patient benefit/cost effectiveness. In these cases, the entire ranking scale, from 1 to 10, will probably be represented. In other contexts, the distribution in rank order can be smaller, when severity level, patient benefit, and cost effectiveness vary less (e.g. between 2 and 7). In these cases, further discussions can be necessary, e.g. to determine which 7s should be primary candidates for rationing.

In appraising patient benefit, one finds care interventions that should be phased out due to inadequate effects or because their risks or side effects are too great in relation to their benefit. Since these should be reported separately, they are not included in the 1 to 10 ranking.

The worksheet includes a column for *ranking* (Figure 12).

Condition	Intervention	Condition's severity level	Patient benefits	Quality of knowledge base	Costs/effects	Quality of knowledge base	Ranking	Comments/consequences

Figure 12. Worksheet for documenting steps in the National Model for Transparent Prioritisation in Swedish Health Care.

#### 4.4.3 Ethics platform sets framework for ranking

The human dignity principle indicates what should not influence prioritisation in health care and emphasises that everyone is of equal value. In practice, this means that those who rank priorities must wrestle with balancing the needs-solidarity principle and the cost-effectiveness principle:

*“A person has greater needs the more severe the disease or injury, or the lower the quality of life resulting from the disease or injury. However, people have no need of interventions that do not improve health or quality of life. To be used as evidence for priority setting, the different aspects of health needs and quality-of-life-related needs must always be weighed.” (Ministry of Health and Social Affairs 1996/97, p.17)*

Although the *Riksdag*'s resolution on priority setting gives substantial weight to the severity level of disease, as mentioned earlier, both the Priorities Commission and the *Riksdag*'s resolution assert that severity level alone cannot determine the priority of a condition-intervention pair. According to the resolution, the patient/patient group's ability to benefit from an intervention must also be considered in prioritising. Consequently, even conditions with a high severity level could be given a lower priority if patient benefit is limited.

In weighing the needs-solidarity principle against the cost-effectiveness principle, the guidelines can be interpreted to mean that patients with more-severe conditions could be treated by interventions that cost substantially more per health benefit compared to patients that have less-severe diseases:

*“In choosing among different areas of activities or interventions, the objective is to strive for a reasonable relationship between costs, in terms of different types of resource inputs, and effects, measured as improved health or higher quality of life... According to the Commission, a consequence of the cost-effectiveness principle being subordinate to the needs -solidarity principle is that severe illness and substantial deterioration in quality of life outweigh the less severe, even though care for severe conditions can cost substantially more.” (Ministry of Health and Social Affairs 1996/97, p. 21)*

In practice this means that society has a substantially greater responsibility to pay for treating more-severe conditions compared to treating milder conditions.

In ranking, according to the guidelines, if the severity level is high, then even interventions with lower cost effectiveness can be given a higher priority compared to conditions where the severity level is low:

*“Cost-effective delivery of services must never mean neglecting to give care or reducing the quality of care for the dying, severely and chronically ill, elderly, or people with dementia, developmental disabilities, severe functional impairment, or others in similar situations.”* (Ministry of Health and Social Affairs 1996/7, p. 22)

#### **4.4.4 Quality of the knowledge base can affect ranking**

The appraisal of severity level and patient benefit must be based on some type of knowledge base (scientific evidence or experienced-based knowledge). The quality of the knowledge base gives an indication of how certain the health services can be regarding the effects of an intervention.

Hence, it is reasonable to assume that interventions with major consequences (e.g. high costs, or substantial organisational requirements, or associated with risks and side effects) must have strong scientific support to receive high priority. One example is fibrillation ablation therapy, a procedure for atrial fibrillation that carries a certain level of risk and requires special expertise. However, if the need (i.e. severity level combined with level of patient benefit) is great, and the intervention is non-controversial and has been in use for a long time, then the priority could be high even though scientific evidence is weak. The use of morphine in controlling pain in terminal cancer patients is one such example.

Although the quality of the knowledge base can affect prioritisation, strong scientific evidence does not necessarily mean that an intervention receives higher priority. However, the strength of the scientific evidence can influence the internal ranking between two alternative interventions. If strong scientific evidence supports the effects of one intervention, while the evidence is weak for another in treating the same condition, and if the benefits are equal, it is reasonable to assume that the intervention with the strongest evidence will rank higher. Likewise, interventions supported by consistent, longstanding, experienced-based knowledge, which demonstrate high patient benefit/cost effectiveness, are prioritised above those supported by weak experienced-based knowledge, all else being equal.

## **4.5 Reporting the ranking, reasoning, and consequences**

*The government bill states that health services have an obligation to inform those affected by the priorities about the reasons for and the consequences of the priorities chosen. Therefore, the National Model for Transparent Prioritisation in Swedish Health Care is based on open reporting of the results of the process, i.e. the priorities chosen. The target group determines the type of presentation. A ranking list always needs to be accompanied by a description of consequences or other types of documents that explain how the ranking should be interpreted and applied.*

### **4.5.1 Content and consequences of prioritisation**

The National Model for Transparent Prioritisation in Swedish Health Care does not answer how to specifically interpret and apply the results of a priority setting process.

The only guidance offered by the *Riksdag's* guidelines is that the highest priority (1) means that health services should allocate relatively more resources to this condition-intervention pair to assure that the interventions are used for these conditions.

Correspondingly, priority 10 means that health services should use the interventions for certain identified conditions only if sufficient resources are available to address those with higher priority.

As regards the consequences for the other selected priorities, these must be clarified and reported by the entity responsible for prioritisation.

### **4.5.2 Different types of reporting**

Health services have an obligation to inform those affected by priorities about the reasons for and consequences of the priorities chosen (Ministry of Health and Social Affairs 1996/97). Therefore, the National Model for Transparent Prioritisation in Swedish Health Care is based on open reporting of the results of the process, i.e. the priorities chosen. The target group determines the type of presentation, e.g. depending on whether it concerns internal transparency within health services or external transparency for the public.

A ranking list is one way to present an overview of the evidence used in ranking (e.g. the worksheet presented in this report).

Different types of comments, e.g. concerning the consequences of ranking, can be entered in the *comments/consequences* column on the worksheet. (Figure 13)

Condition	Intervention	Condition's severity level	Patient benefits	Quality of knowledge base	Costs/effects	Quality of knowledge base	Ranking	Comments/consequences

Figure 13. Worksheet for documenting steps in the National Model for Transparent Prioritisation in Swedish Health Care.

The worksheet is not sufficient for reporting the consequences of the chosen priorities. The content must be useful and therefore needs to be presented in different ways depending on the target group and area of application.

According to the National Model for Transparent Prioritisation in Swedish Health Care, a priority setting process can identify interventions that should not be performed for medical reasons, i.e. interventions that should not be performed even when sufficient resources are available (as differentiated from those with priority level 10, which may be performed if resources allow).

Another outcome could be the identification of interventions that have not been sufficiently assessed and therefore should not be introduced in routine health services. Although these are not included in the ranking, they may need to be documented nevertheless. The National Board of Health and Welfare uses a “don’t do list” and a research and development (R&D) list in developing their national guidelines.

Prioritisation can aim at creating a basis for decisions to ration care or to introduce new, highly prioritised interventions. To support such a process, it is particularly important to produce some type of description addressing consequences. The aim is to quantitatively and qualitatively describe different consequences that can be expected from a patient’s perspective and also the potential consequences for the healthcare budget and structure.

In describing consequences, some of the questions to be addressed are:

- What changes in the supply of services are involved?
- Which patient groups are affected? (Brief description of the condition and its specific problems.)
- How many patients are affected?

- What consequences for patient benefit/effects can be expected from the change?
- What other societal consequences (e.g. for the municipality) can be expected?
- How will a change affect the healthcare budget?
- What are the organisational consequences (e.g. need for expertise) of a change?
- Are there other healthcare options for the patient group in question?
- Will the costs (healthcare/social service expenditures) be shifted to the individual patient, other care providers, or community sectors?

#### **4.6 Concluding remarks**

We introduced this report by noting that the National Model for Transparent Prioritisation in Swedish Health Care should not be considered finalised in its present form. Our aim has been to clarify and further facilitate the application of the *Riksdag's* guidelines and ethics platform. As the model becomes more concrete, the need for supervision and more specific interpretation of the *Riksdag's* guidelines arises once again in order to create opportunities for further clarifying the direction for the future.

Viewing the National Model for Transparent Prioritisation in Swedish Health Care as a living tool that can be changed and refined in step with experiences gained continues to be an ambition, and its suitability as a means for applying the *Riksdag's* guidelines will continue to be monitored and assessed.

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## Appendix 1

Basis for discussing a **condition's severity level**, developed by Kalmar County Council (National Center for Priority Setting in Health Care, Report 2008:5). The content of the cells below has been used by other county councils and adapted to their situations as necessary.

	Impairment of body functions <i>A loss of, or deviation in, physiological functioning (e.g. impaired joint stability, pain, impaired awareness, motivation, or memory).</i>	Activity limitations <i>Difficulties that a person may have in performing activities, e.g. problems with mobility, communicating, or helping others (e.g. caring for one's children).</i>	Participation restriction <i>Concerns the social consequences of a disability (e.g. difficulty in managing important aspects of life, e.g. education, work, employment).</i>	<u>Dur- ation</u>	<u>Risk of not intervening</u>	<b>Severity level</b>  <i>Overall appraisal</i>
<b>Very high</b>		The patient group cannot, or has very great difficulty in, managing current activities. Completely dependent on help to manage current activities.	The patient group cannot manage current social functions, has very great difficulty with current social functions.	>10 years to life-long condition	Very high risk for becoming worse <i>or</i> for serious condition.	
<b>High</b>		The patient has great difficulty in, managing current activities. Largely dependent on help to manage current activities.	The patient group has great difficulty with current social functions.	1 to 10 years	High risk for becoming worse <i>or</i> for serious condition.	
<b>Moderate</b>		The patient group has difficulty in managing current activities. Needs some help to manage current activities.	The patient group has difficulty with current social functions.	>3 mo. to 1 year	Moderate risk for becoming worse <i>or</i> for serious condition.	
<b>Low</b>		With some difficulty the patient group can manage current activities. Does not need help.	With some difficulty the patient group can manage current social functions.	<3 mo.	Low risk for becoming worse <i>or</i> for serious condition.	

## Appendix 2

Format used as a basis for discussing the **condition's patient benefit/intervention's effect**, originally developed in the prioritisation initiative by Kalmar County Council (National Center for Priority Setting in Healthcare, Report 2008:5).

	<u>Effects on</u> <sup>19</sup> impairment of body functions <i>Effects on a loss of, or deviation in, physiological functioning (e.g. impaired joint stability, pain, impaired awareness, motivation, or memory).</i>	<u>Effects on</u> activity limitations <i>Effects on difficulties that a person may have in performing activities, e.g. problems with mobility, communicating, or helping others (e.g. caring for one's children).</i>	<u>Effects on</u> participation restriction <i>Effects on the social consequences of functional impairment, e.g. difficulty in managing important aspects of life (e.g. education, work, employment).</i>	<u>Dura- tion of effects</u>	<u>Effects on risk</u>	<b>Patient benefit/ effects of interven- tion</b>  <i>Overall appraisal</i>
Very High						
High						
Mod- erate						
Low						

<sup>19</sup> After the publication of Report 2008:5 the words "effects on" have been added.

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