

## **National Model for Transparent Vertical Prioritisation in Swedish Health Care**

***Per Carlsson, Christina Kärvinge, Mari Broqvist, Kristina Eklund, Bo  
Hallin, Catrine Jacobsson, Gunilla Jacobsson Ekman, Christina  
Källgren Peterson, Marion Lindh,  
Britt Nordlander, Per Rosén, Urban Sjöblom, Anna Sohlberg***

This is a translation of The National Centre for Priority Setting in  
Health Care's report no 2007:1,  
*"Nationell modell för öppna vertikala prioriteringar inom svensk hälso-  
och sjukvård."*

ISSN 1650-8475



## FOREWORD

Greater transparency in priority setting was a primary objective of the Swedish *Riksdag* when it established a set of prioritisation principles, an ethical platform, which has applied to health services in Sweden since 1997. Ways to achieve the intent of these principles in practice have been debated ever since. Although modest attempts have been made towards more transparency in setting health care priorities, the prioritisation process nearly always remains hidden. We found that awareness of the ethical platform is limited, and that some find it difficult to interpret and implement in practical decisions. Experience shows that methods/models are needed to support priority setting. Alone, the *Riksdag*'s guidelines for priority setting in health care are shown to provide insufficient support in this respect.

In recent years, several activities in Sweden have aimed at ranking health services as a means to support prioritisation decisions. Ranking usually takes place by developing a list of alternatives. This type of prioritisation – carried out mainly *within* a disease group, a clinic, or professional group – is usually referred to as *vertical prioritisation*. Aims can vary when ranking health care priorities vertically. One aim is to provide support and guidance to clinical care activities and to better understand the reasoning behind the priorities set.

Since transparent prioritisation is somewhat new, there are no established methods for this process. Rather, different actors have chosen different approaches. These variations make it difficult for one body to compare and utilise data developed by others. Hence, the National Board of Health and Welfare and the National Centre for Priority Setting in Health Care have jointly taken the initiative to develop a national working model. In collaboration with other organisations involved in vertical prioritisation, a proposal was developed and has been accepted by representatives from regions/county councils and several professional interest groups. In developing this proposal there was excellent collaboration among all parties involved. We would like to thank all participants for their input and look forward to learning how the working model functions in the practical process of priority setting.

We would also like to thank Katrin Lindroth for her editorial work on this report.

*Per Carlsson*  
*National Centre for Priority Setting in Health Care*

*Christina Kärvinge*  
*National Board of Health and Welfare*



## SUMMARY

The proposed national model described in this report has been developed by a working group comprised of staff from the National Board of Health and Welfare, the National Centre for Priority Setting in Health Care, and other organisations involved in vertical prioritisation – including the Östergötland County Council, Stockholm County Council, Västra Götaland, the Health Services Region of Southern Sweden, the Swedish Society of Medicine, the Swedish Society of Nursing, and the Swedish Association of Health Professionals. Throughout the process of designing the model, the Swedish Federation of Occupational Therapists and the Swedish Association of Registered Physiotherapists were regularly informed and given opportunities to review and comment on the proposal. Furthermore, the report was reviewed and discussed at a meeting with invited representatives from the other county councils, the Pharmaceutical Benefits Board, and several professional interest groups. Viewpoints were also obtained at a seminar arranged by PrioNet, a network of individuals interested in prioritisation.

Potentially, the working model described in Chapter 4 could be used in any context where vertical prioritisation takes place, e.g. activities arranged by the state, county councils, municipalities, hospital departments, and professional groups.

This report is designed to be a useful tool for those working on development projects in priority setting. We believe that the contents must be adapted, with the help of relevant examples and some simplifications; to fit the specific needs of different projects or groups. The text must also be adapted to a target group's knowledge and previous experience in dealing with transparent priority setting. It must be the responsibility of each provider and other affected organisation to adapt the material to the given situation and project. The National Centre for Priority Setting in Health Care, the National Board of Health and Welfare, and others who have participated actively in this effort can be helpful to various target groups in adapting this report.

When and how to engage in practically implementing vertical prioritisation are questions that need to be answered at the local level. Primarily, it is the duty of the local authorities/providers to take responsibility for implementation. Professional organisations also play an important role. Public agencies, universities, and knowledge centres should be sources of support for the local authorities/providers.

The *Riksdag's* resolution on prioritisation served as the foundation for developing the model.

## II

Where there are areas of uncertainty in how to translate these guidelines in practice, or where practical implementation might conflict with the principles, we have pointed this out.

Our conclusions and proposals are the following:

- When facing a choice – regardless of whether it involves allocating new resources for different purposes, or to implement cutbacks – it can be advantageous to rank the possible choices in order of priority. In our model, only the relevant options can be ranked by priority. The consequences of this ranking are not obvious at the outset, but can serve as a basis either to allocate more resources or ration by some means.
- In vertical prioritisation, it is advantageous to organise the prioritisation process starting from a general categorisation of health problems/disease groups. As a rule, these categories cover many organisational units/clinical departments, specialties, or professional groups, thus providing a more multidimensional view of the problem. Furthermore, this allows the process to start from a patient/population perspective, which appears to be more goal-oriented than an organisational/staff perspective.
- That which is ranked, i.e. one of the choices, we refer to as a *prioritisation object*. We suggest that prioritisation objects consist of different combinations of health conditions and interventions.<sup>1</sup> When deciding on the appropriate level of detail, the decision must be based on the context in which prioritisation is carried out. A starting point would be to focus on typical cases, large-volumes services, and controversial care.
- All forms of vertical prioritisation should be based on the ethical principles that the *Riksdag* decided should apply in prioritising health services. However, these ethical principles must be made known, clarified, and perhaps complemented before they can be applied to practical priority setting. Furthermore, we believe that the *Riksdag*'s four so-called *priority groups* should not be part of the model.

---

<sup>1</sup> In the report, we use the terms *intervention*, *action*, and *programme* synonymously.

### III

- The *human dignity principle*, i.e. that all people should have equal value and equal rights to care irrespective of their personal characteristics and function in society, is the undisputed cornerstone in priority setting. When personal characteristics such as age, gender, lifestyle, or function of a group are expressions of the presence of special needs, so that benefits of the interventions are different, these personal characteristics could be addressed in a priority at the group level. Further discussion is needed regarding the question of how external effects (i.e. the effects of an intervention on families and groups other than the individual directly affected by the intervention) should be valued in priority setting.
- The concept of *need* in health care includes both the severity level of the condition and the expected benefits of intervention. As a patient, one needs only those interventions that can be expected to yield benefits. Based on this definition of need, a person does not need an intervention that does not improve health and quality of life, i.e. an intervention with no benefit. In such cases, health services have a responsibility to refer people who seek care for some type of problem, to other appropriate services.
- The *Riksdag's* guidelines regarding the *cost-effectiveness principle* (applied to individual patients) are too limited to provide guidance for vertical prioritisation at the group level. From the outset, the Government's bill (*Priority Setting in Health Care*) highlighted the importance of differentiating a *cost-effectiveness principle* that applied to choices among various interventions for the individual patient (where the principle can be applied as the Commission of Inquiry proposed) and the aim of health services to achieve high cost-effectiveness in health care generally. Here we also refer to the *Riksdag's* directive to the Pharmaceutical Benefits Board. In its decisions on subsidising (prioritising) a drug, the Board should determine, e.g. whether the drug is cost effective from a societal perspective, which requires comparing the patient benefits of the drug to its cost. In such decisions, the cost effectiveness should be considered along with the needs and solidarity principle and the human dignity principle.
- The proposed working model essentially concurs with the working model used by the National Board of Health and Welfare in developing national guidelines. In describing a national working model, it is not possible to include every aspect that might be considered. Hence, one must start from the model and decide which other relevant aspects should be included. For instance, the International Classification on Functioning, Disability, and Health (ICF) can be used as guidance to describe the severity of health conditions.

#### IV

- Due to the wealth of variety in outcome measures for different activities, and the limited experience in working with explicit threshold values, we believe would be premature to recommend standardised categories, e.g. risk levels. However, it is important that those working with prioritisation describe their reasoning. Primarily, the categories applied by the Swedish Council on Technology Assessment in Health Care (SBU) to grade the scientific evidence of an intervention's effects should be used. Local prioritisation projects with limited resources at their disposal should describe (text) their appraisal of the scientific evidence and reference the scientific sources used. The strength of evidence should be expressed in numbers only when supporting a conclusion of a systematic review by SBU, or other literature reviews of good quality.
- Prioritisation projects having access to health economic evaluation should, until further notice, adhere to the approach used by the National Board of Health and Welfare and present cost-effectiveness on a scale from *low* to *very high* cost per life-year gained or cost per quality-adjusted life-year. Economic evidence should be presented according to the principles applied by the National Board of Health and Welfare. In local projects with limited resources, or problems in consistently acquiring information on cost effectiveness, we recommend that the authors at least discuss cost effectiveness in cases where the priority ranking would be decisively affected when costs are weighed in.
- A 10-level ranking list should be used. The ranking list should be complemented by a "don't do" list for methods that should not be used at all, or not used routinely, and a research and development (R&D) list for methods where the evidence still insufficient to motivate their use in standard practice. In the absence of an objective quantitative/mathematical method, a qualitative method should be used in the appraisal. Here too, we believe that it is not yet possible to establish standard criteria to determine within which ranking level a prioritisation object should fall.
- Results should be presented as a ranking list. The parameters used as a basis for prioritisation should also be presented in a uniform manner in ranking lists that are shared with other parties. For pedagogic reasons, details concerning language and format need to be adapted to the respective target groups.
- Thresholds for what constitutes an acceptable coverage of need (care quality, volume, and percentage of the patient group with access to services) are regional and local issues, and hence are not included in the national model.

## CONTENTS

<b>1. TRANSPARENT AND SYSTEMATIC PRIORITISATION .....</b>	<b>1</b>
<b>2. INITIATIVE FOR A NATIONAL MODEL.....</b>	<b>4</b>
<b>3. WHAT DO WE MEAN BY A MODEL FOR VERTICAL PRIORITISATION? .....</b>	<b>7</b>
3.1 GENERAL STARTING POINTS FOR THE WORKING GROUP .....	7
3.2 KEY CONCEPTS .....	7
<b>4. PROPOSED COMMON WORKING MODEL FOR TRANSPARENT VERTICAL PRIORITISATION.....</b>	<b>10</b>
4.1 CATEGORISING AND DEFINING SUB-AREAS FOR PRIORITISATION.....	10
4.2 WHAT SHOULD BE SUBJECT TO PRIORITISATION?.....	10
4.3 UNDERLYING PRINCIPLES OF PRIORITISATION.....	12
4.4 THE ETHICAL PLATFORM .....	14
4.4.1 <i>Human dignity principle</i> .....	14
4.4.2 <i>Needs and solidarity principle</i> .....	18
4.4.3 <i>Cost-effectiveness principle</i> .....	19
4.4.4 <i>How do we translate the principles into a practical prioritisation process?</i> .....	21
4.5 RECOMMENDED PROCESS FOR PRIORITY SETTING .....	24
4.6 PRESENTING THE RESULTS .....	32
4.7 LIMITATIONS .....	32
4.8 HOW CAN THE RESULTS OF PRIORITISATION PROJECTS BE USED? .....	33



## 1. TRANSPARENT AND SYSTEMATIC PRIORITISATION

As long as there are unmet needs in health care it will be necessary to choose the needs that one wants to meet first. This applies to public health services and other public services. The fundamental issue in prioritisation concerns how much of our collective resources should be allocated to public use, requiring some form of distribution principle, and how much should be left to the individual to manage and allocate to their various needs and desires as they see fit. The next level concerns how public resources should be distributed across public sectors, e.g. schools, the judicial system, and health services.

Setting priorities in health care can involve: how to allocate new resources among groups and/or services in need at a general level; whether to introduce new treatment methods that require new resources; and how to rank patients in the queue for clinical services. Different types of choices or priorities, where one must select something ahead of something else, can be done transparently and systematically to greater or lesser degrees. Greater transparency in priority setting was an objective of the *Riksdag* when it established the prioritisation principles that have applied to health services since 1997. (Committee on Health and Welfare 1996/97) How these intensions should be implemented in practice has been the subject of debate since that time. Limited attempts have been made towards more transparency in priority setting, but in practice prioritisation in health care nearly always remains hidden.

The Government, in its bill on priority setting in health care, states: “The prerequisites for democratic discourse and public acceptance of necessary priorities include; knowledge about the grounds on which priorities are developed, the options available for patient input, and how to proceed if one is dissatisfied with the priorities set. Health services have an obligation to develop methods for making such information accessible to those who are patients today and those expected to be patients in the future.” (Ministry of Health and Social Affairs 1996/97) At that time, the Government expected that a higher level of patient influence would affect the work of health care staff and organisations. Patients would ask for more information and offer their viewpoints on the content and delivery of care, and it would be necessary to follow up these viewpoints in the day-to-day delivery of care. Knowledge and information must be developed and be accessible to a wider public so patients can participate more in decisions concerning their care and treatment. About a decade later most signs point to continued development in this direction, although citizens in general have shown weak interest in participating in discussions about health services and prioritisation.

The investigation that served as a foundation for the *Riksdag*'s resolution also found that if the considerations and decisions concerning prioritisation "are based on a clear and generally accepted ethical platform, this can promote understanding among the general public and care staff for the priorities that must be set and can thereby help preserve confidence in publicly financed health services, even when resources are insufficient to meet all needs." (Ministry of Health and Social Affairs 1995) However, the ethical platform contains general principles that are difficult to interpret and implement in practical decisions by those who have tried to use this in transparent priority setting. Many have expressed the need for methods/models to help support priority setting. The *Riksdag*'s guidelines alone have not provided sufficient support in this respect. Furthermore, studies have shown that the knowledge about the *Riksdag*'s ethical platform is very limited among health services' staff. (Broqvist 2006, Mårtensson et al 2006) In addition to methodological development it is important to disseminate knowledge in health services about the existence of the prioritisation principles.

For several years, many activities in Sweden have aimed at developing support for priority setting decisions, e.g. through ranking health conditions and interventions. Ranking is usually done by establishing a list of relevant combinations of health conditions and interventions. This type of priority setting, which is done mainly *within* a disease group, a clinic, or professional group, is usually referred to as *vertical prioritisation*. Aims may vary in using ranking to develop vertical priorities in health services. One aim is to provide support and guidance to clinical care practices and to better understand the reasoning behind the priorities set. We also believe that the ongoing efforts to develop national indications for care that should be covered by the general *waiting time guarantee* can be promoted by a systematic approach that is essentially similar to the work with vertical prioritisation.

We do not think that ranking of indications, and limiting the care not covered by the maximum waiting time guarantee, should be based on principles different from those that apply to prioritisation of health services. Discussions have been held between people that participated in the development of this report and representatives of the project that developed the maximum waiting time guarantee. There is agreement that the national model for vertical prioritisation should be used as a basis to define the care to be covered by the maximum waiting time guarantee.

*Horizontal prioritisation*, on the other hand, usually characterises the choice between, e.g. disease groups, service areas, health care centres, and clinical departments and primarily involves political officials. The border separating vertical and horizontal prioritisation is not clearly distinct.

Political priorities generally deal with allocating resources to various service areas rather than decisions about specific interventions. In some situations, however, political priorities can be detailed and address specific care interventions. This might apply when defining the threshold for public intervention, as when politicians support health services to further sharpen the indications for various treatments, or in setting fees for particular medical interventions. Politicians are also involved in detailed decisions concerning the introduction of certain new methods in health care, e.g. screening programmes or treatments that attract media interest. A fundamental idea is that decisions involving political prioritisation should provide guidance for the large volume of priorities set by care staff.

In many situations working groups/sections/departments have developed their respective ranking lists, which are then consolidated into a common rank order. This of course, involves some “horizontal” decisions between different patient groups/health service areas. It illustrates that the concepts of vertical and horizontal prioritisation are not always clear-cut.

## 2. INITIATIVE FOR A NATIONAL MODEL

Since work with transparent prioritisation is generally recent, no established methods are available. Rather, different actors have chosen somewhat different approaches. There is, however, considerable value in agreeing on a uniform working model for vertical prioritisation in Sweden. A common point of departure would be to aim at increasing transparency in the priority setting process. The motives for this are many. One is to assure that the best available knowledge is used in setting the priorities that constantly arise. Another motive is to create a common frame of reference for difficult decisions and to communicate this to others. This applies to all contexts where such priorities must be set, e.g. activities arranged by the state, county councils, clinical departments, professional groups, or corresponding categories. Some experience in vertical prioritisation can be found at the local and national levels, not least at the National Board of Health and Welfare. The National Centre for Priority Setting in Health Care, in collaborative projects with the Swedish Federation of Occupational Therapists (FSA), the Swedish Association of Registered Physiotherapists (LSR) (Broqvist 2006), the Swedish Association of Health Professionals (SAHP), and the Swedish Society of Nursing (SSF) tested a working model for prioritisation proposed by the Swedish Society of Medicine. The model essentially agrees with that applied in the prioritisation project by the National Board of Health and Welfare. (Swedish Association of Health Professionals, Swedish Society of Nursing, Swedish Society of Medicine 2004, Jacobsson 2006)

Generally, the model has been found useful and important as a roadmap for the practical application of the *Riksdag's* prioritisation guidelines. In conjunction with these attempts, important development needs are highlighted to be able to create a model with a broad care perspective where many professional groups in municipal and county council health services can participate. We started by studying these experiences and the experiences from development projects in several regions and county councils, e.g. Västra Götaland Region (Västra Götaland Region 2005) and Östergötland County Council (Östergötland County Council 2004) in designing a proposal for a national working model. The National Board of Health and Welfare's work on national guidelines played a particularly important role in designing the following proposal.

The aim of this report has been to design a proposed national working model for prioritisation using the *Riksdag's* guidelines, hopefully in a way that most will find reasonable and that is accepted by health care regions, county councils, and professional organisations.

The working model should be applicable in all contexts where such prioritisation takes place, e.g. activities arranged by the state, county councils, clinical departments, professional groups, or corresponding bodies. There is nothing to suggest that the same working model could not be applied to vertical prioritisation in municipal health services.

The advantages of a common national model are that it would:

- enhance the opportunities to communicate about prioritisation and its fundamentals among different professions, different care levels, between county councils and municipalities, between different parts of the country, organisations, and authorities
- foster a shared vision about what should be included in vertical prioritisation.

The initiative for this project was a joint effort by the National Board of Health and Welfare and the National Centre on Priority Setting in Health Care. A working group of individuals (Appendix 2) from these two organisations and from other organisations working with vertical prioritisation, e.g. Östergötland County Council, Stockholm County Council, Västra Götaland, the Health Services Region of Southern Sweden, the Swedish Society of Medicine, the Swedish Association of Health Professionals, and the Swedish Society of Nursing have developed this proposal. Representatives from these organisations met on several occasions to develop this report. Furthermore, the Swedish Federation of Occupational Therapists and the Swedish Association of Registered Physiotherapists were able to follow the project and provide viewpoints concerning the design of the model. Furthermore, the report was reviewed and discussed at a meeting with invited representatives from the other county councils, the Pharmaceutical Benefits Board, and several professional interest groups. Viewpoints were also obtained at a seminar arranged by PrioNet, a network of individuals interested in prioritisation.

The report has been written with the intent to be useful in supporting development efforts involving prioritisation. We believe the contents must be adapted, e.g. through other examples and some simplifications, to fit the needs of different organisations. The text must also be adapted to a particular target group's knowledge and previous experience in working with transparent prioritisation. Each provider organisation must develop a version adapted to its situation and activities. The National Centre on Priority Setting in Health Care, the National Board of Health and Welfare, and other parties that actively worked on this report can be helpful resources for different target groups.

The question of when and how to work with vertical prioritisation can only be answered locally. Primarily, it is up to the provider to take responsibility for implementation. Public agencies, universities, and knowledge centres can be sources of support for provider organisations.

The *Riksdag*'s resolution on prioritisation, the so-called ethical platform, provides the starting point for model development. When we noticed a weakness or lack of clarity in the guidelines we have pointed this out.

We do not claim to have found the ultimate solution – naturally, development of the working model must continue. The prerequisites for prioritisation can change, e.g. the Government has commissioned the National Board of Health and Welfare to survey how health service providers and other actors set priorities in health care. The assignment also involves assessing how this prioritisation work complies with the intent of the *Riksdag*'s resolution on priority setting in health care and – based on the findings of the survey mentioned above – analyse whether there are problems with implementation. If so, changes and clarifications of the guidelines should be proposed. The National Board of Health and Welfare commissioned the National Centre on Priority Setting in Health Care to carry out this survey, based on interviews with those active at various levels in all county councils, a sample of municipalities, public agencies, and healthcare-related organisations. The result was published in May 2007 (*Resolving Health Care's Difficult Choices. Survey of Priority Setting in Sweden and an Analysis of Principles and Guidelines on Priorities in Health Care, National Centre for Priority Setting in Health Care 2007*)

### **3. WHAT DO WE MEAN BY A MODEL FOR VERTICAL PRIORITISATION?**

#### ***3.1 General starting points for the working group***

To be perceived as credible, priorities in health care must result from a decision-making process that society broadly accepts. For prioritisation to be perceived as fair, two conditions are usually fulfilled – it is public and viewed as relevant, i.e. the decision is based on adequate facts and generally accepted principles. To fulfil these requirements, some type of systematic method must be used. As a working model for transparent vertical prioritisation we refer to the systematic method presented in Chapter 4 of this report.

A national model for vertical prioritisation must be understood and accepted not only by health care professionals, administrators, and politicians, but also by the public. The aim is to develop a basis for determining priorities that is useful for decisions at the group level that concern selection of interventions for all types of care needs. Policy decisions concerning groups of patients are assumed, indirectly, to provide guidance and support for decisions concerning individual patients, even if there are conditions that obviously motivate deviating from recommendations that apply to the entire group. This approach has been well established for many years as regards treatment guidelines in various clinic practice guidelines, and should be understood and applied in the same way when one uses prioritisation guidelines in supporting decisions concerning individual patients.

It should be possible to apply the results of this work to all care interventions involving diagnostics, treatment, nursing care, habilitation/rehabilitation, and prevention in health services, including municipal health services. Also, hopefully, it should be possible to use the results in a model for developing the indications that apply to the maximum waiting time guarantee.

#### ***3.2 Key concepts***

The use of terms and concepts related to prioritisation vary. The definitions we use were formulated by Per-Erik Liss and presented in a report from the National Centre on Priority Setting in Health Care. (Liss 2004) Discussions on priority setting include closely related concepts, such as allocation, redistribution, rationing, savings, or reduced supply.

At times, however, prioritisation is used to designate all activities that are considered in making decisions on how resources should be allocated. Liss has discussed how “prioritisation”, “allocation”, and “rationing” relate to each other.

The concept of “prioritisation” is usually defined as “give priority to”. The decision to assign priority to one thing or another means making a choice based on a rank order. According to Liss, rank order is a central component in the concept of “prioritisation”. But prioritisation also means that, based on rank order, one chooses the alternatives that should be placed ahead of others and acted upon before the alternatives intended for later, or no, action. Certain conditions must be met before a rank order or choice can be considered a priority:

- the alternatives must be weighted
- the alternatives must be relevant in the sense that they must come under consideration.

The items that are ranked or prioritised, e.g. various health disorders, treatments, nursing interventions, etc are called *prioritisation objects*.

The term “allocation” can refer either to a *process* where something (e.g. money) is distributed, or a *condition* that results (e.g. a clinic’s budget) from a process. The necessary criteria for “allocation” are that the decisions are intended and the recipients are known. Allocation can be preceded by prioritising among the potential recipients.

“Rationing” can refer to both a decision and a condition. The rationing concept involves setting limitations on needs satisfaction. This can be done in several ways:

- Goal rationing – limitation of the needs goal, i.e. optimum health or quality of life will not be achieved.
- Exclusion – some problems, disorders, health risks, or impaired quality of life will not be addressed.
- Time rationing – e.g. increased waiting times for patients – limits how quickly patients’ needs will be met.
- Dilution – e.g. less frequent follow-up visits, lower quality of prostheses, less-educated staff, cheaper drugs with lower effects or more side effects than more expensive alternatives.
- Changed indications – conditions must become worse before needs are addressed.

*When someone faces a choice – regardless of whether it deals with allocating new resources for different purposes, or saving money – it can be advantageous to rank the conceivable choices in order of priority. In our model, prioritisation involves ranking only the relevant alternatives. The consequences of this ranking are not known in advance, but can serve as a basis for additional resources or for rationing of some type. The consequences of prioritisation are situation-dependent and are not determined in advance by the working model one uses.*

## **4. PROPOSED COMMON WORKING MODEL FOR TRANSPARENT VERTICAL PRIORITISATION**

The working group has discussed the components that should be included in a national model, how they should be described, and ultimately operationalised. We do not believe that we have found the ultimate solution, or that a single true solution exists. Discussion and development work needs to continue on a range of points. Nevertheless, we propose that work proceed in a united manner, using this model to drive the process forward. The proposal is clearly linked to the current ethical platform for prioritisation adopted by the *Riksdag* and to practical solutions that have been tested to some extent. A uniform approach across the health services is probably more important than having a method that is “finished” in all respects.

### ***4.1 Categorising and defining sub-areas for prioritisation***

The sub-areas to be covered by vertical prioritisation should be categorised in a way that includes a broad needs perspective and involves all health care jobs and professions. Categories based on the organisation of health services into medical specialties, departments, catchment areas, professional groups, etc can cause problems in prioritisation at the national level since the organisation of county councils varies across Sweden. In each prioritisation project the categories that are most suitable must be determined from case-to-case and adapted to the situation in which priorities are set.

*When categorising activities into sub-areas it is advantageous to start from health problems/disease groups. Generally, such categories cover several organisational units, departments, specialties, and professional groups, giving a more multidimensional view of the problem. Hence, a patient/population perspective is used from the outset, which appears to be more appropriate than using an organisational/personal perspective.*

### ***4.2 What should be subject to prioritisation?***

Prioritisation always involves ranking something (e.g. different patient groups) for some purpose (e.g. need for care and cost-effectiveness). That which is ranked and which is an object of choice can be referred to as the *prioritisation object*. The ranking process starts by identifying suitable prioritisation objects for the activity in question.

In the working model that we propose, prioritisation objects are comprised of various combinations of health conditions within a group and interventions in health services, for instance:

- increased health risk, e.g. people older than 65 years and influenza vaccination
- suspected pneumonia and physician visits
- diabetes and medical check-ups
- difficulty with personal hygiene in MS patients and testing of assistive devices
- daily smokers and smoking cessation treatment by trained professionals
- risk for pressure sores in conjunction with stroke and assurance of appropriate diet and skin care
- breast cancer and surgery
- multiple disorders and physical therapy assessment.

We believe that dividing an activity into health services based on diagnosis alone, or on physical and mental conditions alone, would lead to over-simplification. For instance, in rehabilitation and social services it is particularly important to consider functional impairments, activity limitations, reduced participation, and/or environmental obstacles in addition to the diagnosis given a target group. This would influence how the prioritisation objects are categorised. Prioritisation objects should be selected with regard to their importance to the activity rather than based on what has been studied scientifically.

It is also important to note that different phases in the course of a disease can be divided into different prioritisation objects. There are substantial differences in how to prioritise various interventions for preventing the onset of prostate cancer, early detection, diagnostics, early treatment, and palliative treatment for advanced prostate cancer. In addition to variations in the severity level of disease, the magnitude of benefit/effect also differs for different types of interventions.

We recommend that even initial appraisals be included in identifying prioritisation objects and in the subsequent ranking process. In these cases, prioritisation objects are identified as combinations of a suspected disease or functional/activity limitations and an intervention such as a physician visit, a particular type of examination, or self-care advice.

Not least, this applies to primary care or various types of acute care services where a high percentage of care involves decisions on problems presented to the staff for the first time.

Generally, it is difficult to determine a suitable level of detail for prioritisation objects. One is often forced to balance exactness, completeness, and practical management. General categories allow objects to encompass many situations. However, they risk being too heterogeneous and difficult to evaluate in terms of severity levels, etc. For example, the condition of “stroke” could include everything from life-threatening to very moderate symptoms, or the intervention of “physiotherapy” ranges across a broad treatment spectrum yielding everything from major benefits to questionable benefits. On the other hand, a detailed description offers a sharper definition, but presents the risk of creating an unmanageable number of prioritisation objects. Here, general recommendations are not possible, but the context and the purpose of the evidence must be allowed to guide the level of detail. A list of conditions/interventions can never be inclusive enough to cover every type of decision-making situation.

Categorisation could potentially focus on:

- Different types of relevant, typical cases (common patients, regular clinical activities)
- Conditions and interventions representing large volumes
- Controversial issues (ethical dilemmas, expensive treatment, uncertain effects, and questionable cost-effectiveness).

*That which is ranked and which someone chooses between, is what we refer to as the prioritisation object. We suggest that prioritisation objects are comprised of different combinations of health conditions and interventions. Context must determine the level of detail. Focusing on typical cases, large-volume care, and controversial care is a starting point.*

### **4.3 Underlying principles of prioritisation**

Fundamentally, all types of priorities in health care should be based on a common foundation of values, i.e. the ethical principles presented in the prioritisation inquiry, the Government’s bill, and the report from the Committee on Health and Welfare.

These are the:

- *human dignity principle*, all humans have equal value and equal rights, irrespective of their personal characteristics and functions in society
- *needs and solidarity principle*, resources should be allocated based on need

- *cost-effectiveness principle*, in selecting among different activities or interventions, there should be a reasonable relationship between cost and effect, measured in terms of improved health and quality of life.

These three principles appear in rank order, with the human dignity principle ahead of the needs and solidarity principle, followed by the cost-effectiveness principle. (Ministry of Health and Social Affairs 1995)

The Government's bill provides examples of the guidelines using four broad priority groups:

- *Priority Group I*  
Care for acute, life-threatening disorders  
Care for disorders that left untreated would lead to permanent disability or premature death  
Care for severe chronic diseases  
Palliative care and terminal care  
Care of people with limited autonomy
- *Priority Group II*  
Prevention  
Habilitation/Rehabilitation
- *Priority Group III*  
Care for less-severe acute and chronic disorders
- *Priority Group IV*  
Care for reasons other than disease or injury

In many cases, the need for care coincides with a particular diagnosis. The inquiry illustrated this with clinical examples in the priority groups. However, the Government's bill emphasises that the priority groups serve only as examples. "We want to emphasise that these are only examples, and that the care needed in each particular situation must be determined based on the conditions of that case. Severity levels, and hence care needs, in acute and chronic disorders can vary from one time to another in the same individual. Hence, care for the same disease could fall under different priority groups during different stages." (Ministry of Health and Social Affairs 1996/97)

The Committee on Health and Welfare made the same determination as the Government, and suggested that the determination of care need in each situation must be based on the specific conditions of that particular case. "The diagnosis or disease involved is not the important issue.

Rather, the decisive issue concerns the condition and care needs at each particular point in time.” (Committee on Health and Welfare 1996/97)

We think that “priority group” is an unfortunate term since the priorities do not take into consideration, e.g. the effects of different care interventions. The prioritisation inquiry and the *Riksdag*’s resolution on priority setting in health care both established that the patient’s ability to benefit from a treatment is integral to the needs concept since patients need only the interventions that can provide benefit. In other words, patients do not need interventions that provide no benefit. Hence, an order of priority that does not consider the patient benefits or cost-effectiveness of different interventions does not appear to be useful in systematic prioritisation. Consequently, the “priority group” concept is confusing. These priority groups have been disproportionately emphasised in prioritisation discussions. Potentially, they could serve as a rough guide in grading the severity level of various conditions. However, even here there are obvious limitations. Combining different dimensions (patients groups, interventions, types of care, and groups with limited autonomy) is also confusing. Hence, the categories are too general and incomplete to be used as the only basis for priority setting –since, for instance, a disease that can be generally classified as a serious chronic disease can also appear at different levels of severity in different stages.

*The model for vertical prioritisation should be based on the ethical principles that the Riksdag resolution applied to priority setting in health care. The ethical principles need to be more widely disseminated, clarified, and possibly complemented to be implemented in practical priority setting. Furthermore, we believe that the model should not include the Riksdag’s four priority groups.*

#### **4.4 The ethical platform**

##### **4.4.1 Human dignity principle**

The Government’s bill established that “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.” (Ministry of Health and Social Affairs 1996/97)

The human dignity principle stands above the other principles in all types of prioritisation. This principle has broad support, and at first glance appears to be uncontroversial. In practice, however, it can be difficult to implement.

Many different interpretations are found among health service staff and other actors. For instance, the question of age thresholds is often discussed since a mix of chronological and biological ages are often involved.

For guidance regarding how to approach prioritisation at the group level, we adhere to the intentions in the Government's bill. The Government has ruled that it is a type of discrimination, and inconsistent with ethical principles, to *generally* allow needs to go unmet simply because of gender, age, birth weight, lifestyle, or economic and social situation (*per se*). Concurrently, it notes that characteristics or functions in a group can be an expression that special needs exist. A distinction is made between chronological age (determined by birth date) and biological age (a concept involving medical judgment), and in this context: "It is the overall appraisal of the patient's needs and how the patient can benefit from care that should determine the interventions." (Ministry of Health and Social Affairs 1996/97) In other words, it is a departure from the human dignity principle to treat someone special on grounds of chronological age alone. However, the ability to benefit from treatment must be included in the determination. At the group level, this could mean that characteristics such as age and gender or function of a group might actually be an expression of special needs. For instance, an age threshold of 35 years is used for amniocenteses in screening for Down syndrome. At this age, the risk for malformation is so high that the advantages of the test outweigh its disadvantages.

In the individual case it might be relevant to include lifestyle when appraising the benefits of a planned intervention. Here the issue is whether or not the patient can benefit from treatment if his/her behaviour does not change. This should not be interpreted to mean that health services do not have a responsibility to influence a person's ability to benefit from treatment if possible. For example, if a patient's lifestyle further complicates the condition, an effective treatment must also give high priority to the lifestyle problem.

Reasoning similar to that described above that associates risk with an age threshold also applies to recommendations on influenza vaccination. Some may think that younger people are discriminated against in targeting older people. Gender could also play a role in medical need, and hence in the effectiveness of an intervention. Apart from obvious interventions such as mammography or prostate cancer surgery, different principles apply to men and women in screening for abdominal aortic aneurysm, where survival gains have been shown in men but not in women.

Likewise, average age often plays a role for a patient group when estimating the possibility to benefit from an intervention and the risks for complications and side effects from the intervention itself.

We view this to be in line with the *Riksdag*'s intention to consider personal characteristics at the group level when they are an expression of special needs. It is the total appraisal of the patient's needs and ability to benefit from care (expected patient benefit) that should determine the intervention. This reasoning also has implications for the application of cost-effectiveness. Given that costs are the same, it is more cost-effective to treat patient groups that can be expected to benefit greatly than to treat those that derive little benefit from treatment.

It is more complicated to determine how one should assess cost-effectiveness in relation to the human dignity principle when the *cost* for the intervention or the *economic consequences* differ between different groups. Most of the guidelines for health economic assessments used around the world recommend a social economic perspective that includes all relevant consequences (costs and revenues) that appear in society. Direct costs are simply the costs for health care. Indirect costs are the other costs that arise due to disease and treatment, e.g. transportation, sick leave etc (or revenues when one is cured). When including indirect costs/revenues in the analysis, the composition of the patient group in question – as regards social position (gender, employment, age, etc) – is important. Lost productivity, and thereby socioeconomic losses, from disease vary by group. Less work performed leads to a less favourable social economy and fewer resources for health care and other services. For this reason, many defend this approach. A program for rehabilitation aimed at individuals on sick leave can result in better cost-effectiveness than a program aimed only at patients who are not gainfully employed. Whether it is right or wrong to consider this in a cost-effectiveness analysis and priority setting is an unanswered question.

Limiting the analysis to covering only direct costs would not resolve the problem that patient groups with different characteristics vary in cost-effectiveness. A particular operation in a group of elderly people can be less cost-effective than a corresponding intervention in a younger patient group. This could depend on the higher cost for the elderly resulting from a higher risk for complications, longer rehabilitation time, and lower overall benefit due to shorter expected survival in comparison to the younger group.

The problem, however, remains even if costs are completely excluded from the assessment. Since the ability to benefit from a treatment varies among groups with different characteristics, e.g. gender and age, those involved in priority setting at the group level must draw a balance between treatment, needs, and cost-effectiveness and every person's equal right to care. In setting priorities at the individual level, it is obvious that generally a person's needs cannot be passed over solely on the basis of gender, age, birth weight, lifestyle, or economic and social conditions (*per se*).

Although addressing the expected benefits of care and treatment is not controversial, questions regarding who should determine this benefit and whose benefits should be included are subject to debate. This concerns, e.g. external effects – the benefits to people other than those directly affected by the intervention. This might involve an increased workload for family members who care for someone at home, or perhaps the opposite – greater wellbeing thanks to increased functional capacity of a family member. This could include external effects for an entire population group protected from a carrier of infection who is forced into isolation. It could also include children who benefit from a parent's early recovery from disease. Involved are the costs and health gains for family members and others, and the consequences on other sectors of society.

Is it appropriate to consider benefits for people other than the individual patient? It appears reasonable to apply this, e.g. in compulsory care or treatment of infectious diseases, and to prioritise some groups ahead of others for immunisation prior to an expected epidemic that threatens society. A motive for this is that the group's social position *per se* does not determine the priority, but the benefits that health services staff, public agencies, etc are expected to achieve for other people. Many suggest that the *Riksdag's* guidelines on priority setting provide insufficient guidance. On the other hand, the Prioritisation Inquiry found that: "benefit in a care context can be viewed from the individual's perspective, not from a socioeconomic perspective. Rehabilitation is useful if it helps improve an individual's quality of life, even if that person cannot return to gainful employment. However, benefits for individuals and society often coincide." (Ministry of Health and Social Affairs 1995) On the other hand, the Government's bill states that "benefits should not be viewed only from a narrow perspective, but in relation to what appropriate health services on the whole can offer." Clearly, future review of the guidelines, should discuss and clarify these issues.

*The ethical principles for prioritisation can be interpreted to mean that when personal characteristics, e.g. age, gender, lifestyle, or function, in a group can be an expression that special needs exist, they can – according to the Riksdag's guidelines – be included in determining priorities at the group level. The question regarding how to value the external effects in prioritisation must be further discussed and clarified in future review of the guidelines.*

#### 4.4.2 Needs and solidarity principle

The needs and solidarity principle means that – when it is necessary to prioritise among different, 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.

The *Riksdag*’s resolution on prioritisation gives importance to the severity level of disease, but it cannot be the only grounds for prioritisation. As mentioned above, 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 – since one needs only that which one can benefit from, or conversely, one does not need that which one has no benefit from. In some cases, health services can influence the ability to benefit from an intervention. If the patient’s lifestyle further complicates the condition, an effective intervention must also give the lifestyle problem a high priority. If a patient’s poor dietary habits impair the effects of insulin, and he/she finds it difficult to change diets, shouldn’t we prioritise dietary education/information higher instead of considering that the patient does not derive sufficient benefits from insulin?

Since the needs and solidarity principle takes precedence over the cost-effectiveness principle patients with severe diseases and substantial deterioration in quality of life should take precedence over those with milder problems, even if caring for severe conditions costs substantially more. We interpret this to mean that patients with more severe conditions should be able to receive treatment interventions that cost substantially more per health benefit compared to those with less severe disorders. In practice, this means that society is more willing to pay the cost per life-year gained or cost per quality-adjusted life-year for more severe conditions versus treatment for minor conditions. An important question is: When are costs viewed to be too high to be reasonable and acceptable?

According to the Government’s bill, solidarity means “also to pay particular attention to the needs of the weakest. This includes children, elderly with dementia, the unconscious, and others who for various reasons find it difficult to communicate 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) It states that one should *pay particular attention to the needs* – not that they should have a *higher* priority because of lower autonomy. The need for care determines the priority.

An interesting question associated with the above discussion on external effects is: Whose needs should be included in assessing need? Whose values should determine the magnitude of need?

*In health care, need refers to both the severity level of the condition and the expected benefit of intervention. As a patient, one needs only those interventions that one can expect to benefit from. Likewise, based on this way of defining need, people do not need interventions that do not improve health and the quality of life, i.e., interventions they do not benefit from. Here, of course, health services have a responsibility to steer people to other suitable actors when they have a problem of some type.*

#### **4.4.3 Cost-effectiveness principle**

Cost-effectiveness is a ratio between the health effects and costs of an intervention. In choosing among different activities or interventions, the objective is to strive for a reasonable relationship between costs and effects, measured as improved health or higher quality of life. Nearly all cost-effectiveness analyses compare at least two options – a new treatment versus the best available option. It is interesting to identify the differences in effects and costs between these alternatives. The relevant information in a cost-effectiveness analysis is the ratio, which describes the extra cost for achieving an extra health gain. In Sweden, the most common measure is *kronor* (SEK) per quality-adjusted life-year gained (SEK/QALY).

According to the Priorities Commission, the cost-effectiveness principle should be applied only when comparing methods of treatment for the same disease, since the effects cannot otherwise be compared in an equitable way. However, the Government states in its bill "...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)

The guidelines do not describe in detail how the Government intended the cost-effectiveness principle to be interpreted at the operational level.

However, the Government's bill states that it is essential to differentiate between a cost-effectiveness principle that addresses the choice of interventions for individual patients (where the principle can be applied as the Commission of Inquiry proposed) and cost-effectiveness regarding health services in general, where the desirable objective is "...that resources are used in the best way, and that the resources can benefit many." (Ministry of Health and Social Affairs 1996/97) This could be synonymous to considering cost-effectiveness among different types of interventions for different health conditions at the group level. Concurrently, the Government emphasises that "cost-effective delivery of services must never mean denying 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 1996/97)

Also in this context we refer to the guidelines that the *Riksdag* issued for the Pharmaceutical Benefits Board (LFN) in the Pharmaceutical Benefits Act. (Ministry of Health and Social Affairs 2002) In its decisions on drug subsidies (priorities), the agency should determine, e.g. if the drug is cost-effective from a societal perspective, which involves weighing the costs and benefits of the drug. Decisions should also weigh the cost-effectiveness against the needs and solidarity principle and the human dignity principle.

In practice, the cost-effectiveness principle plays a central role in LFN's decisions. In 7 of the 9 cases of denied subsidies in 2003, the denial was motivated by deficient cost-effectiveness. For a drug to be judged cost-effective, LFN must find a reasonable relationship between cost and effects measured in terms of improved health and quality of life. This reasonable relationship should be determined from a medical, humanitarian, and economic perspective. (Anell and Jansson 2005) We cannot find any grounds for basing LFN's activities on prioritisation principles different from those that apply to health services in general.

*The type of systematic vertical prioritisation that we discuss here, and the use of cost-effectiveness analyses generally in health care, concerns priority setting at the group level. As stated by the Riksdag, this means using resources in the best way to benefit more people. The Riksdag's guidelines on the cost-effectiveness principle (applied to individual patients) are too limiting to provide guidance for vertical prioritisation, which addresses priorities at the group level. To support our position here, we refer to the Riksdag's directive to the Pharmaceutical Benefits Board to consider cost-effectiveness in all decisions involving the subsidisation of pharmaceuticals.*

#### **4.4.4 How do we translate the principles into a practical prioritisation process?**

In ranking patient groups at the group level it is practical and reasonable to assume that all people have equal value and the same rights to health services, regardless of personal characteristics and functions in society. Hence, it is inappropriate to use characteristics or functions in society *per se* as prioritisation criteria – but personal characteristics such as gender, age, and social function can be indicators of cost effectiveness and the magnitude of need. Hence, those who rank priorities in practice often struggle with weighing needs against cost-effectiveness. “A person with more severe disease or injury has a greater need, or a worse quality of life, as a result of the injury or disease. However, he/she does not need an intervention that will not improve health or quality of life. The different aspects of health- and quality-of-life-related needs must always be weighed in creating a basis for prioritisation. For example, this may include perceived suffering, the medical prognosis, or the degree of functional impairment.” (Ministry of Health and Social Affairs 1996/97)

We believe that a prioritisation process should clarify and openly describe the grounds used to appraise need and cost-effectiveness. Since the expected patient benefits of an intervention are included as a part of cost-effectiveness (the cost to achieve a health gain), there is a risk for “double-counting” when patient benefit is included both in assessing the effects of an intervention and the intervention’s cost-effectiveness. This suggests that one would only need to report on the condition’s severity level and the cost-effectiveness of different combinations of conditions and interventions. However, several reasons also suggest that one should always report benefits (effects of intervention). One reason is that the basis for assessment is easier to follow; another is that health economic data are often missing. In cases where there is adequate information on the cost-effectiveness of an intervention, one can weigh the severity level and cost-effectiveness. In other cases, where information on cost-effectiveness is missing and cannot be estimated, one can appraise only the severity level and patient benefit.

Several variables should be considered in appraising the severity level of a health condition for a defined target group/patient group. We recommend that an appraisal of the severity level should, in accordance with the Government’s bill, consider both the current health condition (i.e. how the patient group in question actually experiences health in terms of suffering, degree of functional impairment, and quality of life) and the prognosis (in terms of risk for premature death, disability, or continued suffering and impaired health-related quality of life). Hence, the current condition and future risks must be weighed.

To the extent possible, determination of the severity level should be based on scientific facts and clinical experience. This requires adding in the time aspect/course of the health condition, e.g. whether the condition is acute or chronic.

As with the *health condition* concept, the content of the concepts of *suffering*, *level of functional impairment*, and *quality of life* have also been debated. What do these mean, and what should actually be appraised to establish the severity level of a health condition? This must be further developed through concrete efforts. Likewise, it was not possible to include every aspect in the basic figure (Figure 1) – rather, in every type of vertical prioritisation one must consider, discuss, and report on the aspects that are weighed into the concept, e.g. suffering. In describing a condition's severity level and the expected benefit, a classification system such as the ICF (International Classification of Functioning, Disability, and Health) can be helpful. (Appendix 1)

According to WHO's ICF classification, a health condition (disorder/disease) includes several dimensions:

- Anatomic structure/body structure (organs and anatomic parts)
- Body functions (e.g. mental functions, pain, cardiovascular functions, motor-related functions)
- Activity (e.g. mobility, personal care, housekeeping, employment, and occupation)
- Participation (e.g. ability to participate in certain important areas of life such as education, employment, and occupation, but it can also mean helping to decide how an activity should be performed given one's incapacity, e.g. help with personal hygiene)
- Environmental factors (external factors, e.g. access to personal support)
- Personal factors (e.g. age, gender, and life experiences)

In determining the severity level and benefits/effects of an intervention for a health condition, one or more of the dimensions may be applicable – depending on the context of discourse and who participates in the prioritisation process (see discussion on personal characteristics above). In some contexts, problems at the organ or anatomic levels are decisive in determining the severity level, e.g. gallstone disease. In rehabilitation, however, the level of severity is determined by the degree to which a disease/injury impairs one's ability to perform an activity. Likewise, in nursing, the impact of a health condition on daily life is in focus when determining the severity level. In addition to appraising the extent, e.g. of brain injury, it could involve appraising the consequences of an impaired activity level (e.g. eating problems), with particular consideration to participation.

Factors in the surrounding environment could also be relevant to consider in determining a condition's severity level. The lack of personal support, e.g. relatives or personal caregivers, could mean that an activity impairment resulting from disease/injury is judged to have a higher severity level in that group than in patient groups with the same disease/injury, but who have a functioning support system.

Another example would be victims of stroke who cannot feed themselves in the fashion expected by others. This can cause embarrassment and result in patients avoiding other people at mealtimes. Hence, the severity level is somewhat determined by considering the dimension of environmental factors, e.g. attitudes of others. Giving consideration to environmental factors can be perceived to conflict with the human dignity principle in various respects. Is it reasonable for an elderly patient with multiple illnesses, who is already receiving care in a nursing facility, to be less likely than a patient living at home to receive acute care at a hospital during a minor stroke? Is it reasonable for a person on the path towards alcoholism, who is employed and has a social safety net, to receive lower priority for treatment versus someone with no safety net, or is it perhaps the opposite? Again, there is a need for further discussion.

Figure 1: Schematic description of the key components to be considered in priority setting.

Human Dignity Principle			
Needs and solidarity Principle		Cost-effectiveness Principle	
<b>Severity level of a health condition</b>	<b>Patient benefit/effects of the intervention</b>	<b>Cost-effectiveness of intervention</b>	<b>E V I D E N C E</b>
<ul style="list-style-type: none"> <li>* Current health condition</li> <li>- suffering</li> <li>- functional impairment</li> <li>- quality of life</li> </ul>	<ul style="list-style-type: none"> <li>* Effects on current health condition</li> <li>- suffering</li> <li>- functional impairment</li> <li>- quality of life</li> </ul>	<ul style="list-style-type: none"> <li>* Direct costs</li> <li>- health service interventions,</li> <li>- other measures, e.g. travel</li> </ul>	
<ul style="list-style-type: none"> <li>* Risk for</li> <li>- premature death</li> <li>- disability/continued suffering</li> <li>- lower quality of life</li> </ul>	<ul style="list-style-type: none"> <li>* Effects on risk</li> <li>- premature death</li> <li>- disability/continued suffering</li> <li>- lower quality of life</li> </ul>	<ul style="list-style-type: none"> <li>* Indirect costs</li> </ul> <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-top: 10px;"> <p>... in relation to benefit of the intervention</p> </div>	

The *expected benefit* should be determined according to the way that an intervention affects the health condition or compensates for a deficiency. Furthermore, the risk of an intervention *per se* must be determined and weighed in the appraisal. In this appraisal we start from the *average expected benefit* for a group. Often, some people benefit substantially from an intervention while others receive less benefit, and yet others may experience a loss in health due to side effects and complications from the intervention. Preferably, the expected benefit should be assessed based on scientific facts and clinical experience. Even if economic studies in health care and social services are limited, cost-effectiveness should be addressed in some manner.

*The proposed working model essentially agrees with the working model used by the National Board of Health and Welfare to develop the national guidelines. It is not possible to encompass all aspects that might be important to consider when describing a national working model. Hence, we must start from the model and consider what other aspects could also be relevant to include. The International Classification of Functioning, Disability, and Health (ICF) can provide guidance concerning what other dimensions are important in appraising severity levels and patient benefits.*

#### **4.5 Recommended process for priority setting**

##### *Step 1: Define the area for prioritisation*

Previously we stated that the sub-areas for vertical prioritisation should cover a broad needs perspective and involve all professions in health care. Each prioritisation project must determine, on a case-to-case basis, the most suitable groupings and adapt them to fit the situation.

##### *Step 2: Identify prioritisation objects*

The work of ranking starts with identifying suitable prioritisation objects (conditions and interventions). Prioritisation objects should be formulated in the context of understanding their clinical relevance rather than using rigid scientific criteria, e.g. based on a specific study design. As we noted earlier, finding an adequate level of detail can be complicated. By using general groups, the various objects might encompass many situations. Such groups are at risk of being too heterogeneous and difficult to assess in terms of severity level, etc. On the other hand, very detailed descriptions would define groups more sharply, but the volume might become unmanageable. A condition/intervention list can never be comprehensive enough to cover every type of decision-making situation.

A possible method of classification would be to focus on:

- Different types of relevant, typical cases (common patients, clinical services delivered with high regularity)
- Combinations of conditions and interventions involving large volumes
- Controversial areas (ethical dilemmas, expensive treatments, questionable cost-effectiveness).

To achieve sufficient systematisation and manageability, combinations of conditions and interventions, and the available facts, need to be identified, appraised, and presented in a uniform manner. Figure 2 below presents a proposed worksheet design.

Figure 2: Worksheet for facts and rank order

First describe the condition in the patient group and the situation in which it is assessed/stated (e.g. acute phase) Then describe current actions/interventions.	Describe the severity level of the current condition and the risk for progression and permanent problems. Indicate the magnitude of need for the specific intervention.	Describe patient benefits/effects from the intervention. Include positive effects (should correlate with the level of the severity) and potential risks, side effects, etc of the intervention.	Indicate the scientific evidence on the intervention, effects, patient benefit/effect as regards the specific health condition.	Appraise the health economics (in terms of life-years gained or quality-adjusted life-years)	Present the economic evidence	Weigh the severity level, patient benefit, and cost-effectiveness and the relevant evidence to arrive at a basis for ranking.
<b>Health condition Intervention</b>	<b>Health condition severity level</b>	<b>Patient benefit/effects of intervention</b>	<b>Evidence of benefit Effects of intervention</b>	<b>Cost/life- years gained or Cost /QALY</b>	<b>Health economic evidence</b>	<b>Ranking "Don't do" R&amp;D</b>
Specified condition, subgroup (e.g. unstable coronary heart disease, RA with mobility problems)  <i>Intervention (e.g. diagnostic procedures, drugs/assistive devices, type of care)</i>	The current health condition in terms of suffering, functional impairment, and quality of life Prognosis: Risk for premature death Risk for disability/ongoing problems Risk for deterioration in quality of life Very high, high, moderate, low level of severity	Disease-specific survival, morbidity, symptom alleviation, effects on functional disability/activity limitations Complications/side effects Very high, high, moderate, low benefit/effects	Evidence grades 1-4, or Very good to insufficient scientific evidence Standard clinical practice	Low Moderate High Very high or Cannot be appraised	Good Some Calculated or Estimated	1-10 (relative scale) Don't do R&D

*Step 3: Collect and appraise the facts*

This step involves searching for the information/facts that describe the condition's severity level, benefits, and cost-effectiveness. Preferably, this should be done in an integrated manner where people with different skills collaborate to develop evidence that is as well founded as possible, based on literature reviews and consensus discussions. Initially, at least, we can reasonably assume that prioritisation, e.g. within a clinical department or municipal agency, will be based on the collective competencies of the staff.

From the outset, one must decide on a system for classifying the severity level, benefits/effects of interventions, and cost-effectiveness. No uniform standard has been established. Hence, we propose that severity levels be categorised as *very high, high, moderate, and low*. Correspondingly, patient benefit should be expressed as *very high, high, moderate, and low*. These scales have been tested in various contexts and were found to be reasonable in dealing with estimates. If possible, a set of categorisation criteria should be established. The national guidelines for cardiac care from the National Board of Health and Welfare (2004) use the following categories:

*Low* if the impact on 1-year mortality is below 3%, *moderate* if it ranges between 3% and 10%, and *high* if it exceeds 10%. In other contexts it could be more relevant to use categories related to the impact on quality of life or on the capacity to be active.

Scientific knowledge about the effects of different interventions is often based on clinical trials that focus on clinical outcome measures. This is important, of course, but not always sufficient. Hence, it is essential to always question how a treatment benefits the patient or group targeted by the intervention. Too often, one equates clinical effect with patient benefit, which might be a reason why elderly in special housing take, on average, 10 to 12 medications. Perhaps this is also why we do not always respect the right of the elderly to refuse treatment in the final phase of life. In practice, we are referred to intermediate outcome measures, which appear in the column on patient benefits. However, we should always aim for measures that describe effects that are as relevant as possible from a patient perspective. For that reason, we use "Patient benefit/effects of intervention" as the heading.

We propose using a uniform approach to categorise severity levels and benefits.

Because of the wide variation in outcome measures among different services, and the limited experience in working with expressed threshold values, we believe it would be premature to recommend a uniform definition of categories, e.g. regarding risk levels. Nevertheless, it is important for those involved in priority setting to present their reasoning.

Furthermore, the scientific evidence used as a basis for severity levels and patient benefits should be reported. Identifying the scientific evidence is generally very work-intensive. The standards of systematisation and completeness must be set higher in national projects, e.g. under direction of the National Board of Health and Welfare, than in projects by a single county council or within a workplace. It should be noted that the National Board of Health and Welfare uses only numerals to express the strength of evidence, adhering to the grading scale applied by SBU when conclusions are based on systematic reviews of good quality. When such evidence is unavailable, a general literature search for original studies is conducted. If one or more randomised clinical trials (RCT) are found, the quality/evidence of the trial(s) is appraised and described in words, e.g. “Since the randomised trial reported no effects, but included few patients, the study’s quality/internal validity is found to be low”. If no RCTs are found, but other scientific evidence is available, this material is appraised using relevant criteria.

A brief description of grading the scientific evidence is presented below.

Table 1: Grading the evidence of individual studies in the absence of a systematic review. (National Board of Health and Welfare)

Grade	Evidence
Very good scientific evidence	At least two prospective controlled studies* of high quality and internal validity with consistent results.
Good scientific evidence	At least one prospective controlled study* of high quality and internal validity, or at least two prospective controlled studies* of lower quality that point in the same direction
Limited scientific evidence	At least one cohort or case-controlled study of satisfactory quality or at least one prospective controlled study* of lower quality
Described (text)	Studies with heterogeneous results, observational studies, etc of lower quality, expert opinion, consensus statements, etc

\* A prospective study can be an intervention study (e.g. randomised trial) or an observational study (cohort study)

Further information on the principles for literature reviews and evidence grading used by the National Board of Health and Welfare in developing national guidelines can be found on their website. The Swedish Council on Technology Assessment in Health Care (SBU) describes an attempt to grade evidence in qualitative studies in its report *Methods of Treating Chronic Pain* (2006).

These sources can provide important knowledge for showing the effects of different interventions.

A prioritisation process also needs to weigh patient experiences related to the severity level of different conditions and patient benefits from different interventions. This can be appraised by using, e.g. current knowledge about quality-of-life perceptions or information about interventions that patient groups view as most important.

In this context it is essential to seek the best possible information so we can avoid, to the extent possible, the situation where staff use their own interpretation of what good quality of life means to the patient – since there are many different ways to define the concept of quality of life.

*SBU's classification should be used to grade the scientific evidence for the patient benefit/effects of an intervention. We suggest that local prioritisation projects with limited resources use text to report on their appraisal of scientific evidence, referring to the evidence base used. Numerals should be used to express the strength of evidence only when supporting a conclusion drawn from a systematic review by SBU, or another review of good quality.*

The work involved in presenting economic facts in health care is essentially the same as that involved in presenting facts about effects. However, the databases searched should also include those targeted at economic literature. Despite the limited availability of health economic studies, cost-effectiveness should be addressed and presented in some manner, e.g. simple quantitative appraisal of the most important effects in relation to the estimated costs (in the absence of economic data).

When economic data are available, we recommend using primarily the cost per life-year gained and the cost per quality-adjusted life-year (QALY). The advantage of using cost per QALY instead of cost per life-year gained is that it allows us to more easily compare treatments that mainly affect survival versus treatments that mainly improve health-related quality of life.

It has been discussed whether there is *one* particular threshold for how much society is willing to pay to achieve an additional QALY or additional life-year. Some people prefer to establish a threshold, e.g. 500 000 SEK, and then consider everything below this figure to be cost-effective while everything above is not.





























