# **Decision Making Criteria in Public Health**



# The illusions, elucidations and elusiveness of decision making criteria

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Front page: Left hand with touchstone, Werner Jacobsz.van den Valckert's, 1617, Detail

The man's left hand is brightly lit, focusing attention on the touchstone on which it rests. This was an attribute of the assayers of the gold- and silversmiths guild. Touchstone was used to test the purity of precious metals. The assayer would rub the metal over the black stone; the tint that it left showed how pure the gold or silver was. By placing the touchstone in the limelight, the artist was not only drew attention to assayer's honourable position, but also to himself. The black stone bears Van den Valckert's signature: W v Valckert fe 1617.

Portrait of a man holding a ring, painted in 1617, is simple yet subtle. It was one of Werner Jacobsz.van den Valckert's first portraits, but already his talent is evident. The man is leaning over a stone windowsill placed diagonally across the panel. Various suggestions have been made concerning the identity of the subject. Today, the consensus is that he was Bartholomeus Jansz. van Assendelft, a goldsmith and assayer from Leiden: he is holding a gold ring in one hand while the other rests on a touchstone.

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# 1 Preface

Prioritization of preventive and curative interventions is something which is preoccupying the minds of policymakers and researchers in the public health field. There is even a kind of grimness towards the topic of public health policy. The proponents of an extensive and integrated public health policy aimed at longer and healthier living find opponents in the political arena who prefer a liberal public health policy founded on individual responsibility and regulated competition. Some proponents even show a kind of resignation because the epidemiological facts and health problems show the importance of integral health policy for such a long time but still this is not the major tendency in actual public health policy. Opponents question governmental responsibility: is the government the designated actor to act on this problem in a efficient way?

While observing this process within the Ministry of Health, many questions came up. Why does rational decision making seem impossible? What is the issue of solidarity? How are solidarity and individual responsibility linked in public health? There is a fascination about the fact that people try to make things rational, even though they are not. Even economic evaluations are based on many assumptions like the preferences and beliefs of people about their health status and differences in how to calculate costs<sup>1</sup>. Is the right question whether we agree together that economic evaluation is rational? Is it the best solution out of many restricted options?

And if there is so much attention for economic evaluation in the public debate, why is it that many curative and preventive programmes which are not cost-effective have been awarded, and vice versa?

Why is it difficult to agree on a basic benefit package concerning something which is so precious to all of us? How do we choose policy measures which optimalise a long and healthy life? Why is integration of cure and prevention not self-evident? People would like to prevent illness. We wish each other lots of health every New Year's Eve or every birthday. The Chinese wish each other happy meals by means of saying of goodbye, because they hope they stay healthy. The Dutch standard of living is very high, but how do we deal with our luxurious life? Health care is part of everybody's' life: we all get sick, we all die and our last year of life is the most expensive one because we consume the most healthcare. Despite Western prosperity, it is difficult to agree on accessibility, quality and efficiency. A clear explanation of this problem is stated: 'More budget simply means rationing at another level'<sup>2</sup>. The problem of decision making is not becoming any easier because of another budget level.

We have to define and quantify criteria. Criteria are needed to make decisions, like a touchstone was used to test the purity of precious metals. A quantified measure helps to understand the things we would like to express in a better way. Freemasons once choose for terminology of the masons. They thought that the exact terminology could help to develop a language which was understood by all different members in the same way. They hoped it would prevent misunderstandings in communication. Technical and mechanical rationalities, things that can be measured, can help to build good foundations. Is this an implication of economic evaluation? Does it help to decide on prevention and cure? Which other criteria are possible in public health? Which of these criteria is the most important one? Is it possible to decide on hierarchy in decision making criteria or do we have to weigh every other issue in a different way?

These questions have brought me to writing this thesis. The process of writing this thesis generated more questions than answers.

<sup>&</sup>lt;sup>1</sup> Integration of societal costs, discounting debate, friction costs

<sup>&</sup>lt;sup>2</sup> Maynard 1999

# 2 Samenvatting

Deze scriptie is geschreven voor het ministerie van Volksgezondheid, Welzijn en Sport, directie Publieke Gezondheid. De aanleiding is het besluitvormingsprobleem van preventie en public health. De hoofdvraag luidt: Wat zijn de besluitvormingscriteria in public health? De deelvragen zijn als volgt geformuleerd: Wat is een besluitvormingscriterium? Wat is het verschil tussen besluitvormingscriteria voor cure en voor preventie? Hoe kunnen besluitvormingscriteria geordend worden in de beleidscontext? Door middel van een kwalitatieve studie is antwoord gegeven op de genoemde vragen. Literatuuronderzoek en interviews waren onderdeel van de studie.

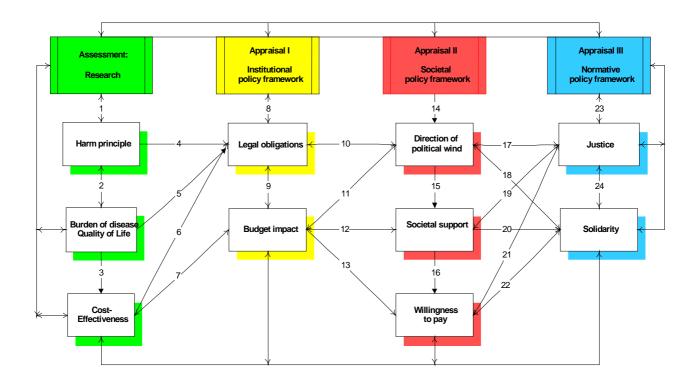
Een besluitvormingscriterium kan gezien worden als een toetssteen. Het criterium moet gedefinieerd en geoperationaliseerd zijn. Er zijn 23 zeer diverse criteria benoemd. Een ander kenmerk van de criteria is dat ze onderling nauw samen hangen binnen het besluitvormingsproces. De besluitvorming kan over alle mogelijke interventies in de public health gaan. Het besluitvormingsperspectief is bepalend voor de interpretatie van het beleidsprobleem en de criteria. Dit wordt nader uitgewerkt. Een besluit op basis van een bepaald criterium herbergt een vaak impliciete keuze voor een verdelingsprincipe zoals het utilitarianisme, socialisme of het 'fair innings' concept.

Alle criteria zijn van toepassing op cure en preventie, maar de operationalisatie en prioritering verschilt. Kosten-effectiviteitsanalyse wordt verschillend uitgevoerd bij cure en preventie. Ziektelast wordt bij preventie op bevolkingsniveau bekeken en bij cure op het identificeerbare individuele niveau. Politiek gezien ligt preventie heel anders dan cure, omdat het handelt over niet identificeerbare individuen en de lange termijn. Een nog uit te voeren case-analyse zou moeten aantonen welke criteria in het verleden doorslaggevend zijn geweest bij implementatie van curatieve of preventieve interventies en welke andere verschillen aan te geven zijn tussen besluitvorming voor cure en preventie.

De in literatuur en interviews geïdentificeerde criteria zijn geordend op basis van wetenschappelijke achtergrond en de "hardheid" binnen besluitvorming. Politiek is onvoorspelbaar, incidentie en ziektelast zijn meetbaar en daardoor harde criteria. De lijst van 23 criteria is gecomprimeerd tot tien criteria, de 13 andere criteria zijn een verondersteld onderdeel van de tien hoofdcriteria. Het schema is opgebouwd uit een Assessment fase en drie Appraisal fases: Institutioneel Beleidskader, Maatschappelijk Beleidskader en Normatief Beleidskader. Een case-analyse, het HPV-vaccin, is beschreven aan de hand van het schema. De besluitvorming ten aanzien van het HPV vaccin is omschreven in termen van de beleidscyclus en elementen van beleid. Hierbij bleek dat er nog veel onzekerheden blijven bestaan over de onderzochte criteria. Bij besluitvorming moeten onzekerheden blijkbaar ingecalculeerd blijven worden. De Gezondheidsraad brengt een advies uit over opname van het HPV-vaccin in het RVP.

Het schema geeft een goede leidraad om inzicht en overzicht te krijgen in de aspecten van besluitvorming en het besluitvormingsstadium. Hierdoor is het eenvoudiger om succes en faalfactoren te benoemen en besluiten te nemen waarbij de risico's expliciet benoemd zijn. Dit kan de evaluatie en het effectief bijstellen van beleid sterk bevorderen. De veelheid van actoren bij een beleidsproces belemmert besluitvorming, maar een besluit uitstellen of een slecht compromis is geen goed alternatief. Het sociaal-constructivisme is aangedragen als mogelijke verklarende theorie voor de subjectieve preferenties die beleidsmakers en onderzoekers met zich meebrengen bij de uitvoer van hun werk.

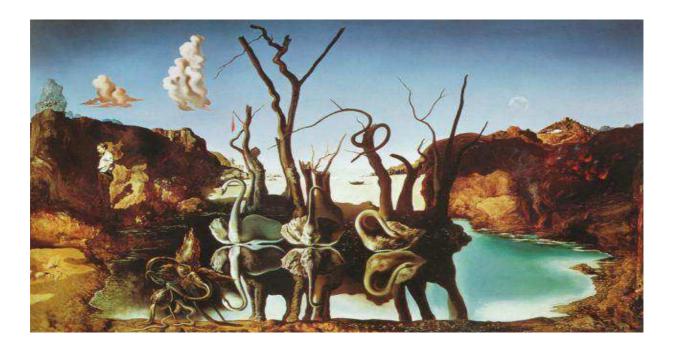
Het kwantificeren van verbanden tussen criteria kan de ontwikkeling van besluitvormingssystematiek ten goede komen. Een discrete choice analysis zou uitgevoerd kunnen worden om de subjectieve preferenties van beleidsmakers expliciet te maken. Dit kan aanleiding geven tot een representatieve hiërarchie van besluitvormingscriteria. Het is aanbevolen om de efficiëntie van preventie en cure te vergelijken. Verbeterde toegankelijkheid van alle uitgevoerde kosten-effectiviteitsstudies zou nieuwe onderzoeksvoorstellen besluitvorming kunnen verbeteren. Een studie naar de kosten-effectiviteit van intersectoraal volksgezondheidsbeleid ligt als uitdaging te wachten. De onderliggende ethische verdelingsprincipes zouden nader uitgewerkt kunnen worden, opdat de gevolgen van keuzesystematiek inzichtelijker wordt gemaakt. Deze aanbevelingen kunnen bijdragen aan de nadere ontwikkeling van systematisch en consistent public health beleid.



A Descriptive Scheme of Decision Making Factors for Public Health Policy

Part I Methods & Results:

Make intuitions explicit. W.K. Redekop, June 2006



The illusions, elucidations and elusiveness of decision making criteria

## 3 Introduction

Every day policy making implies the art and challenge of making decisions which support the realization of public health goals. According the Public Health Status and Forecasts 2006, overweight and unhealthy behaviour, especially among younger people, are becoming a source of concern for public health in the future. Furthermore, many differences in health and in health risks among regions and neighbourhoods have been observed.

Decisions have to be made to guarantee equal access to high quality healthcare in order to improve the health of a population. Policy needs to be developed to prevent disease and to cure people once they have become ill. Overweight is the first part of a chain of many physical and mental problems. It will cause many health problems in future, which will cause societal losses. Costs of healthcare may rise and loss of productivity due to absenteeism may become a bigger burden on society.

Choosing solutions which balance efficiency, equity and quality simultaneously is a provocative exercise. The structuring and financing of public health and healthcare is an ongoing process. Rationing means prioritisation. Clear cut criteria are essential in this process of decision making in public health. A system of decision making criteria, based on scientific evidence and including many ethical considerations, to perform prioritisation in an undisputable, decent and supported way, seems not available<sup>3</sup>. Sir Isaiah Berlin once said: "We live in a world of conflicting values where clear cut solutions cannot in principle be found"<sup>4</sup>. Wheale added: "To suppose that we can escape this conflict of values by retreating to an ideologically and organizationally simpler world, casts a veil of deceit over the choices that we must make"<sup>5</sup>.

The health status, determinants of health status and social economic differences are the point of departure for decision making in public health. The final purpose of public health policy is to maximise health and to reduce health inequalities<sup>6</sup>.

One of the conclusions of the PHSF 2006 is that integral public health policy is important to deal with current developments of Dutch health. A more specific suggestion is that prevention should not only focus on the individual, but just as much on the social and environmental factors of the individual.

As said, efficiency is a major issue in public health policy making, due to cost constraints. The Dutch Council for Public Health and Healthcare  $(RVZ)^7$  recommends a cost-effectiveness threshold of  $\in$  80.000, - for an additional quality-adjusted life year related to burden of disease. In the recommendation report 'Sensible and sustainable care' the RVZ advises that the process of decision making should include a quantitative and qualitative assessment phase and a appraisal phase, in order to obtain the necessary panoramic view for optimal decision making.

The recommendation of the implementation of a cost-effectiveness threshold is disputable according to many scholars who expressed their opinions in newspapers during the summer of 2006<sup>8</sup>. Again it seems that decision making in healthcare involves unwinnable dilemmas. Government has to make choices concerning public health and healthcare within the boundaries of a given budget. Therefore it seems impossible to pay attention to all important aspects.

In a dynamic context with many different actors, stakeholders, perceptions and interests, decision making asks for an elucidated vocabulary and an agreed standard for instruments of decision making.

<sup>&</sup>lt;sup>3</sup> Boot & Knapen 2001: 338

<sup>&</sup>lt;sup>4</sup> Sir Berlin I. 1969. *Four essays on liberty* 

<sup>&</sup>lt;sup>5</sup> Wheale 1998 British Medical Journal

<sup>&</sup>lt;sup>6</sup> Mayard 1996 (rationing assumptions)

<sup>&</sup>lt;sup>7</sup> RVZ: Raad voor de Volksgezondheid en Zorg <sup>8</sup> NBC Handelahlad Trauw, Einensieel daghlad

<sup>&</sup>lt;sup>8</sup> NRC Handelsblad, Trouw, Financieel dagblad

In 1992, the committee 'Choices in healthcare' with chairman Dunning developed a system for setting priorities, pictured as a funnel with four sieves: necessary cure, effective cure, efficient cure and individual responsibility. This didn't offer the wanted univocal decision making instrument, mainly because of the complexity of these criteria.

Decision making criteria are very diverse. These criteria or factors appear to be elusive. Heclo describes this as follows: "Policy makers are forever put in the position of desperately seeking solutions to the possibly unwinnable dilemmas of social policy"<sup>9</sup>. There is a permanent search for solutions to achieve better health and a higher standard of healthcare, as can be found in literature.

Health is the key issue in public health policy. The complex mainframe of interrelated economic, epidemiological and policy factors and a dynamic context of many actors with their own perceptions and convictions intertwine into final outcomes. Is it possible to improve and elucidate this process of decision making in public health any further?

Initial observations have revealed that some criteria play a very important role in public debate, one of these being a cost-effectiveness threshold. However, the interrelatedness between different criteria seems just as important, it seems to be understood poorly, difficult to include in the decision making process or just not very transparent.

This has brought forth the following research question:

## What criteria for decision making in public health can be identified?

The following sub questions are defined:

- What is a decision making criterion?
- What is the difference between decision making criteria for cure and for prevention?
- How can decision making criteria be arranged in a policy context?

First the methodological aspects will be explained. After this, the theoretical concepts will be cleared up. Then, the findings in literature and interviews are presented. A synthesis of these findings follows in chapter 7. The criteria have been elucidated in relation to each other, which also resulted in a structure of the decision making criteria. This structure is connected to the policy making process, which is illustrated by a case. After some discussion and reflections, it ends with conclusions and recommendations. Several recommendations have been done based on the findings in this study. The recommendations can be found in chapter 11. A description of all decision making criteria has been added in the appendix § 13.1.

<sup>&</sup>lt;sup>9</sup> Heclo 1975 in Hunter 1997: 8

# 4 Methods

The aim, the perspective, the design of the study and the way a synthesis has been performed will be explained in this chapter. A motivation for the main research question and the sub questions is given.

## 4.1 Aim and perspective of study

This study is a policy oriented study. The aim of the study is to determine decision making criteria in public health. To demarcate the focus of this study it is chosen to identify decision making criteria for public health in general, and to discuss these criteria from the more specific perspective of prevention policy. This perspective is chosen because many previous studies about decision making criteria have been focused on decision making in cure. A shift from the current focus on cure to a more extensive prevention policy and integrated health care are part of the policy recommendations of the PHSF 2006, an important source of information for public health policy.

The scope of the study is limited to public health policy making in the Netherlands. This study used a qualitative approach to identify all possible criteria in public health, with the latter aim of connecting these to the policy making process. The complex process of decision making is described, in order to understand and identify the policy problem and context.

The central question of the thesis is:

#### What criteria for decision making in public health can be identified?

The question seems simple, but a list of decision making criteria will not be satisfying. A condition of decision making is definition, operationalisation and implementation of decisive criteria. The decision making criteria are divers. Because of this, each criterion has a specific impact on decision making and causes different methodological problems. Many authors described decision making criteria, but after exploring literature, it seems that there is no comprehensive summary of all interrelated decision making criteria. Observing a criterion in relation to only a few decision making factors does not cover the whole solution. This was part of the problem of the Funnel of Dunning. There may be many more decision making criteria and they are probably all interrelated. This is a supposition and it is the way the criteria have been observed while performing this study.

The following sub-questions have been defined:

#### What is a decision making criterion?

In order to identify a criterion, decision making criteria in general have been defined. Then, the 'decision rule' for selecting decision making criteria in public health is given. Based on this frame, the selection of criteria through literature and interviews can be performed. In order to answer this question and the main question, a definition of criteria is developed. In addition, all criteria and the underlying rationing principles have been described and added in the appendix. This information is necessary in order to understand the problem of decision making, the interrelatedness of criteria and the development of the decision making scheme.

#### What is the difference between decision making criteria for cure and for prevention?

The distinction between prevention and cure is not logic from a theoretical point of view. One could argue cure and prevention are complementary and would have the same criteria. In practice there is a lot of difference between cure en prevention. The recommendation of the PHSF as cited in § 1.1 refers to this difference. Cure and prevention have different budgets. The difference is, in favor of cure, roughly 45 billon euros<sup>10</sup>. The difference in decision making might also be explained as follows. The rule of rescue<sup>11</sup> refers to the essence of helping somebody who needs cure at that instant moment. Prevention helps to avoid health loss, but it is difficult to determine the exact consequences of prevention. When it will happen and to whom is not explicit. The prevention paradox is manifold: screening helps to detect breast cancer for one woman, but it may be a burden to another one who did not have the risk at all. Screening has to be performed with an entire population in order to detect all possible risks. Clean air and healthy food will keep people healthier, but nobody knows what would have happened to each specific individual if these conditions would have been different. Decision making for cure and prevention is different. There are methodological and practical issues which causes these differences.

The decision making process and decision making criteria have been described from a descriptive and contemplative perspective. The important concepts and definitions concerning decision making criteria, prevention and public health policy will be explained and connected, through which a theoretical framework evolves.

There should be no explicit assumptions about the ideal constellation of health care and public health policy, because this might restrict the way the criteria are studied. Moreover, there should be no restriction in the way of reasoning concerning possibilities and limitations of the current configurations of health care and public health.

#### 4.2 A qualitative study

Two different methods were applied to determine the information to describe the problem of decision making, the possible decision making criteria and the interrelatedness between decision making factors: a literature search and different kinds of interviews.

#### # Literature search in which various types of publications have been examined:

Inclusion criteria for publications:

- Recent (1999-2006) peer reviewed publications dealing with decision making in public health, preferably referring to the Dutch situation;
- Studies concerning decision making in public health in general or prevention;
- Recent publications by important advisory organizations of the Dutch government, like the study Sensible and Sustainable Care;
- Recent newspaper articles describing the debate about decision making by relevant scholars;
- Notes, official letters, communiqués, drafts and white papers written by the Ministry of Health, Welfare and Sport to identify current criteria and policy stages;
- Reports describing important studies about decision making in prevention and public health policy (references from interviews, studies referred to by many other authors, snowball method).

Exclusion criteria for publications:

- literature from before 1999, with some motivated exceptions;
- literature applied to other countries;
- literature which was covered already by other authors.

<sup>&</sup>lt;sup>10</sup> This is not entirely right because there is overlap in calculations.

See: Costs of illness and Costs of Prevention, RIVM 2006

See explanation appendix § 14.1

Literature was searched on the internet through Google with key word combinations like prevention, public health and decision making criteria. Websites of Dutch and European institutes have been explored (universities, European Union, World Health Organization). The databases of important Dutch research and advisory institutes have been checked (RVZ, GR, RIVM, RMO, WRR, ZonMw, TNO, SCP, CBS, RK). Databases online like PubMed and other digital databases linked to the Erasmus University have been explored. Specific authors have been checked; many authors referred to Lalonde, therefore original documents of Lalonde have been found through the internet. As far as possible, original sources have been used. Some older documents (like Lalonde) have been referred to by many authors, and are taken in to account also. Literature which was used during the master Health, Economics, Policy and Law has been taken into account as far as relevant.

The decision rule for taking into account decision making criteria in public health, has been defined as follows. Sources are only taken into account if a broader definition and operationalisation of criteria has been found. All criteria are referred to in many sources, but because the focus of this study is to identify them and therefore to understand them thoroughly, only broader descriptions have been identified. Implicit referrals to criteria do not count. The literature search is not covering everything. Many more international sources can be identified, and maybe Dutch sources are missing. The international part is not the focus of this study. International literature brings forth a lot of valuable information, but because of the Dutch perspective of this study, this has not been done systematically. Some sources which may have considerable influence on Dutch policy making or sources which imply the Dutch situation, have been taken into account. Handbooks are taken into account regardless from their origins, because these are seen as a general accepted source of knowledge.

The criteria extracted from the literature, were systematically ordered: kind of source, decision making criterion, context (health care or prevention), definition, operationalisation and implementation. Based on this literature search, a table with literature and identified criteria is produced, in order to depicture the information in a comprehensive way. Some hypotheses about the literature search and the findings have been explained.

#### # Several types of interviews

Individual interviews were arranged with policymakers and researchers. All respondents had to have a professional function that was related in some way to decision making criteria and public health policy. An attempt was made to find respondents from different backgrounds and contexts, to make it possible to extract information from different frames of minds. The questions were put in front of a number of respondents. The answers were written down literally. Some questions were prepared for all respondents; other questions came up during the interviews. Four types of interviews concerning decision making criteria were conducted, in following order:

1) Three in-depth interviews were conducted to gather supplemental information about the topic not previously found in literature. Decision-making criteria, personal preferences and ideas about decision making criteria and public health policy, prevention, epidemiology and economics compromised the issues under focus. The respondents consisted of the following: a public health researcher, a researcher of cost-effectiveness of the RIVM and a policy maker at the Ministry of Health.

2) Eight semi-structured individual interviews were conducted to identify decision making criteria. The respondents were asked about their ideas about prioritization, about a cost-effectiveness threshold and possible alternatives. They were also asked to relate the topic of decision making to prevention. The respondents consisted of personnel working at the RIVM and the Ministry of health. Their work is related to prioritization and prevention policy.

3) Four semi-structured individual interviews were conducted with the aim to collect information about decision making, prevention and public health policy. These interviews had a broader perspective

then the preceding eight interviews, to find out more about the interrelatedness of decision making criteria.

Many participative observations and informal conversational interviews took place, mainly with policymakers from the Ministry of Health.

4) After collecting information from literature and interviews, a synthesis was performed. This synthesis was then substantiated by two experts of public health policy. Some respondents have been contacted again to make sure that the information was correctly interpreted.

Interviews were analyzed as follows:

- statements were analyzed, designation of criteria and factors was derived, as well in abstract terminology as described in cases;
- statements were compared;
- references to literature or cases have been studied/ checked.

The questions and most of the answers can be found in the appendices. A selection of the main findings is integrated in § 6.2.

#### # Synthesis

A list of 23 decision making criteria was developed based on findings in literature and interviews (see appendix). This was done after performing literature search and conversations which grew to be more systematic during the process of writing this thesis. The 23 criteria have been grouped in order to make it comprehensible and to find out whether something was missing. Three groups followed: epidemiological and demographic, economic and policy decision making criteria. Another check in order to find out relationships and missing criteria or missing links was the search for a structure with interrelatedness between criteria. The results of this analysis have brought forth the structure of an observational scheme of all identified criteria, as can be found in chapter 8. This scheme shows ten criteria. The other identified criteria are valued as part of the ten selected main criteria. The numbers on the arrows between the main criteria correspond with the explanation of the interrelatedness between all criteria or miss of the literature and interviews are integrated and shown. A case description of the HPV-vaccine was the final task performed, in order to find out three things:

- does the structure make sense;
- is the gathered and the produced information covering public health decision making;
- will the structure lead to useful suggestions for policy makers.

After the collection of decision making criteria and the observational scheme was made, a second scheme followed. The first observational scheme is a descriptive framework to interpret all decision making factors in relation to a public health problem under focus of a policy maker. A second decision making flow diagram was invented. Several cases have been led through both schemes during interviews. Only one case is described.

It was tried not to be prescriptive in any way, but the way the decision making flow diagram is structured, betrays a certain preferable order of criteria. Even though both schemes have been developed with no intention to prescribe where to begin or when to end and in an iterative way, a certain order of steps appears to be inherent. While producing these schemes, the focus was to order the relatively most undisputable, 'hard', and scientific criteria and to untie these from more subjective criteria or criteria which are more sensitive to political agenda's and preferences. This was done in order to make criteria understandable and to make them less elusive and less dependent on possible preferences.

# 5 Theoretical frame

The concepts and definitions concerning public health and decision making have been elucidated in the theoretical frame.

#### 5.1 Decision making and decision making criteria

**Decision making** has everything to do with making choices. To make a choice, there is need for decision making criteria. The choice 'to act or not to act' is based on the decisive criterion. A decision involves an allocation of resources. It is irrevocable, until a new decision reverses it. A prioritization might be an intermediate step en route to a decision. The **decision making factors** have their influence on decision making processes and the ultimate decision. There is a distinction between decision making criteria and decision making factors. After a decision was made there is one decisive criterion, the other criteria are influencing factors.

A **criterion** is a distinctive feature, a standard of judgment, a norm or touchstone. A criterion is a measure of something. A decision making criterion concerning public health, is a rule of definition which is decisive for the choice which has to be made between preventive and curative programmes.

To develop a standardized framework of judgment in which all identified criteria are incorporated is complicated. To consider all the consequences of a decision is not an easy task either. The decisive criterion, the notion of the criterion and the connected principles and many other factors will influence the consequences of a decision. Policy outcomes are depending on the quality of the decision making process and the quality of the decision itself.

#### 5.2 Prevention and public health

Prevention includes all measures aimed at collective prevention, health promotion and health protection<sup>12.</sup>

- collective prevention: acts on endogenous determinants (influencing the immune system through vaccination), but also on (preliminary stages of) diseases (screening for cervical cancer and breast cancer).

health promotion: acts on lifestyle factors (antismoking campaigns, information on nutrition)
 health protection: acts on physical environment (emission standards for air pollution, traffic measures) or social environment (socio economic and socio-cultural measures, working conditions)<sup>13.</sup> A derived objective of these prevention goals is the extension of life expectation by reducing sickness and death and the improvement of health related quality of life.

Prevention is divided into **primary, secondary and tertiary prevention**. Primary prevention is aimed at preventing new cases of the disease; therefore it is aimed at the determinants which cause illness. Secondary prevention is aimed at early discovery and early treatment, in order to improve the (healthy) life expectation. Tertiary prevention is prevention and reduction of consequences of a diagnosed disease.

**Health** is the state of complete physical, mental and social well-being, according the WHO-constitution<sup>14</sup>.

<sup>&</sup>lt;sup>12</sup> van der Maas & Mackenbach 1999

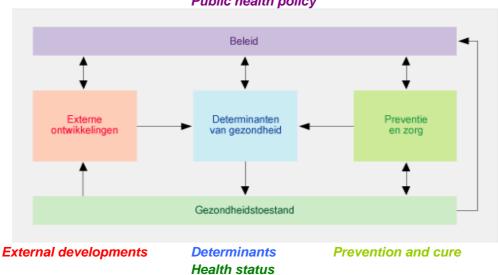
<sup>&</sup>lt;sup>13</sup> PHSF2006

<sup>&</sup>lt;sup>14</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

Further more, health is considered as a basic human right<sup>15</sup>. This emphasises the importance of public health policy. The Dutch Scientific Council for Government Policy (WRR) made a specification: facilities which only contribute to the happiness, hale and hearty of somebody, cannot be identified as healthcare facilities, as long as they are not curative or preventive<sup>16 17</sup>.

**Public health** covers the whole picture of health promotion, prevention of disease, curation and care. Curative and preventive facilities, intersectoral health measures and furthermore taking care of and nursing the sick and incurable are part of public health policy.

**Integral public health** policy refers to two things. The first is policy aimed at maximizing health through policy of different departments aimed on the same goal of health gain. There exists cooperation between departments concerning the same policy<sup>18</sup>. Secondly, 'integral' also refers to integral healthcare: integration of prevention and curation, integration of several disciplines or integration of alternative and regular medicine. **Intersectoral policy** has a less structural nature than integral public health policy. It refers to policy making in cooperation with different ministries, but the way the cooperation, responsibilities, transfers of money and decisive power are organized is not defined in principal<sup>19</sup>. The phenomenon public health and integral public health are familiar since ages. In 1848, Rudolf Virchow used the term 'Volksgesundheid' in his magazine: "Medicinische Reform". He emphasizes the governmental responsibility concerning integral public health policy. The ancient oath of Hippocrates is slightly modernized nowadays and reads as follows: "I will take care of the diseased, promote health and relieve suffering". This corresponds respectively with cure, prevention and care. The professional task of a physician is not only to cure people, but to promote health in an integral way. The conceptual model of public health developed by the RIVM shows the relationships as explained.



The conceptual model of public health
Public health policy

Measures in the field of prevention of disease and health promotion have been aimed at the individual (and based on population incidence and prevalence rates). Prevention of disease has been aimed at congenital or acquired characteristics of people (cholesterol level), and health promotion in lifestyle

<sup>&</sup>lt;sup>15</sup> Art 22. Constitution. Art 152 EU treaty: Protection and promotion of public health (and the derived right on health or healthcare)

<sup>&</sup>lt;sup>16</sup> WRR 1997

<sup>&</sup>lt;sup>17</sup> This refers to a more direct causality between intervention and effects, because feeling happy and relaxed might probably influence health.

<sup>&</sup>lt;sup>18</sup> As an example of integral public health policy: the interdepartmental policy committee concerning prevention (IBO Interdepartementaal beleidsonderzoek Preventie) which started in September 2006

<sup>&</sup>lt;sup>19</sup> As an example of intersectoral policy: 'Action programme health and environment' <u>http://www.vrom.nl/pagina.html?id=11126</u>

(smoking, exercise). Health protection has been aimed at the physical and social environment (living and working conditions, education, social networks). It is not possible to prevent all sickness from occurring. For instance the number of chronically ill patients is increasing because of demographic ageing<sup>20</sup>. This indicates an increasing demand for preventive actions<sup>21</sup>.

Different preventive methods are tied in with each other, particularly because characteristics, environment and lifestyle of people are strongly related to each other. There is a relationship between health, genetic predisposition and the risks because of an unhealthy lifestyle. Lifestyle influences the health of the individual. Because of insufficient exercise and too much nourishment, a person can become overweight or obese. In turn this is a risk factor for diabetes and intestinal cancer. Environmental determinants and the related health protecting measures have an important influence on health. Sedentary life influences physical activity. Another example of preventive policy is the quality of potable water and clean air, which are essential for prevention of infectious disease. Policy which combines initiatives of several policy areas like environment, housing, education and labour, used to be called '**facet policy**'<sup>22</sup> and is nowadays referred to as intersectoral policy or integral policy, as explained before.

#### 5.3 Health technology assessment

Methodologically, **Cost-effectiveness** refers to the study of costs and effects alone. It does not say anything about the broader economic and epidemiologic picture of the studied programme. **Economic evaluation** entails **cost-effectiveness studies**, **cost-benefit studies** and **cost-utility analysis**. There is a health care perspective which only takes costs of treatment and of patient into account. There is the societal perspective which takes into account the broader economic picture like the societal costs (productivity losses). The two perspective approach combines the two options. This way results and costs only for the healthcare sector can be compared with macro-economic consequences<sup>23</sup>. **Health Technology Assessment** (HTA) offers the integral research perspective on cost-effectiveness. The following disciplines are related to HTA: medical and biological expertise about disease and effective programmes, epidemiology (determinants and causation) and demography, psychology and sociology concerning social aspects, legal and ethical aspects, economics and political science. In general, all methods of economic evaluation are referred to as cost-effectiveness studies.

## 5.4 Qaly's as utility's<sup>24</sup>

Economic evaluation has implications for fairness and solidarity. Generally, Qaly's are used as utilities. This is an implicit choice, when making decisions based on cost utility analysis.

- In the context of Cost Utility Analysis (the method where the Qaly's are the output), a utility is a non-monetary utility (cost-effectiveness analysis has a monetary output);
- All Qaly's which are measured in any other way than with a Standard Gamble, cannot be utilities (SG is a technique to weigh and express preferences by patients about their health situation).

There are specific methodological assumptions, which concern SG. Because these conditions, are uncommon in practice, and thus even a utility-weighted QALY is generally not in itself a utility. It is difficult to say whether all cost-utility studies have been performed according these conditions. Utilities should be used when<sup>25</sup>:

• Health-Related Quality of Life is an important outcome;

 $<sup>^{20}</sup>$  This development refers to the epidemiological transition, which is explained § 6.1

<sup>&</sup>lt;sup>21</sup> PHSF 2006

RVZ Gezond zonder zorg 2000

<sup>&</sup>lt;sup>23</sup> Brouwer et al 2006

<sup>&</sup>lt;sup>24</sup> Drummond ao. 2005: 188-189

<sup>&</sup>lt;sup>25</sup> Stolk. sheets HEPL

- A health care programme affects both morbidity and mortality and you wish to have a common unit of outcome that combines both effects;
- You wish to compare programmes that have a wide range of different kinds of outcomes (resource allocation decisions);
- You wish a comparison with programmes evaluated by CUA in the past.

There are several alternatives to Qaly's and Daly's. The following alternatives have been found: Years of Healthy life YHL (USA), Health Adjusted Person Years, Health Adjusted Life Expectancy HALE (Canadian), Years of Potential Life Lost YPLL. YPLL is a measure of the relative impact of various diseases and lethal forces on society. It highlights the loss to society as a result of early deaths. The figure for potential years of life lost due to a particular cause is the sum, over all persons dying from that cause, of the years that these persons would have lived had they experienced normal life expectation. The measures are comparable to the Daly's and Qaly's and will not be explained any further, because they are not relevant for the Dutch situation.

#### 5.5 Policy

In this paragraph some policy definitions have been explained. Policy, policy system, social policy regime, social learning, and social constructivism define the theoretical frame of the policy part of this thesis.

**Policy** is a plan or course of action, as of a government, political party, or business, intended to influence and determine decisions and actions concerning societal matters<sup>26</sup>. The concept of policy covers the policy cycle<sup>27</sup>, policy goals and objectives, policy evaluation, policy instruments and policy concerning specific area's of attention.

A **policy system** is a set of institutional rules and organisations associated with the provision of categorical social goods and/or services, including the response and demand structure of clients and/or citizens in a particular area of provision<sup>28</sup>.

A **social policy regime** is described as follows: an enduring configuration of institutions, organisations and policy programmes, exhibiting shared values, aims, characteristics and specialised knowledge and techniques, evolving in tandem over long periods of time<sup>29</sup>.

The core of optimal, suitable and efficient policy should be rational decision making. The search for a rationalised qualitative and quantitative criterion might be put as a struggle for decision making. The question is raised, whether rational decision making is possible at all. Policy makers are subject to bounded rationality: the reality of a policy maker is defined by the personal frame of reference, the current available knowledge and insights, the perceptions and preferences. Related to this explanation is 'social learning'<sup>30</sup>: the structure of beliefs and ideas within a policy system.

A explanatory theory for this phenomenon is **social constructivism**<sup>31</sup>. This is based on the idea that people themselves assign a meaning to their social context. The social developments play an important role in this process. Every human being constructs his own frame of reference and while doing so he or she is influenced by the responding social context. The black box of cognitive and normative actor-orientations in politics and policy is a very important aspect of decision making<sup>32</sup>. Decision making and making of policy may be studied and observed, but after discovering what is in the black box, researchers are not sure about the black hole which may still be in there.

<sup>&</sup>lt;sup>26</sup> Bovens et al 2001.

<sup>&</sup>lt;sup>27</sup> See chapter 9 and § 13.4.

<sup>&</sup>lt;sup>28</sup> Bovens 2001.

<sup>&</sup>lt;sup>29</sup> Hacker, 2002: 233, Howlett and Ramesh 1995.

<sup>&</sup>lt;sup>30</sup> Sabatier in Howlett and Ramesh 1995.

<sup>&</sup>lt;sup>31</sup> Social Constructivism: Abma 2001. <sup>32</sup> Homorijek A 2002

<sup>&</sup>lt;sup>32</sup> Hemerijck A 2003

#### The elements of public health policy-making

The elements of policy making (who, what, how, context) help to identify the landscape of prevention policy. The **policy model** of prevention is slightly incremental and but mainly mixed because of need for mutual adjustment of policy goals and instruments. The policy model describes the actors and their intended roles and actions. There is still a gap of knowledge, for instance concerning the cost-effectiveness of prevention and the comparison of prevention and cure. The policy process is diffuse. More insight in positions of powerful actors and stakeholders and the support and feasibility of prevention policy is preferable.

## • Mixed policy model<sup>33</sup>

The assumptions about what & how:

- Different conflicting policy goals & objectives exist
- The sequence of policy steps depends on type of policy (strategy/ operational)
- There is limited knowledge of policy instruments and alternatives
- The assumptions about who & context
- Policy actors have limited decisional power
- There are many different powerful stakeholders
- The stakeholders' interests are negotiable

#### Policy actors concerning prevention & the social context

The political, socio-political and social actors like the Minister of Health Welfare and Sport; the Secretary of State; public health policy makers; political parties; health insurance companies; patient organizations; professional organizations; hospitals, pharmaceutical companies; advisory committees (RVZ, GR); research institutes (RIVM, ZonMw, TNO, iMTA) and employers have been depictured in the **Pyramid of Bondieu**. There is a dynamic context with many stakeholders. There is a lobby of healthcare organizations and pharmaceutical industry. The pyramid of Bondieu can help to visualize the social context of policies. The social actors and socio political actors act within the national and international legal structures.

#### • Policy goals and objectives

The goals and objectives of public health policy and prevention have been described in chapter 3. Goals refer to the intrinsic goals of health systems and public health policies. The objectives are the more operationalised goals described in policy.

Policy goals are depending on the actual possibilities like budget or support. Scarcity is one of the limiting factors of policy goals. There will be never enough resources to satisfy all human wants and needs and at the same time demand has no end. This is a conflicting situation. The role of healthcare is to improve health and to reduce health inequalities<sup>34</sup>. Governments seek to guarantee equal access to public health facilities and a high quality of healthcare with limited resources<sup>35</sup>.

#### • Policy instruments

The instruments to realize objectives are the following information campaigns; political and policy coordination; financial incentives; regulation; policy making and implementation.

#### • Policy resources

To choose instruments, the following resources are needed.

- Knowledge based resources (informal experience based knowledge and formal evidence based knowledge)

<sup>&</sup>lt;sup>33</sup> Grinten van der 2005. See appendix § 14.5

<sup>&</sup>lt;sup>34</sup> Mayard, A. Rationing assumptions

<sup>&</sup>lt;sup>35</sup> Nota Volksgezondheidbeleid bij beperkte middelen 1983

- Collective action resources (internal cohesion, coalition capacity and external support)
- Financial resources (ownership or sponsorship)
- Institutional resources (formal political power and formal organizational power).

These resources correspond with instruments. Instruments need to correspond with the right objectives. Objectives need to correspond with the right intrinsic goals of the system. The actors influence the choice and the use of instruments. They are part of the policy process. The explained resources have been called power resources. Actors who own resources have a dominant impact on the decision making process.

One of the main characteristics of a budget is the limitation of the budget. Therefore, prioritisation and rationing takes place. To achieve optimal outcomes, information and insight are indispensable. The process of decision making is embedded by a complicated policy process and political agenda setting. The possibilities for policy also depend on internal and external support for a certain issue. To seize these 'windows of opportunity' is worth a try, but it seems to be rather elusive.

# Part II Results and Synthesis

.....the idea of a sharp distinction between health and disease is a medical artefact for which nature, if consulted, provides no support<sup>36</sup>.

G. Rose 1992

<sup>&</sup>lt;sup>36</sup> An individual is always the same person, regardless from periods when he is called patient, healthy, potential patient, consumer of employee. His body has only one biological history which is affected by every time he is diseased. Both prevention and cure will affect the future of the body of this person. Genetic predisposition, behaviour and environmental factors will decide when he is healthy, diseased or dead. One Daly is not the same as another Daly.

#### 6 Decision making criteria in public health: literature search and interviews

This chapter describes the findings from literature and interviews. The relationship between prevention and cure, the impact of prevention on (public) health, epidemiological transition, prevention and integrated and intersectoral healthcare are described, in order to draw the scenery of all related issues. Main characteristics concerning decision making dilemmas in public health are put forward. A systematic search for decision-making criteria was conducted.

#### 6.1 About public health

In the theoretical framework, prevention and public health policy have been defined. Prevention is a part of public health policy. Health is the main focus of public health, and health promotion, health protection and collective prevention are ways to support this.

The comparison of effects of prevention and cure is nowadays becoming a more important topic in literature. It is done by Mc Keown, some 25 years ago. Mc Keown proved that the contribution of healthcare to the health of people was relatively small. The major improvements of health were attributed to hygienic measures. Environmental conditions of people improved, therefore the incidence of infectious disease dropped.

"In order of importance the major contributions to improvement in health in England and Wales were from limitation of family size (a behavioural change), increase in food supplies and a healthier physical environment (environmental influences) and specific preventive and therapeutic measures"<sup>37</sup>.

Times change, diseases change also. The epidemiological transition was thought to be a unidirectional process, beginning when infectious diseases were predominant, emerging into deficiency diseases and ending when non communicable diseases dominated the causes of death. It is now evident that this transition is more complex and dynamic where health and disease evolve in diverse ways. The effects of welfare, ageing, technological developments in cure and preventive strategies influence incidence and prevalence of disease. It is rather a continuous transformation process with some diseases disappearing and others re-emerging<sup>38</sup>.

Governments are challenged to adjust strategies to epidemiological tendencies. Until today, many dilemmas have to be overcome, to achieve optimal results of public health policy. The English economist Maynard expressed the universal problem of decision making: "There seems to be a consensus that rationing is ubiquitous in all health care systems, yet in no country is there a clear and publicly accepted set of principles that can determine who gets what healthcare and when"39.

Marc Lalonde, Canadian Minister of National Health and Welfare from 1972 until 1976, emphasised the benefit of prevention. He developed a new perspective on the health of Canadians: the Health Field Concept. The four elements; human biology, environment, lifestyle and healthcare organization, were identified through an examination of the causes and underlying factors of sickness and death in Canada, and from an assessment of the parts the elements play in affecting the level of health in Canada<sup>40</sup>.

The Health Field Concept proved to be a foundation of many public health models, including the Conceptual Model of Public Health and the Dutch Chronic Disease Model<sup>41</sup>. The Public Health Status and Forecasts have been calculated and described by means of the Chronic Disease Model. Both

<sup>37</sup> Mc Keown 1976

<sup>&</sup>lt;sup>38</sup> Dror, Preker & Wahdan 2002

<sup>&</sup>lt;sup>39</sup> Maynard 1996: 1499

<sup>&</sup>lt;sup>40</sup> Lalonde 1974 <sup>41</sup> VTV 2006, RIVM

have been developed by the Dutch National Institute for Public Health and the Environment. The Public Health Status and Forecasts (PHSF) is an integrated study of all epidemiological trends and determinants of disease in the Netherlands. In June 2006, the fourth edition was presented.

One of the messages of the PHSF 2002 was that prevention is essential to gain health, rather than by health care. This is because a considerable part of mortality and morbidity is caused by unhealthy behaviour, and prevention is often a cheaper way<sup>42</sup>. The PHSF 2006 repeats this same message. The PHSF may be appreciated as an important document for policy preparation and policy evaluation on all issues related to health and health care organization and prevention policy.

Health promotion has a potentially large influence on burden of chronic disease in 2025. Because of permanent policy focus on health promotion, the incidence and prevalence of diabetes, cardio vascular disease and lung cancer may decrease considerably. The burden of chronic disease because of an ageing society may increase with about 40% or 50% during the coming 20 years. Currently, chronic disease counts for 75% of the total burden of disease in developed countries according the World Bank.

Based on demographic projections, the expenses on health care will rise from 57 Billon euros in 2003 up to 70 Billon in 2025. This is partly because of the growth of the population (5 Billon) and mainly because of changed characteristics like ageing. Within these calculations, rising costs because of medical technological developments and a changing demand for health care were not taken into account<sup>43</sup>. The focus of this thesis is the search for decision making criteria, in order to elucidate the public health debate. In the light of this search, the difference in decision making for cure or prevention has been given attention. The way criteria seem to be used is different when one is weighing prevention or when one is weighing cure. What is the optimal way of spending this health care budget? What is the optimal mixture of prevention, cure and care, in order to reach the highest level of health in a whole population? Economic, moral and political motives are (implicit or explicit) part of the budget debate. Cure is motivated with explicit health gain directly related to treatment, outcomes of randomised controlled trials and information about cost-effectiveness. Prevention seemed to be a part of public health which could be financed with the leftovers of the budget. Why is it difficult to value prevention equal to cure in the decision making process?

There are several reasons which explain the difficulty of decision making for prevention policy compared to cure:

- There is no acute urgency to invest in prevention, when compared to the acute urgency in the situation when somebody is ill or dying. This is a short term perspective.
- Methodological difficulties to proof cost-effectiveness of prevention confine the transparency of the discussion. For instance, a preventive programme needs ten or twenty years before effects become visible. This delay is difficult to convert in cost-effectiveness calculations and it troubles the perspective of prevention policy<sup>44</sup>. The effectiveness and cost-effectiveness of curative interventions is measurable on patient level. For preventive interventions, calculations are based on modeling and future projections on population level.
- Prevention paradox: population effect versus individual effect. There needs to be a distinction between the **epidemiological prevention paradox** and the **policy prevention paradox**. Three examples to explain the epidemiological prevention paradox:
  - Screening has a positive effect on the prevalence of breast cancer. The individual burden of being part of a screening programme is not preferable, if the person has no chance of getting the disease. But we do not know this. Only the probability of getting the disease is known, because of epidemiological figures. Decision makers must bear

<sup>&</sup>lt;sup>42</sup> Wit de, Schuit et al. RIVM 2006. Cost-effectiveness of prevention.

<sup>&</sup>lt;sup>43</sup> Costs of prevention 2003, *Zorgbalans*.

<sup>&</sup>lt;sup>44</sup> A bird in the hand is worth two in the bush. Politicians would probably prefer to observe the consequences of their actions in a short while. It is difficult to show the public what a long term policy is worth.

in mind that there is a continuous tension between the statistical facts on level of the population, and the insecurity on level of the individual. When choosing a certain policy, the consequences on both levels have to be weighed.

- A curative treatment is aimed at a specific person, the costs and effects are related to this specific case<sup>45</sup>. Prevention is policy on population level aimed at reducing incidence and prevalence. To show costs and consequences of prevention is mainly possible in general terms.
- There is a relationship between health, genetic predisposition and risks because of an unhealthy lifestyle. But the direct individual causality is difficult to determine.

Optimal way of spending might imply acceptation that not all victims of loss of health can be avoided. The national budget needs to be spent for optimal health gain for a whole population and for long term effects. Not individual burden of disease is the main focus, but the sum of all individual burden of disease. This is burden of disease on population level. Some comfort for politicians who prefer short term success, might be that Lalonde is probably the most famous Minister of Public Health ever. It might be illustrative to quote Geoffrey Rose here. It is terrible if a traffic accident, involving alcohol, causes death. This pleads for governmental responsibility. "If a small amount of alcohol slightly impairs a driver's judgement, then the large number of drivers who have had one or two drinks would collectively incur a large excess of accidents, even though none of them individually had an obvious problem, but current policy assumes that this is not the case"<sup>46</sup>. The perspective of the individual can be different from the facts on population level. A small amount of alcohol might not be harmful. The population effects might indicate a policy which makes the autonomous need of the individual is subordinate to protection of the collective need. As a result from certain policies, incidence and prevalence will reduce. To whom this has effect and with what savings, cannot be made explicit at forehand. The example and the explanation refer to the policy prevention paradox.

It is said that health care costs will rise in stead of diminish, because of prevention<sup>47</sup>. The costs of health care because of gained healthy years of life after curative treatment have been explained by Brouwer, van Baal and van Exel<sup>48</sup>. The short cut of their article might be that the longer people live, the probability of higher health care costs increases, whether it is due to cure or due to prevention.

As shortly explained in the introduction, efficiency is a major issue in public health policy making, due to cost constraints and rising costs.

The Dutch Council for Public Health and Healthcare (RVZ)<sup>49</sup> is the independent body which advises the government on public health and care. In the recommendation report 'Sensible and sustainable care' the RVZ advices that the process of decision making should include a quantitative and qualitative assessment phase and a appraisal phase, in order to obtain the necessary panoramic view for optimal decision making. The RVZ identifies the important decision making criteria and their operationalisation.

An optional instrument on which choices can be based is cost utility analysis. The cost-utility ratio based on this analysis can become a leading principle for decision making for the basic benefit package. A cost-effectiveness threshold may be introduced to value health care benefits. The RVZ recommends a cost-effectiveness threshold of  $\in$  80000 for an additional quality-adjusted life year for cure. In the report considerations are taken along with respect to both the cure, care and the prevention sector. The implications of the use of the cost effectiveness ratio are illuminated in the

<sup>&</sup>lt;sup>45</sup> Note that effectiveness of cure is difficult to measure also. A cure can help on short term and might have many indirect health complications on longer term. Sometimes the effects of a treatment are not even sure. The causality of treatment and health is not always self evident.

<sup>46</sup> Rose G. 1992: 86

<sup>&</sup>lt;sup>47</sup> RIVM 2005 Feenstra TL, PHM van Baal et al

<sup>&</sup>lt;sup>48</sup> WBF Brouwer, P van Baal, J van Exel. 2006: 7 – 10

<sup>&</sup>lt;sup>49</sup> RVZ: Raad voor de Volksgezondheid en Zorg

recommendation of the RVZ. Outcomes of economic evaluation and the operationalisation of a threshold are considered of large value in the debate concerning decision-making.

There was a tendency until 2007 to find cure more important than prevention. This is confirmed by the expenditures on both prevention and cure. Concerning prevention, there are preventive programmes which are not cost-effective but have been implemented. Other preventive programmes are costeffective but these were not implemented<sup>50</sup>. This is illustrated with the table 'Prevention often more cost-effective'.

cost-saving	Vaccination several diseases (measles, polio, influenza), stop-smoking-program
0 -1000 euro	Safety belt, screening Chlamydia
1000 -10.000 euro	Chlorination potable water, pacemaker, Screening breast cancer, vaccinations Meningo Coccus C
10.000 -100.000 euro	Screening cervical cancer, trauma helicopter, heart transplantation, lung transplantation,
100.000 -1.000.000 euro	Neurosurgery brain tumour, Measures for controlling Legionella pneumophila in water distribution

Prevention often more cost-effective<sup>51</sup> (in euros per added Quality-Adjusted Life Year)

#### 6.1.1 Identified criteria

Many criteria for decision making in public health (prevention and cure) have been collected. The following list of criteria evolved, based on literature search and interviews:

- 1) Quality of Life, Health Gain, Quality Adjusted life years (QALY)
- 2) Burden of Disease, Disability adjusted life years (DALY)
- 3) Maximize population health
- 4) Target group policy
- 5) Prevention paradox: population effects versus individual effects, epidemiological and demographic transition
- 6) Medical effectiveness
- 7) Harm principle, external effects of disease
- 8) Necessity
- 9) Equity & fairness
- 10) Solidarity
- 11) Poverty reduction (social economic status, social economic differences)
- 12) Justice
- 13) Societal support
- 14) Political agenda, political reality
- 15) Individual responsibility
- 16) Governmental responsibility
- 17) International standard, regulation, decisions
- 18) Regulation: legal institutions, laws, rules, professional standards, guidelines, protocols
- 19) Efficiency

 <sup>&</sup>lt;sup>50</sup> Dirkmaat ao 2003, Wit de et al 2005
 <sup>51</sup> Oers v H, Costs of Illness 2003, PHSF

- 20) Cost-effectiveness (cost-effectiveness threshold)
- 21) Budget impact
- 22) Societal costs, productivity losses
- 23) Willingness to pay and ability to pay, individual account, out of pocket (individual responsibility)

After creating this list it is tried to look after logic and order. This way missing criteria or overlap could be avoided. A certain classification of decision making criteria is developed. To make clear the meaning of the criteria properly, each criterion is classified according to the related research area. Criteria can also be described from different points of view; the description might also be multidisciplinary. For instance 'target group policies' can be defined by social-economic characteristics, epidemiological characteristics and demographic characteristics. The question is whether it is a criterion or not. This is depending on the possibility of operationalisation. Because necessity is difficult to operationalize, it is left out. The definition and operationalisation of each criterion can be found in the appendix.

Epidemiological and demographic decision making criteria							
Burden of disease and quality of life, respectively Daly and Qaly							
Medical effectiveness of instruments							
Harm principle, external effects of disease							
Maximize population health,							
Prevention paradox: population effects versus individual effects							
Economic decision making criteria							
Efficiency, cost-effectiveness, budget impact							
Societal costs, productivity losses, social economic status,							
Poverty reduction, social economic status/ social economic differences							
Individual responsibility, ability and willingness to pay							
Policy decision making criteria							
Institutional configurations, national and international regulation (law and system)							
political reality, Individual responsibility and governmental responsibility							
societal support, target group policies							
principles like equity, fairness, justice and solidarity							
Table: Classification of desision making factors							

Table: Classification of decision making factors

#### 6.1.2 Results of literature search

In the following table, the information extracted from literature is ordered in a comprehensive way. If a criterion is described, the sign O shows this. If the quantification of a criterion is explained, the sign  $\Delta$  shows this. If an author did both, the little man  $\Upsilon$  shows it. If the relationship between criteria is explained, the spider web shows that there is this interrelatedness.

Each row contains the results of an individual study or publication. Each column contains the results for one criterion. These criteria are grouped into three categories. The pink columns represent the epidemiological and demographic criteria. The blue columns show the different policy criteria. The green part represents the economic criteria. Cost-effectiveness is on top of the list with the most references. International standard as a decision making criteria in literature is the bottom line. The shared second bottom positions are political agenda and poverty reduction. Lot of literature is available about poverty reduction<sup>52</sup>, but apparently not in this literature search. Maybe sources are

<sup>&</sup>lt;sup>52</sup> See for instance the World Bank (one of the Millennium Development Goals)

missing. Maybe it is not a common criterion in health care. Maybe it is not an important criterion in the Netherlands. These are only hypotheses, more literature and an evaluation of decision making needs to be done to draw any conclusions concerning this. Political reality might have a huge impact on decision making. But based on this literature search, the amount of studies which refer to political reality and political agenda's as a decision making criterion is small. The idea of the black box might come up as a possible explanation: it is difficult to identify the exact criterion on which a final decision for a certain public health policy (or intervention) was based. The policy process is referred to as black box, as described earlier. As can be seen lots of handbooks have a little man, criteria have been defined and operationalised. Typically, not many criteria and the relationships between criteria have been quantified (triangle).

The symbols express the way the authors studied the criterion:

Qualitative (descriptive)

Quantitative (statistical) Operationalisation & definition of criteria (measurement and definition) Relationship between several criteria and principles

0								
$\Delta$								
<del>۲</del>								
<b>\$</b>								

(\* Cost effectiveness is including cost-effectiveness threshold)

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#### 6.2 Interviews with policymakers and researchers

Policy makers and researchers have expressed their ideas about a cost-effectiveness threshold and alternative criteria, the comparison of prevention and cure, a more integrated healthcare and intersectoral public health policy. The statements are translated in English and schemes have been designed to compare the answers and to extract information from these statements. Some quotes have interesting implications and will therefore be put forward. The interviews took at least half an hour, most of the interviews took one to four hours. Especially the in-depth interviews started with the defined questions and then developed into a dialogue to discuss the related topics to the questions. The information is written down while talking and was analysed later on.

A major topic while discussing with policy makers en researchers was what decision making criterion should be leading. The expressed opinions and ideas sometimes reflect political and ethical preferences.

Some people reject the 'number' (the cost-effectiveness ratio). Others see it as the only way out of decision making dilemmas. A cost effectiveness threshold concerning prevention or public health will be difficult to maintain, because of the absence of underpinning of criteria. Therefore it is difficult to reach agreement and to make decisions. Others referred to the steering principle of the system. 'It is the question which incentive you want to use, in order to get the wanted results: steering with financial incentives evokes certain responses'. There is a tendency that a criterion should be leading and other need to be weighed in addition.

Individual responsibility needs to be emphasized in order to achieve responsible behaviour, said someone of the Ministry. By means of premium differentiation people are forced to take responsibility, but this has several positive and negative consequences. It is important to find the right combination of incentives in order to promote healthy life, which eventually may lead to a more efficient demand for cure. Another policy maker said: if a cost-effectiveness threshold will lead to efficient demand for cure, sustainability of the system and support for solidarity is promoted.

Another statement was, that it is not right if the position of the weak is the leading principle in decision making on macro level. This might lead to a weaker society in economic terms. The leading principle should emphasize the stronger aspects, in order to achieve a strong and stable system. Only in such a system, the weak can be helped. Added to this statement might be the problem of solidarity: in order to maintain the level of solidarity, there must be enough shoulders to carry the burden.

Cost-effectiveness of prevention seems to be unattractive according a study of the RIVM, because of deferring health care costs to a later stage of life. To prevent sickness may cause more costs. The same can be said about cure: curation of a disease may cause a longer life and therefore more demand for cure and care. This remark emphasizes the fact that comparison between prevention and cure might shed interesting light on decision making.

Intersectoral public health policy is defined in the theoretical frame. In practice, this quote shows how it is experienced by policy makers: "intersectoral public health policy is like a car with eight wheels pointing in a different direction". This refers to the enormous efforts which have to be made to cooperate with other parties in the field: one budget, many objectives, goals, preferences and interpretations.

If the government would like to have support for its decisions, policies should be motivated. The decision making criteria and motives should be made explicit. Policy making will always be a black box, whether this is on purpose or not. Decision making and policy are complex and dynamic. It is even more important to substantiate decisions as far as possible.

Government must foresee in the right incentives for prevention in relation to health insurance, healthcare workers and healthy behaviour. An example of a financial incentive for health care insurance would be a differentiated premium.

Some policymakers emphasize that there is too much difference in the way cure and prevention are structured in the health care system. In the Dutch system of regulated competition, prevention is not systematically embedded.

The implementation of preventive strategies is not performed according cost-effectiveness outcomes. There is no agreement about the financial responsibilities of prevention. It is argued that prevention programmes aimed at chronic patients cause gain of Qaly's. This is prevention related to cure and care. Therefore, it was said, it should be covered by health insurance. On the other hand, Minister Hoogervorst<sup>53</sup> expressed the idea that only primary prevention is the responsibility of the government, further preventive actions belong to supplementary health insurance and individual responsibilities.

<sup>&</sup>lt;sup>53</sup> Dutch Minister of Health, Welfare and Sports from 2002 until 2007.

# 7 Discussion

The way a criterion is operationalised and interpreted while considering and weighing solutions is crucial for the successful implications of a decision. Operationalisation of criteria seems to depend on perspectives on decision making and the related criteria. The interrelatedness of some criteria is explained in this chapter.

#### 7.1 Various possible perspectives on decision making

Decision making can be approached from different perspectives. The perspectives may be used to weigh decision making factors. The chosen perspective depends on the general goals of the healthcare system and the way the policy goals are formulated in the current political debate. The policy problem also influences the perspective. The decision may concern a complicated problem or a paradigm or impasse. The same decision making criterion can be approached:

- from the perspective of cure or the perspective of prevention (or a combination of these);
- prevention arrangements from different perspectives, like collective perspective or individual perspective (prevention paradox);
- as a cause or as a consequence;
- as something which serves the policy goal or does harm to the policy goal;
- as something which serves one policy goal but does harm to another;
- as an objective or as a means (league table);
- from the perspective of primary prevention or secondary prevention;
- based on different underlying rationing principles;
- from different methodological perspectives and therefore different operationalisation.

This variety of perspectives on the criteria and therefore on decision making, makes decision making even more complex. To reduce something which is multidimensional to something linear could raise more problems than solutions.

Although there are different perspectives, the list of possible involved criteria will stay the same. Operationalisation of the criteria can depend on the chosen perspectives. In daily reality, the perspective will not always be chosen conscious or explicitly. It might be helpful in the decision making process to all involved actors and stakeholders to make the perspective and the criteria explicit. The abstract policy goals of the government agreement and the national budget will be operationalised top down. The importance of each criterion depends on the choices which are made; an analysis of the choice clarifies the perspective and the criteria. This process might also help to evaluate the decision and the policy.

Prevention can be arranged in primary, secondary and tertiary prevention, other arrangements are also possible:

- I Prevention in cure and care (integrated prevention policy); this is arranged in the Health Insurance Act. It concerns secondary and tertiary prevention
- II Collective prevention; this is arranged in the Collective prevention law. It concerns primary and secondary prevention.
- III Intersectoral prevention<sup>54</sup> and integrated prevention policy (care/ cure and prevention)
- IV Prevention paid collectively and prevention paid individual (for example vaccines)
- V Prevention related to institutes and organisations: prevention divided in societal organisations which elaborate the different prevention acts.

<sup>&</sup>lt;sup>54</sup> Different ministries: SZW, LNV, V&W, VROM, OCW, BZK-VNG

#### 7.2 Necessity, burden of disease and quality of life

For many reasons, decision making based on necessity, burden of disease and quality of life is difficult. Burden of disease may be seen as the need for treatment and prevention within a population. But need is not necessarily a demand. There is not a cure for all disease. The effectiveness of preventive measures may be diffuse.

Need is defined as the expenditure required to effect the maximum possible health improvement or, equivalently, the expenditure required to reduce the individual's capacity to benefit (from medical service) to zero<sup>55</sup>. Medical need is the need of a patient for medical service, judged by 'neutral experts'; doctors. Utility represents satisfaction or the level of welfare of an individual, measured in cardinal or ordinal utility terms. The utility function expresses the person's utility as a function of all possible combination of goods and services<sup>56</sup>. The awkwardly aspect is expressed by Maynard; "Need is not necessarily expressed as a demand, and demand is not necessarily followed by utilisation, while, on the other hand, there can be a demand and utilisation without a real underlying need for the particular services used"<sup>57</sup>.

In a normal market, demand and supply may be adequately balanced because of the price mechanism. In health care, the patient's demand should be equal to medical need for services, in order to achieve optimal use of scarce resources. All people need health care, demand is infinite. The judgement of the amount and the kind of health care which is needed is subject to medical opinions. The decision about who is going to pay for health care is up to policy makers.

Another way to approach need is to say that there is no need if there is not a (CE) treatment. The ability to purchase the treatment is a condition to respond to need; otherwise there is no 'effective demand'. The first sieve of the Funnel of Dunning is the necessity criterion. In fact, it is a question whether this is a criterion or not. Quantification of the criterion is difficult. In the observational scheme necessity was left out, and replaced with less implicit criteria like burden of disease. The governmental responsibility concerning the harm principle may be expressed as a 'necessity'.

Policy makers have to decide about the combination of strategies to obtain optimal health for the population as a whole. Amongst these strategies are the basic benefit package, preventive measures and a combination between these. Necessity as a criterion should guide this decision. Because of the subjectivity of the criterion itself and the complexity of aspects implied, the necessity criterion doesn't seem to lead to a bright and transparent motivation of a decision. In fact, it is a question whether this is a criterion or not. The Dutch Council for Health (GR) has expressed preferences to replace 'necessity' by 'burden of disease'. Burden of disease is defined as average, individual diagnosis-related burden of disease. Burden of disease can be used for curative and preventive programmes. In case of prevention, this is expressed as the expected burden of disease as a consequence of not having conducted the preventive programme<sup>58</sup>.

Qaly's are of equal value, no matter who gains them or when they occur during lifespan. People value different periods in life in a different way. Qaly's are based on subjective preferences. This value based method is not entirely representative for realistic values of preferences<sup>59</sup>. Many people may have a burden of disease which is not very severe. Few people may have a burden of disease which is very severe. Societal values are not equal for all health gains. This example shows a problem of equity or distributive justice. The distributive effect of the Qaly's may not be the targeted effect in this case.

<sup>&</sup>lt;sup>55</sup> Folland Goodman and Stano 2004

<sup>&</sup>lt;sup>56</sup> Cuyler and Wagstaff 1993

<sup>&</sup>lt;sup>57</sup> Maynard 1999: 7

<sup>&</sup>lt;sup>58</sup> GR 2003 Contouren van het basispakket.

<sup>&</sup>lt;sup>59</sup> Gold 1996

#### 7.3 Equity, efficiency, solidarity & responsibility

The interrelatedness of the four themes equity, efficiency, solidarity and responsibility in relation to prevention and cure will be explained here. More prevention may lead to an efficient demand for cure. Because of effective prevention, the demand for cure may change. Demand for cure may be more effective, because avoidable health damage was prevented. Healthy behavior may result in better support for solidarity. If people know that other people take responsibility for their own health, they probably feel more comfortable with paying tax for a premium related health care system.

When starting to reason out horizontal equity (equal health care for equal need), one could argue that collective prevention is a way of equitable allocation of health gain to all people. Everybody has an equal chance to gain health.

Al et al<sup>60</sup> studied the relationship between equity and efficiency. A comparison was made between priority setting based on efficiency aspects and efficiency combined with equity. Then the impact of equity in decision making was weighed. Finally the equity weights in decision making were projected into seven selected interventions. The equity adjustment procedure resulted in a lower amount (CUratio<sup>61</sup>) per Qaly gained. It seems to be an advantage to take equity into account: the costs per Qaly are lower. Because of societal benefit of the purpose of equity it can be called an advantage. The purpose of healthcare is to improve health and to reduce health inequality. The pursuit of equity involves the reduction in health inequalities over the life cycle.

Adverse selection may threaten good quality care for the chronically ill. Insurers aim at healthy patients, they are focused to avoid arrangements for chronically ill patients. This can ruin efforts to achieve equity, solidarity and efficiency.

WTP depends on perceived individual responsibility, institutional configurations, solidarity, political perspectives and the kind of goods. Rose expressed the tension between solidarity and individual responsibility: 'Much can be done by individuals themselves to improve their own health prospects, but whether or not they will actually take such action depends substantially on economic and social structures for which governments are responsible'.

Preventive strategies follow age. The lifecycle compromises certain health risks at certain ages and more and less financial possibilities. The vaccine and screening programmes are programmed based on this kind of epidemiological information. A combination of preventive strategies, the definition of the basic benefit package and the level of premiums may be adjusted to age. The health risks and financial possibilities may be combined to transfer from age group to age group in order to maintain an integrated system based on solidarity. Willingness to pay, ability to pay, solidarity, equity and efficiency need to be combined in order to have a feasible system.

#### 7.4 Cost-effectiveness threshold, equity and solidarity

The English NICE argues that prioritisation based on cost effective cure is the most honest way<sup>62</sup>. NICE has not decided on a specific level of a cost effectiveness threshold<sup>63</sup>, although they maintain a threshold of  $\pounds$  42.000,-. According NICE:

"The existence of factors other than cost-effectiveness may mean that there is in practise no threshold at all; any new technology has a finite probability of being accepted or rejected, whatever its CQG (threshold Cost per Quality adjusted life year Gained), if other factors are important enough to outweigh its cost-effectiveness. Alternatively, there may be no single threshold but a lower and an upper threshold. Below the lower threshold, low CQG technologies are certain to be accepted; above the upper threshold, high CQG technologies are certain to be rejected. Within the range between the

<sup>60</sup> Al, Stolk 2003

<sup>&</sup>lt;sup>61</sup> Cost-Utility Ratio: is a ratio expressed in costs per Qaly

 <sup>&</sup>lt;sup>62</sup> Oortwijn, RVZ 2006: 7
 <sup>63</sup> Oortwijn, RVZ 2006: 7; Devlin and Parkin 2001

two, cost-effectiveness may be traded off against other objectives that are seen as relevant to decision making<sup>64</sup>. The Dutch RVZ also considers that a cost-utility analysis<sup>65</sup> results in the best quantified criteria to weigh equity and efficiency. Here it is argued that the outcomes of economic evaluation need to be weighed next to other criteria and depends on the chosen perspective. A lower and upper threshold might help the decision making process.

#### 7.5 Cost-effectiveness and budget impact

Additive to information about the cost-effectiveness of a programme, the total impact of that programme on the budget needs to be considered. A cost-effectiveness threshold controls the budget impact. According the strict interpretation of a cost-effectiveness threshold, every programme which costs more then the agreed amount per Qaly will not be implemented (for instance for prevention: € 20.000,- and for cure € 80.000,-). A cost-effective programme which cures a disease with a high burden (lots of Daly's), might shrink the budget that much that it is not fair to other patients. One can compare cure and prevention, two curative programmes or two preventive programmes. If a disease is easy to prevent and expensive to cure, it would be a societal loss not to choose for the preventive programme. If prevention is not effective or expensive, options for curation need to be preferred.

Not every Qaly is the same. Qaly's are criticized for discriminating against elderly people and those with disabilities. Qaly's are calculated with burden of disease. Burden of disease is based on preferences of people themselves. Different groups of people might experience a disease more or less serious. Studies show that people with different age or health situation can value Qaly's differently. One could argue that there is no solidarity from one healthy people to unhealthy people, if all groups are weighed the same. In practice, some groups will need more health care then others. People never know for sure when they will be part of a patient group. One could say that preventive strategies are inherently attached to age or to a certain target group. Every target group has its own characteristics and costs. If there is diversity between Qaly's, maybe it will be easier to implement the right strategies to influence the determinants in the right way. On the other hand, everybody has the same chance to become part of a certain group. If all Qaly's are weighed the same, maybe at the end there is still enough solidarity to maintain the system. It is a question of the way of rationing and the way of distribution of health between all people.

#### 7.6 Weighing cure and prevention

The conclusion of Brouwer, van Baal and van Exel<sup>66</sup> is that the probability of higher health care costs increases as people grow older. However, it would not be correct to connect this observation to prevention as a cause for increasing costs. All efforts which increase life expectancy, will increase the probability for a higher demand for health care. Increasing costs are a consequence of more people who live longer. The fact that people live longer is because of hygienic measures, preventive strategies, access to healthcare, universal coverage, technological improvements of curative interventions, etc. Apart from these issues, the societal perspective needs to be taken into account. When performing economic evaluation from a societal perspective, productivity gains because of preventive measures need to be taken in to account. The golden cost-effectiveness ratios might show another picture. A lot of cure is needed at a higher age, when societal gains in terms of productivity are much lower. Is the preference of the dominant cure sector at cost of prevention the optimal solution for rationing scarce resources? Again, the acute character of patients in cure will always ask for attention. An integrative and sophisticated way of weighing the optimal outcomes for a healthy population with a limited budget needs to be the leading issue. Not the short term focus of identifiable patients.

<sup>&</sup>lt;sup>64</sup> Devlin and Parkin 2001

<sup>&</sup>lt;sup>65</sup> Policy makers always seem to talk about cost-effectiveness ratio's, most of the time it is methodologically right to talk about cost-utility ratio's

Brouwer, Baal v, Exel v. 2006: 7-10

#### 7.7 Perceptions and bounded rationality

The essence of bounded rationality is that although there is an information surplus, actors still have their own limitations and information gaps. People have conscious ideas and preferences and people have unconscious ideas and preferences. The frontier between these conscious and unconscious perceptions is not rational. Bounded rationality is inherent to human perceptions.

Knowledge is important to improve decision making. The information gaps and the lack of transparency concerning complex policy issues might be an advantage to those who prefer to make implicit choices. This can be called implicit rationing. The challenge is like a game: who can play the game better, who is able to convert knowledge, conscious preferences and ideas into policies? Carr-Hill has noted the following about a cost-effectiveness threshold: "The introduction of a half understood technical device (i.e. cost-effectiveness threshold) will only serve to mystify and obfuscate these discussions and remove them further from democratic control"<sup>67</sup>.

Furthermore, a complicating factor is that the decision maker's response to uncertainty regarding CQG evidence (threshold cost per quality adjusted life year gained) arising, for example from sensitivity analysis, may alter the threshold. If for instance NICE is risk-averse, the probability of rejection will be higher for any given base-case CQG for options associated with the possibility of a high CQG under alternative sets of assumptions, compared to options where the base case CQG is relatively robust to changes in assumptions. If NICE is a risk-lover, it will be prepared to give the benefit of the doubt and the opposite will apply<sup>68.</sup> Rational decision making might be connected to the use of quantified criteria, but because of the limited possibilities to quantify the explained criteria, 'rational' needs to be related to bounded rationality. Cost-effectiveness implies many assumptions in itself. Necessity is expressed as need or as Qaly's. All criteria in phase III of the decision making scheme (next chapter) are difficult to quantify. These thoughts refer also to the social constructivism as theoretical concept in order to explain the problems of decision making.

<sup>&</sup>lt;sup>67</sup> Carr-Hill 1991 in Hunter 1997

<sup>&</sup>lt;sup>68</sup> Devlin and Parkin 2001

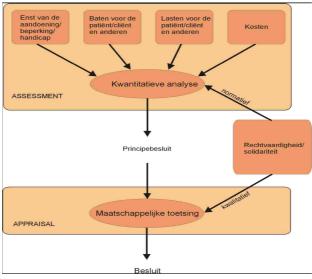
# 8 A structure of decision making in public health policy

In order to find out whether the found list of criteria is covering the options, the criteria can be ordered based on their logic interrelatedness. Missing links or a surplus of criteria might come up. As a result, a structure is produced. The list of 23 is diminished into 10 main criteria. An assumption is that these criteria cover all criteria.

#### 8.1 Assessment and Appraisal I, II & III

The Council for Public Health and Health Care (RVZ) made recommendations about the order of the decision making process<sup>69</sup>. Originally, NICE distinguishes health technology assessment (HTA) and health technology appraisal. Health technology assessment is research aimed at calculations of clinical effectiveness and cost utility or cost effectiveness. Health technology appraisal is referring to the process of decision making about the actual issue based on cost effectiveness, clinical effectiveness and preferences and support of policy actors.<sup>70</sup> The criticism on this system is threefold. There is still too much focus on cost-effectiveness, mainly expensive cure treatments have been evaluated, and finally the ethical aspects of individual patients don't get the attention which it deserves<sup>71</sup>.

The assessment phase covers research and advice. The appraisal phase is to figure out and balance the societal support<sup>72</sup>. This is explained in the following scheme:



The relation between criteria depicted in a process, RVZ 2006

The scheme is, like the Funnel of Dunning, synoptic and abstract. As explained in chapter 8, there are many more criteria and these criteria have underlying principles. A decision which is guided by a certain criterion has specific logic implications according these underlying principles. These principles will influence the outcomes of decision making according the logic implications of these rationing principles. Therefore, policymakers should be able to observe the interrelatedness of decision making factors and to understand consequences of these principles and criteria during the decision making process.

<sup>&</sup>lt;sup>69</sup> RVZ 2006 Sensible and sustainable care (Zinnige en Duurzame zorg).

<sup>&</sup>lt;sup>70</sup> Oortwijn 2006: 7 Background Study Sensible and sustainable care.

<sup>&</sup>lt;sup>71</sup> Maynard, Bloor and Freemantle in Oortwijn 2006.

<sup>&</sup>lt;sup>72</sup> RVZ 2006: 42.

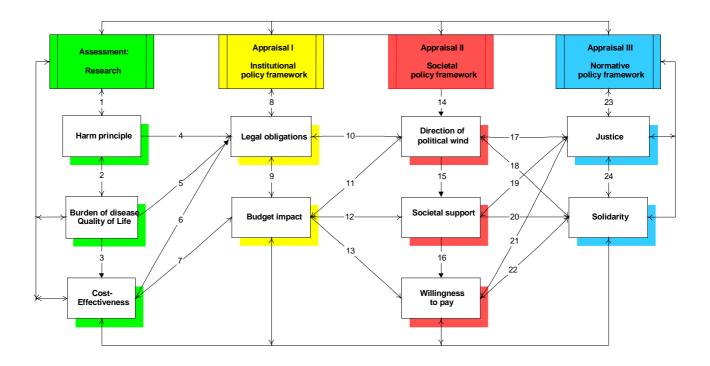
#### 8.2 A structure of decision making factors

To observe the interrelatedness of decision making criteria, a scheme is developed. This scheme was based on the same the stages of decision making of the RVZ, the assessment phase and the appraisal phase, but it is expanded. The criteria which are identified have been arranged according their connection with the policy process. Epidemiological criteria will be put forward by researchers in the assessment phase. Decisions based on solidarity or equity have to do with normative discussions in politics. The following stages of the decision making scheme have been distinguished here:

Assessment:	Research by relevant disciplines
Appraisal I:	Institutional policy framework
Appraisal II:	Societal policy framework
Appraisal III:	Normative framework

The stages are arranged in logic order, but these stages do not imply any prescriptive use of the scheme. In reality, decision makers are guided by their own beliefs and intuitions concerning solutions to problems. Any of the decision making factors of this scheme is a possible decisive criterion. While making a decision, there is one decisive criterion. Multi criteria priority-setting is a way to identify a programme depending on several important criteria.

The scheme is iterative; this implies the absence of a prescriptive order. It emphasises the fact that a logic way of reasoning decides any order of steps through the scheme, depending of the starting point. The starting point is the decisive criterion. The decisive criterion is decided upon by policy makers. The numbers within the observational scheme refer to the interrelatedness of all factors. Again, it is important to know that all factors are interrelated and that the most important factors are the decision making criteria. The numbers are explained below.



#### A Descriptive Scheme of Decision Making Factors for Public Health Policy

Assessment phase:

**Research by disciplines** 

Assessment is research. Different disciplines produce important information to inform doctors, policymakers and stakeholders. As explained earlier, the criteria are mono- and multidisciplinary. A difficulty in daily practise might be the necessary thorough understanding of all criteria for people with different disciplines and backgrounds, in order to use the wanted univocal vocabulary. This is a continuous learning process. In the assessment phase, the following criteria are relevant:

- Harm principle;
- Burden of disease;
- Medical effectiveness;
- Cost-effectiveness.
- The <u>harm principle:</u> is the issue under focus a communicable disease or not? Is there a danger for contagiousness or harm to other people? The harm principle, Daly's and Qaly's are measures which can indicate how to maximise population health.
- <u>Burden of disease (Daly) and Quality of Life (Qaly)</u> (see appendix) (populations effects versus individual effects)
- <u>Cost-effectiveness</u> refers to two questions: Is it an effective instrument and is this instrument cost-effective?

Relationships between criteria

- 1. Different disciplines perform research.
- 2. The fact that a disease is very contagious implies that the potential burden of disease might be high. A high burden of disease might reflect a causal relationship between the disease and the harmfulness. The distinction between population level of individual level needs to be taken into account here.
- 3. If there is a high burden of disease, related information about effectiveness and costeffectiveness concerning treatment or prevention is important in order to respond to the demand for health of people. If there is an effective treatment or preventive strategy, it is important to know how to weigh these interventions compared to other interventions or strategies. Maybe there are lots of Qaly's to gain or Daly's to avoid, with an effective programme. When there is a lot health gain for the whole population, this might counter balance an unattractive cost-effective ratio. All factors need to be weighed together.
- 4. Based on the WCPV and the white paper 'Choosing a healthy life'<sup>73</sup>, there is an obligation to protect citizens against harmful diseases.
- 5. Based on the WCPV and the white paper 'Choosing a healthy life', there is a legal responsibility to prevent high burden of disease and to improve quality of life.
- 6. The probability of loss of health might cause high expenses in healthcare. More people will be diseased; therefore they will demand more health care.
- 7. This relationship might reflect a legal cost-effectiveness threshold. If there is an effective treatment, and it is cost-effective (depending on the decided threshold) and there is a high burden of disease, there is a strong indication or obligation for policy (see also multi- criteria decision making). A programme might be cost-effective, but the total impact on the budget needs to be weighed also. A cost-effective programme for an enormous burden of disease, might shrink the budget that much that it is not fair to other patients. If a disease is easy to prevent and expensive to cure, it would be a societal loss not to decide for the preventive programme. If prevention is difficult or expensive, what are options for curation? There are many options to compare and to weigh.

## Appraisal I: Institutional policy framework

In phase Appraisal I, the following criteria are relevant:

 $<sup>^{73}</sup>$  White paper 'Opting for a healthy life' 2006

- legal obligations, international standard, professional standard
- budget impact, financial agreements

The institutional policy framework refers to regulation. An example of an institute is a law. The criteria in appraisal I are the <u>legal obligations</u>: issues which are agreed upon in laws and other official documents which refer to any obligations of the government to other parties or organisations.

#### Relationships between criteria

- 8. The obligation refers also to legal and financial agreements or budget decisions.
- 9. <u>Budget impact</u> is the second criterion. The question related to budget impact is about the impact of a specific disease on the budget of hospitals, health care insurance or public health budget. In other words: what are the financial consequences of a disease? Both criteria are expressed as transparent agreements, but these agreements might be changed within new policies. Law can have financial consequences. If there is an obligation for certain policies, it has direct budget impact. Governmental responsibilities can be derived from the WCPV.
- 10. Legal obligations might influence political agenda's. Direction of political wind can have impact on regulation: altering regulation, making specific considerations, etc.
- 11. The direction of political wind can change budget agreements and budget is also influencing political agenda's.
- 12. Budget impact influences societal support. Money confronts people with (public) responsibilities. The more complicated the issue, the more stakeholders which are involved, the more opinions and preferences concerning budget will be expressed. Everybody wants to have a part of the pie.
- 13. If there is a big budget impact, there will be bigger interests at stake. This might imply that a consensus is more difficult to achieve.

#### Appraisal II: Societal policy framework

In phase Appraisal II, the following criteria are relevant:

- Direction of political wind
- Societal support: informal and formal power resources, stakeholders in social context
- Willingness to pay, willingness to accept

Relationships between criteria

14. First there is the <u>direction of political wind</u> or madness of the day, always difficult to predict. What the decision of a Minister might be and based on what grounds is often difficult to know at forehand and sometimes it is even difficult to analyse afterwards. The political process is referred to as a big black box by many people.

Second, there is the <u>societal support</u> like support of stakeholders: insurance companies, patient organisations, professional organisations and other actors.

Related to societal support is the <u>willingness to pay</u>: people have different preferences about what they are willing to pay for something. This is depending on ability to pay, but also on political preferences.

- 15. Societal stakeholders will influence the direction of political wind, by means of lobbyists, pressure groups, manipulation, negotiation and influencing public opinion. Vice versa has a political personality the power to influence the public opinion and the stakeholders.
- 16. Societal support depends on willingness to pay. Willingness to pay depends on the ability to pay. Ability to pay depends on income. Progressive financing is based on ability to pay, like progressive income tax rates. The objective of financial equity is usually concerned with establishing a payment system based on ability to pay. Because ill-health can be unpredictable and uncertain, the impact of healthcare costs can be adverse, especially for

poorer members of society. Cost-effectiveness threshold shows the political and societal willingness to pay.

- 17. The direction of political wind is influenced by perceptions about justice and fairness. The outcome might be a consensus between several political parties or a state within the system. It is not easy to realise an ideal situation of perfect justice. Sometimes there is a consensus between the current system, the financial and social conditions and perceptions of decision makers. Different perceptions exist about the definition and interpretation of justice.
- 18. Perception and operationalisation of solidarity is decided within politics. Solidarity is a primary principle of the health care system (of all public money flows). The decision about who needs to pay how much to whom and when is a measure for solidarity<sup>74</sup>.
- 19. Assumptions about justice are controversial. To make decisions about justice, societal support and mutual understanding about definition and operationalisation is needed.
- 20. The same is true for solidarity $^{75}$ .
- 21. Perceptions about what is fair and what is not fair, will influence the willingness to pay. If it is believed to be fair that the healthy pay for the sick, then this is an assumption about justice and a measure for solidarity.
- 22. If people agree that solidarity is the right way to make sure that they themselves and other people will have access to health care if it is needed, then they are willing to pay insurance premium, even though they are not unhealthy and they don't expect to become diseased in the near future. If a very small basic benefit package with only a bold basic minimum is preferred, then people are not willing to pay for a system in which everybody can get all cure and care.

#### Appraisal III: Normative framework

In phase Appraisal III, the following criteria are relevant:

- justice: equity and fairness
- solidarity: individual responsibility, poverty reduction, social economic status
- 23. The concepts of justice and solidarity are generally interpretated in many different ways. Each country has different laws and agreements which reflect the dominant ideas about justice and solidarity. It shows the outcomes of political debate. It is reflected in laws. Norms might be decisive criteria for laws. It is very difficult to rationalise these factors within the normative framework. It reflects a state of consensus of different actors.
- 24. Perceptions about what is fair and just will influence decisions about solidarity.

Furthermore, solidarity might be influenced by the harm principle. Societal support is influenced by burden of disease and the harm principle. Cost-effectiveness has implications for fairness and solidarity.

<sup>&</sup>lt;sup>74</sup> See Esping Andersen 2003.

<sup>&</sup>lt;sup>75</sup> Currently there is a public debate in the Dutch media about responsibility and the measure of solidarity in health care insurance.

Part III Public Health Policy

Much can be done by individuals themselves to improve their own health prospects, but whether or not they will actually take such action depends substantially on economic and social structures for which governments are responsible.

G. Rose 1992

## 9 The policy process: a case description

In this chapter the defined stages of decision making have been integrated in the policy cycle. This way, the different criteria can be observed in the policy making process. Finally, a case will show the possible operationalisation and the application of criteria in the decision making process.

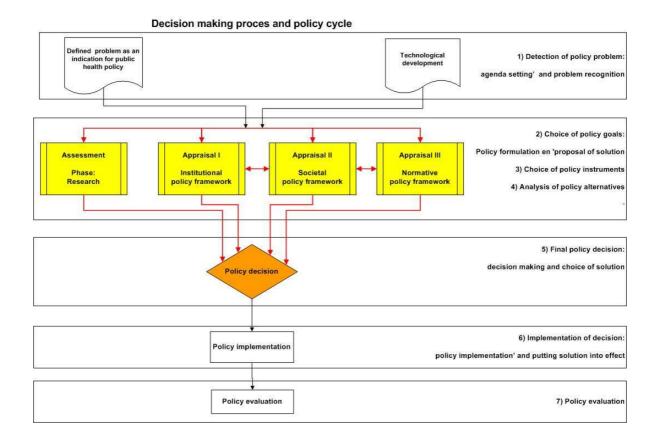
#### 9.1 The decision making process and the policy cycle

Instrumental policy research is aimed at the delivery of information which provides insight in policy problems and solutions. Conceptual policy research is aimed at the enlightenment of policy problems, policy conditions, policy processes and policy effects. The study of decision making criteria concerning prevention is in fact a combination of instrumental and conceptual policy research. It is tried here to provide in overview and insight in decision making criteria and this information is applied in the policy process. To understand the decision making criteria, the interrelatedness and possible consequences of decision making, integration of the attained information into the policy process is helpful.

The policy problem is related to the problematic triad efficiency, equity and quality. The general goal of public health policy is the improvement of health and the reducement of health inequalities. The policy conditions are complicated because of the ethical aspects and the complexity of the policy problem and the variety of actors and stakeholders in a dynamic policy process. As explained in § 5.4, the policy model of prevention is slightly incremental and but mainly mixed because of need for mutual adjustment of policy goals and instruments.

Based on the policy cycle of Hemerijck and the policy cycle of Hunter<sup>76</sup> an integrated model is developed here, with several stages of policy combined with policy instruments and the phases of assessment and appraisal. The elements of the policy making process can be found in the figure below, as well as the Assessment and Appraisal phases.

<sup>&</sup>lt;sup>76</sup> See appendix § 14.5 for original schemes.



#### 9.2 Prevention of cervical cancer with the HPV-vaccine

Two pharmaceutical companies developed a vaccine against HPV. One vaccine is approved; approval of the other vaccine is in process. The HPV-vaccine is an interesting case because there is no decision yet. Therefore this description will not be an historical analysis but a test case for the Descriptive Scheme of Decision Making Criteria. Many insecurities are part of the decision making process. Insecurities about budget impact and effectiveness are substantial and these insecurities will not be taken away in the near future.

The advisory council for healthcare (GR) is going to publish an advice concerning the possibilities of implementation of the Human Papilloma Virus-vaccine in the National Vaccination Programme (RVP) in 2007. The medical effectiveness of the vaccines has been proved for the defined population (girls age 11/12). All different criteria will be analyzed and weighed while writing this thesis. The HPV-case is currently at the second stage of the policy cycle: 'the policy formulation and the proposal of a solution'. The information of these criteria is in fact 'formal evidence based knowledge', a 'knowledge based resource'. A decision can be based on both informal experienced based knowledge and formal knowledge. The 'collective action resources' refer to Appraisal II of the decision making scheme. The advice that the GR is going to publish refers to a question of financial resources: whose ownership and sponsorship should this vaccine be? The institutional resources refer to formal political power and formal organizational power. The minister of health will make the final decision; the GR has formal organizational power to inform policy makers and the minister of health. The policymakers have to contribute in their own way to the decision making process.

#### Assessment

The assessment phase implies the following specific criteria:

- Burden of disease and quality of life;
- the harm principle;
- maximize population health;
- population effects and individual effects, epidemiological & demographic transition
- medical effectiveness
- cost-effectiveness

Burden of disease (expressed as Daly's):

Course of disease	Duration (years)	Disability rate	Cases (per year)	Life years lost	Disease burden (DALYs)
Morbidity prior to cure	5	0.35	395	-	69
Morbidity prior to death	3	0.52	215	-	33
Fatal	-	1.00	215	20.5	440
Overall					543

<u>Harm principle</u>: HPV is a sexual transmittable disease. 50-80% is infected during life. About 20-25% young women have been HPV-infected. Boys are exposed to the risk of genital warts and penile cancer caused by HPV.

Incidence and mortality of Cervix carcinoma:

Year	Patiënts	Mortality
1997	735 (9,3 per 100.000)	234 (3,0 per 100.000)
1999	703 (8,8)	253 (3,2)
2001	604 (7,5)	243 (3,0)
2003	584 (7,1)	214 (2,6)

Medical effectiveness of two available vaccines:

Gardasil® - Sanofi Pasteur-MSD	Cervarix® - GlaxoSmithKline
-HPV type 6, 11, 16, 18	-HPV type 16 and 18
-European Licence september 2006	-Registration request EMEA in march 2006
-Cervixcarcinoom, CIN <sup>77</sup> 2/3, VIN 2/3	-Cervixcarcinoom, CIN 2/3, VIN 2/3
-Women and man	-Injections at $t = 0, 1$ and 6 months
-Injections at t = 0, 2 en 6 months	
-ACIP (USA): 11-12 year girls	
catch-up women 13-26 year	

The vaccines are highly effective against persistent infection. Cervical intra-epithelial neoplasm (CIN) is a potential pre-stadium of cervical carcinoma. Effectiveness of the vaccine against CIN 2/3 and HPV type 16/18 after follow-up (5 years) was 100%. There is a causal relationship between HPV and cervix carcinoma, but more time is needed to bring up data about the effect of the vaccine on incidence of cervical carcinoma.

Effectiveness has only been proven for the age group of women and it is tested for five years. There are no data available about the effectiveness of the vaccine after this period of time. The vaccine is only effective after three repeated vaccinations. Screening by means of a smear (secondary prevention) needs to be continued because of the weak aspect of the vaccine of therapy loyalty (3 times injection) and possibility of infection without vaccination. The implementation of the vaccine needs to be possible in combination with the other vaccinations of the RVP.

With full participation of the target group, it is estimated that there will be a decline of 75% of women with cervix carcinoma. This is also indication of savings in curation.

#### Cost-effectiveness

Vaccination of females seems to be cost-effective. The cost-effectiveness ratio is from \$ 14.000 up to \$ 22.755 per Qaly, which is under or above the potential  $\in$  20.000,- threshold for prevention. Figures are estimations based on modelling (from a health care perspective) for long term calculations. All studies include the screening additive to the vaccine. Estimations depend on the prices, duration of protection, vaccine effectiveness, the health utilities used to estimate Qaly's and discounting levels. The price of vaccine is three times  $\in$  50 -  $\in$  100, in total from  $\in$  16 billion up to  $\in$  31 billion.

#### **Appraisal I Institutional framework**

- legal obligations (and international and professional standard)
- budget impact

#### Legal obligations

Is there an obligation to offer this programme according the Public health act? Is there an obligation to implement this programme because it is under the cost-effectiveness threshold? It depends on agreements, statements and policy targets of the government.

The question is whether one could argue that there should be a collective arrangement to make sure that everybody has access to this vaccine. The fact that a programme is available does not have the consequence that it is an obligation to pay for it in a collective arrangement.

#### Budget impact

The total budget impact of the vaccine and the screening is not estimated yet. The RVP budget was 58 billon Euros in 2004. The costs of current screening are € 26 billion a year. Treatment of preinvasive en invasive leasies is about € 15 billion a year. With these figures and the exact figures of the total costs of the vaccine, including screening and implementation costs the difference of budget impact can be calculated. It can be weighed against impact of other programmes. Cost-effectiveness is to be calculated with exact prices and direct and indirect consequences, individual and population

 $<sup>\</sup>overline{^{77}}$  CIN = Cervicale intra-epitheliale neoplasie VIN = Vulvaire intraepitheliale neoplasie

wide costs of vaccine, cost of screening, costs of implementation, costs of alternative methods (cytological versus HPV-DNA screening), prevented costs of curation, prevented losses of productivity. This way, the information obtained in cost-effectiveness analysis can be used as input for calculation of budget impact.

#### Appraisal II Societal policy framework

- direction of political wind
- societal support, opinion of stakeholders
- willingness to pay (and ability to pay)

#### Direction of political wind

The political wind will be influenced by all influencing factors (possible criteria). It is not possible to predict anything on forehand. It will depend on societal support, stakeholders and political preferences of the minister, and on other factors. If there is societal panic this might be an influencing factor. A representative of the social democratic party asked about the possibility of quick implementation in the national vaccination programme, mainly because other countries have chosen to do so.

#### Societal support

Many newspapers and internet websites have published the news of a vaccine against cancer. There has been an adjustment of the RVP in 2006, is it attractive to change it again? Doctors need to implement every new decision. People might ask for the vaccine. Patient organizations might ask for it. Pharmaceutical industries have an advantage of the publications and of the pressure of potential users. The Pyramid of Bondieu has been used to point out all different political, socio-political and social actors, concerning this case.

#### Opinion of stakeholders

The pharmaceutical industry will bring pressure to bear upon decision makers in favour of implementation of the vaccine, because of an attractive deal.

Now, people who know about the vaccine and who can afford to pay for it themselves and who judge it as a necessary preventive strategy will buy the vaccine. The American Centre for Disease Control advised in favour of the vaccine in the national vaccination programme. The WHO would like to make the HPV-vaccine accessible for developing countries because there is a relative large patient group and curative facilities are scarce.

#### Appraisal III Normative policy framework

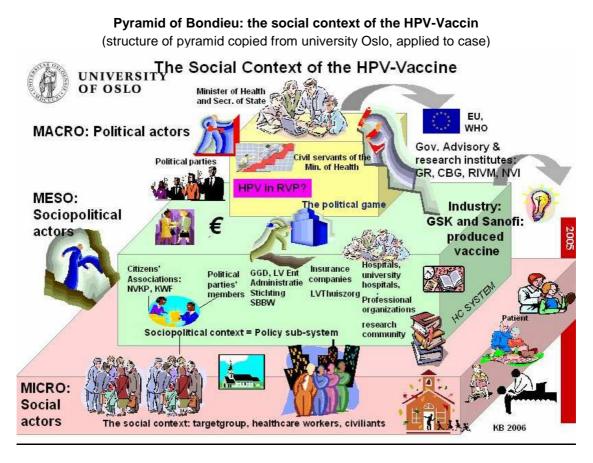
- justice (equity and fairness)
- solidarity (and individual responsibility, poverty reduction and social economic status))

#### **Justice**

It would not be fair probably, if there is a vaccine and it is not accessible for everybody. The risk that somebody dies of cervical cancer caused by HPV because she could not afford the vaccine would not be preferable. Some judge that if the vaccine is cost-effective, implementation in the vaccination programme is fair because it is efficient resource allocation.

#### Solidarity

The relatively well to do can buy the vaccine themselves. People with lower social economic status will be deprived from the vaccine. The question about governmental and individual responsibility comes up. If the HPV vaccine is going to be implemented in the RVP, there is a cross subsidy of the ones who can afford it themselves to the ones who can not afford it.



### **Rationing principles**

The rationing principles depend on the normative judgement of decision makers. A positive costeffectiveness ratio might be valued as the most efficient outcome to allocate resources and therefore as a fair way of distributing health among people (utilities). Economic evaluation does not offer consistent advice yet. For women it appears to be cost-effective, but not all financial and budgetary consequences have been elaborated. Is it fair to deny people the possibility to prevent cervical cancer? Should it be subsidized for the less-well to do, in order to achieve equality of access until more can be said about the implementation in the RVP? Or should it be left to the market mechanism, according to the entitlement theory? Is it the responsibility of health care insurance companies? It is difficult to say anything about the rationing principles on forehand. The principles have general implication. If more information is available, a detailed analysis can take place, also based on preferences of stakeholders.

#### Perspectives

There are insecurities about effectiveness, costs, budget impact. A simple conclusion might be that it is too early to judge about implementation. The different perspectives need to be elaborated.

- Qaly's to gain and Daly's to loose, on individual level and population wide;
- Comparison of this vaccine and alternatives, this vaccines and other current programmes, health gain of curation and prevention, health gain of primary and secondary prevention;
- Costs of curation and prevention needs to be compared;
- Is there any regulation or policy goal which gives indication for implementation;
- What is the societal loss and societal gain;
- Is it an objective or a means, in order to prevent societal losses.

#### Conclusions

This case is elaborated in order to show the dilemma's which are part of a possible decision making process in public health. Criteria both in the assessment phase and in the appraisal phase still need

to be described in a better way in order to make decisions. Lots of discussion will be part of the decision making process, because of the question of governmental responsibility and pressure from actors within the social context.

After applying the HPV-vaccine as a case to the decision making scheme, it became clear that it was difficult to give straight and specific information about any of the criteria. Many insecurities about the decision making criteria are part of the decision making process. This might be a benefit for manipulative actors. Because of the many influencing factors and the technical information about costs and effectiveness, the risk of lack of visibility is major. The facts need to be highlighted. The contradiction between feelings and believes and facts and figures<sup>78</sup>, offers an unpredictable case. Windows of opportunity will be searched in order to decide for this intervention or others. Insecurities about budget impact and effectiveness are substantial and these insecurities will not be taken away in the near future. The medical effectiveness of the vaccine for the defined population has been proved. Questions about governmental and individual responsibility come up.

<sup>&</sup>lt;sup>78</sup> 'Feelings and beliefs' and 'facts and figures' are part of 'Prestation management of policy activities' of Jeroen Geelhoed and others. This figure describes results of decision making.

Part IV Conclusions & recommendations



# Bounded rationality: "Nothing is the truth, even this isn't"<sup>79</sup>.

E.D. Dekker

<sup>&</sup>lt;sup>79</sup> Vrij vertaald: 'Niets is waar, en zelfs dat niet'. Multatuli, De ideeën.

# 10 Conclusions

The conclusions of this pilgrimage to 'solutions to the possibly unwinnable dilemmas of social policy' have been brought together in this chapter. While the decision making criteria might be considered the path, solutions for public health are the major goal. The question around which this thesis is centered is: What criteria for decision making in public health can be identified?

In order to answer the main question, the following questions were answered by means of a literature search and interviews:

- What is a decision making criterion?
- What is the difference between decision making criteria for cure and for prevention?
- How can decision making criteria be arranged in a policy context?

These research questions will be answered one at the time. Subsequently conclusions about the main problem will be clarified. Finally the subtitle is explained.

#### What is a decision making criterion?

A decision making criterion is a touchstone on which the choice for a public health intervention is founded. A criterion must be defined and operationalised; otherwise it is not a criterion. In addition to this definition the distinction between decision making criteria and decision making factors needs to be made. A criterion is directly related to decision making, factors are contributory, influencing elements. Literally, there is only one decisive criterion; the other 'criteria' are the influencing factors. The decisive criterion, the notion of the criterion and the connected principles will influence the consequences of a decisive criterion has an allocative impact on public health resources. The identification of the decisive criterion of a specific intervention is not easy because of the complexity of the decision making process and because of the interrelatedness of all criteria. The necessity criterion is not valued as a criterion because is does not fit within the definition. There is no consensus about operationalisation of necessity. Necessity is generally expressed as need or as Qaly's.

#### What criteria for decision making in public health can be identified?

Based on literature, interviews and participative observations, it is concluded that decision making is difficult and complex. There are three important reasons for this:

- 1) The quantity of possible decision-making criteria
- 2) The diversity of possible decision-making criteria
- 3) The interrelatedness between possible decision making criteria

#### 1) The quantity of possible decision-making criteria

During this study 23 criteria for decision making have been identified. These have been joined into 10 main criteria in a decision making structure. The criteria have been ordered into epidemiological and demographic, economic and policy related criteria. The definitions and operationalisations of these criteria can be found in the appendix.

#### 2) The diversity of possible decision making criteria

This study shows the diversity of decision making criteria. The criteria identified in this study have different scientific bases, several possible underlying moral principles and different decision making perspectives. The following table with a 'Classification of decision making factors' shows the criteria:

Epidemiological and demographic decision making criteria Burden of disease and quality of life, respectively DALY and QALY

Medical effectiveness of instruments
Harm principle, external effects of disease
Maximize population health,
Prevention paradox: population effects versus individual effects
Economic decision making criteria
Efficiency, cost-effectiveness, budget impact
Societal costs, productivity losses, social economic status,
Poverty reduction, social economic status/ social economic differences
Individual responsibility, ability and willingness to pay
Policy decision making criteria
Institutional configurations, national and international regulation (law and system)
political reality, Individual responsibility and governmental responsibility
societal support, target group policies
principles like equity, fairness, justice and solidarity
Table: Classification of decision making factors

Table: Classification of decision making factors

Different perspectives on decision making have been identified. Operationalisation of the criteria can depend on the chosen perspectives. Identification of the perspectives might be helpful in the decision making process to all involved actors and stakeholders. The chosen perspective depends on the general goals of the healthcare system and the way the policy goals have been formulated in the current political debate. The policy problem itself influences the perspective. In policy making, all criteria should be described, operationalised according the different possible perspectives and in a systematic way. The decision making process would become more transparent and possible consequences might be more predictable and observable. The black box of policy making can be like a mysterious ka'baa, but it should be responsible, democratic and therefore transparent. The importance of explicit rationing needs to be emphasized. Transparency of decision making criteria offers more possibilities to evaluate and adjust earlier decisions.

#### 3) The interrelatedness between possible decision making criteria

Based on the literature search, it became clear that only some relationships between criteria have been described, whereas many more relationships can be identified. Interrelatedness is important, because criteria can only be understood well, if their relationship with other criteria is well understood. For example cost-effectiveness is one important factor, but this must be observed simultaneously with factors like burden of disease, equal access, solidarity and budget impact. The interrelatedness between the different criteria depends on the policy issue at stake. Therefore the criteria have to be specified and weighed again with every decision. A 'funnel of Dunning' or a cost-effectiveness threshold alone will not solve this problem. The diversity of criteria cannot be simplified by the agreement of a definition or an agreement about interpretation. The health problem at stake should guide the interpretation of criteria and underlying principles. It is recommended here that the description of relationships between criteria could be operationalised in a more extensive and quantified way.

#### What is the difference between decision making criteria for cure and for prevention?

Based on literature search and the developed structure for decision making, it can be said that all criteria can be applied to decision making in both prevention and cure. Cure and prevention avoid loss of health and lead to a longer, healthier life. Application of decision making criteria for cure and prevention is different because:

- It seems that the difference between cure and prevention is emphasized because of the information problem. The lack of transparency and (political) preferences of policy makers seems to maintain the gap between prevention and cure.
- Prevention policy needs measures at population level. Information about medical treatment is directly related to real patients, as well on individual level and population levels;

- The way the criteria will be operationalised depends on several choices concerning the perspectives and the preferences concerning the criteria. A lot of information about prevention is available after abstract modelling. This is based on assumptions.

Burden of disease based on population level statistics is a criterion for decision making. In relation to cure, the individual burden of disease and the individual health gain can be specified. In relation to prevention this is difficult or impossible. There is always the dilemma that it is not known who will become ill and when. Therefore it seems to be difficult to determine exact effectiveness and cost-effectiveness.

Once somebody is ill, an available cure cannot be denied. A threshold for curative interventions seems to be acceptable at about  $\in$  80.000,- and for preventive interventions this is  $\in$  20.000,-. Based on this study it is not possible to say anything about the actual application of criteria for prevention or cure. An extensive historical case analysis is recommended, in order to draw any conclusions about application of criteria in cure and prevention.

#### How can decision making criteria be arranged in a policy context?

The availability of a standard vocabulary is merely a helping tool, but at the same time it is a condition for decision making. There seems to be a wish for rationalized decision making with a clear cut decision making instrument. Literature reveals some relationships between criteria. The interrelatedness of decision making criteria shows relationships like a spider web. All different criteria have mutual effect on each other. This is the foundation of the 'Descriptive scheme of decision making factors for public health' in chapter 8. The knowledge about criteria, the elements of policy and the policy cycle have been integrated into a single scheme. It may help to identify the relevant criteria related to a health problem and the suggested policy to deal with this problem. However, an observational scheme has no prescriptive order, because the decisive criterion and the major influencing factors will depend on the policy problem.

Reality shows that consensus (based on information from the assessment phase) needs to be found between all actors at stake. A scheme of decision making factors is a way to have a defined starting point while discussing a proposal for public health policy with many policy actors. Policy cleavages and decision making consensus may become obvious while using identified criteria.

After applying the HPV-vaccine as a case for the decision making scheme, it became clear that it was difficult to give straight and specific information about any of the criteria. Insecurities about the decision making criteria are part of the decision making process. This might be a benefit for manipulative actors. Because of the many influencing factors and the technical information about costs and effectiveness, the risk of lack of visibility is major. The facts need to be highlighted. The contradiction between feelings and beliefs and facts and figures, offers an unpredictable case. Policy makers examine windows of opportunity in order to prioritize interventions. Insecurities about budget impact and effectiveness are substantial and these insecurities will not be taken away in the near future. The medical effectiveness of the vaccine for the defined population has been proved. Questions about governmental and individual responsibility come up.

#### What criteria for decision making in public health can be identified?

There are at least 23 decision making criteria in public health. In the Descriptive Scheme of Decision Making Factors, the number of 23 is reduced to 10. There are four phases of decision making: the Assessment, Appraisal I is the Institutional framework, Appraisal II is the Societal Policy framework and Appraisal III is the Normative Policy framework. All criteria in phase III of the Decision Making Scheme are difficult to quantify. Based on interviews and literature findings, there seems to be lots of heterogeneity about the preferences of a decisive criterion. This is, as an example, because some

preventive programmes or health care facilities have more impact on economic differences than others. During interviews, political preferences were revealed by respondents. It was not surprising that individual responsibility as a criterion was preferred by liberal, right wing policy makers. Poverty reduction and government responsibility was preferred by left wing oriented policymakers. The suggestion that policy makers are influenced by their own conscious and unconscious preferences and the explanation of social constructivism seems to make sense. Rational decision making might be connected to the use of quantified criteria, but because of the limited possibilities to quantify the explained criteria, 'rational' needs to be related to bounded rationality.

There is general agreement that rationing and prioritisation imply an ethical debate, because health is a very precious common good. To deny health to someone is unethical. Would the integration of public health in the Dutch system offer a systematic perspective on health, healthy way of life and optimalisation of quality of life and operationalisation of this perspective? Would it lead to a more efficient system? Many sources underwrite the importance of prevention and integrated public health policy. Based on literature search, interviews and current Dutch public health policy, it can be said that a systematic perspective on health and public health policy and prevention is missing. Inconsistency between the described urgency to prevent loss of health and the actual public health policies seems to be the issue.

There are proponents and opponents of the introduction of a cost-effectiveness threshold. A costeffectiveness threshold might control budget impact. It also might control the discussion and the decision making process. The recommendation of the RVZ refers to a threshold which is depending on burden of disease. People seem to agree that cost-effectiveness must not be the only criterion for a decision. As a consequence, the final harmony in agreement is still missing. One must question whether legal implementation of a cost effectiveness threshold would quiet down the conflagrant discussion about decision making.

Despite the suggestion of the RVZ that there should be an official cost-effectiveness threshold, the decisive criterion will probably not always be the threshold or the so called 'yardstick of public health'. As NICE very clearly states: "The existence of factors other than cost-effectiveness may mean that there is in practise no threshold at all". Based on cases in the Netherlands, the same can be said about the Netherlands. Many preventive programmes which are not cost-effective have been implemented and programmes which are cost-effective have not been implemented. It is suggested here that the decisive criterion will always be different, depending on the policy problem at stake. The proof of the pudding is in the eating: future decision making will show what preferences surpass others in importance.

As explained, there is only one decisive criterion while making a decision. Other criteria are left behind as influencing factors as soon as the decision is made. This is way the developed scheme is called the Descriptive Scheme of Decision Making Factors.

As Jakson and de Beer state in their article, not making decisions is unethical also. Deferring decisions into the future will not change the problem. Not making choices is in fact implicit rationing. "The greater the visibility of rationing in the sense of prioritisation, the more difficult it may become to steer resources towards the most vulnerable groups. Lack of visibility may be a necessary condition for the political paternalism required to overcome both consumer and producer lobbies"<sup>80</sup>. Explicit rationing would show the decisive criteria and open the black box. Is that desirable? This question needs not to be answered by students and researchers, but by the decision makers themselves.

The importance of explicit rationing needs to be emphasized. Transparency of decision making criteria offers more possibilities to evaluate and adjust earlier decisions. Decisions are

<sup>&</sup>lt;sup>80</sup> Klein 1992

understandable. The fairness and the quality of decisions may be valued. Although this is not always preferable for related actors and decision makers, it is the only way to develop sustainable policy. It is a responsibility to deal in a responsible way with the possible public resources in order to achieve the highest possible standard of health.

#### Illusions, elucidations and elusiveness of decision making criteria

The difficulty of decision making criteria is explained by the words illusions, elucidations and elusiveness. The criteria are illusionary, elucidative and elusive at the same time. Although an economic evaluation or epidemiological fact seem to offer a proper solution for decision making in public health, decision making is still complex. A cost-effectiveness ratio might be called a decision making illusion. Economic evaluation is not always transparent. Elucidation is a wish: to shed some light on all possible criteria and their interrelatedness, in order to make progress in the debate of public health policy.

A decision may be based on several indicators for policy. Decision making criteria are divers and the definition can vary. The criterion is influenced by underlying rationing principles. The criteria are interrelated, and the way the criteria are selected and interpretated is depending on political preferences and perspectives. This refers to the elusiveness of decision making criteria at the same time.

# 11 Recommendations

Based on this literature and interview study, many recommendations can be done. Eight recommendations concern further studies. Two last recommendations refer to policy making based on output of studies.

#### 11.1 Subjective preferences concerning decision making

This study identified the criteria used in decision making. However, this raises the question of which criteria are more important then others. While interviews might help to establish this, respondents might have difficulty quantifying the relative importance of different criteria. The DCA approach is a method that can establish relative importance of criteria in a quantitative way. Qualitative and quantitative studies are complementary. While performing a qualitative analysis, the reality is construed by the researcher. The relationships have been based upon sources and interviews within the frame of reference of the researcher. Looking for subjective preferences of others, the researcher is victim to his or her own subjective preferences. This inherent bias is a substantial risk of qualitative research. The phrase of the research question implies certain assumptions underlying the research question. Ideally, all assumptions of the researcher and of the study are explicit before and while performing research. The expectations and the assumptions of the researcher concerning the object under focus, can be substantiated with quantitative research. The quality of the study is then dependent on the analytic capabilities with which the researcher prepared the conducted data registration. The comparison and the synergy between qualitative and quantitative research might produce, if performed in 'the right way', the optimal scientific outcomes.

Insight in decision making criteria and the interrelatedness between these criteria is important to identify and improve all consequences of decisions. A sophisticated frame of reference is necessary in order to keep a tight grip on policy decisions. After describing decision making criteria, quantification of preferences is just as important. The information can serve as future input for decision making.

In a DCA policy makers are asked to choose between many interventions, based on different decision making criteria. The respondent has to choose between two interventions, this choice will be repeated many times. After quantitative analysis of the given preferences a representative hierarchy of the preferred criteria is revealed. When this hierarchy is put into the context of policy making, it gives information about responsibilities, possibilities and expectations within the decision making process. The choices which have to be made are:

- between two preventive interventions
- between curative and preventive interventions
- between two curative interventions
- between care interventions.

For the programmes to be compared, information is given about criteria like cost-effectiveness, burden of disease, budget impact, quality of life, severity of disease or poverty reduction. Choices have to be made about the combination of the criteria involved because 23 criteria is too much. Several DCA's can be performed in order to imply all criteria. The respondent makes many choices and each time the answer reveals more information about the preferred criterion (statistical 'weights'). At the beginning it might be easy for a respondent to choose between an intervention based on cost-effectiveness and poverty reduction. Then more information about the criteria for each programme is given; therefore the respondent has to weigh the choices between the two programmes again. In real life it is just the same; there are many healthcare programmes and influencing factors, but there is only one budget.

Decision making is a result of a dynamic process with many stakeholders. The participants of this process cover their own ideas, objectives, interests and preferences. The goal is an optimal outcome, but the expectation of each participant is just as different as the participating individuals themselves. Possibilities for consensus and optimal outcome will be found in the area of the common divisor.

By combining the database of explicit preferences with information about the professional positions and political choices, the differences and agreements become elucidated. Another question is whether the participants of the policy process wield the sword entirely consciously. Are motives rational or irrational? Are motives in alignment with the personal preferences concerning underlying rationing principles? Finally the discrepancies and antithesis of the decision making process concerning prevention and healthcare might be enlightened.

An example of an earlier discrete choice analysis can be found in the table below. A small population (n = 30) of policy makers of the government of Ghana has been asked about their preferences concerning several healthcare and preventive programmes. The prioritisation of these policymakers is compared and a hierarchy was put forward. The level of significance (P= 0,001) shows that three criteria have been significant within this study: cost-effectiveness, poverty reduction and the age of the target group. When there is a positive effect, the value of the coefficient is more than 1, when there is a negative effect; the value is between 0 and 1. This has the implication that, as an example, cost-effectiveness was preferred 42% (1,42 - 1\*100) times more often then the other criteria (apart from marginal side effects).

A discrete choice analysis implies a hierarchic order of criteria; this is of course not the focus underlying this study. The information revealed by a discrete choice analysis might function as a current reflection of the status quo.

Criteria	Coefficient	Standard error	P value
Constant	-1.94	0.25	< 0.001
Cost-effectiveness	1.42	0.17	< 0.001
Poverty reduction	1.25	0.17	< 0.001
Severity of disease	0.38	0.17	0.0257
Large individual health effect	-0.32	0.17	0.0616
Age of target group	0.84	0.17	< 0.001
Budget impact	0.31	0.17	0.0688

# Example of hierarchy of decisions of Healthcare policy makers in Ghana: results from logistic regression:

R<sup>2</sup> (Cox & Snell) = .194

It might have the implication that new ideas come up after comparing statistical analysis and qualitative information. A prescriptive study would probably involve a quantitative analysis, because it would possibly offer some complementary statistic evidence for some hypotheses derived from this study.

#### 11.2 Quantification of relationships of the observational scheme

Like the study of AI and Stolk concerning equity and efficiency, all relationships between criteria can be studied in a quantitative way. This would be an enormous effort, therefore it might be illusionary. Still, it will be a challenge which might enlighten the debate about decision making within the area public health. Esping Andersen<sup>81</sup> connected many policy aspects with which he designed a quantitative policy study for the classification of welfare states. This also might serve as an example. The output of the described discrete choice analysis can supply input for this study. In addition to the quantification, the underlying rationing principles, need to be elaborated.

#### Historical analysis of decision making 11.3

It is recommended to study the Basic Benefit Package and all preventive interventions which are currently performed in order to find out which criteria were dominant when the decision was made to implement them. Curative and preventive interventions can be studied for cost-effectiveness. This is compared to the final decision concerning the implementation of the specific interventions. A lot of interventions in the basic benefit package have not been studied about cost-effectiveness. These programmes have been awarded after a randomized control trial. There are no facts about costeffectiveness. In many cases, cost-effectiveness is not the decisive criterion. Interventions have been implemented although they are not cost-effective and vice versa. There is a demand for more costeffectiveness information concerning prevention. It is stated that there is not much information about the cost-effectiveness of prevention. A lot of interventions have been studied before. There are many methodological problems which have to be overcome; this is alike for cure and prevention. The specific methodological problems are not entirely the same.

#### 11.4 Comparison of efficiency of prevention and curation

A question during one of the participative observations was: "Can euros spent on prevention lead to savings for cure?" The comparison of the efficiency of cure and of prevention is a current topic of debate. Some evidence concerning the balance between investment in prevention and cure might help the debate. There is a possible outcome that prevention and curation are complementary and therefore more efficient.

#### 11.5 **Cost-effectiveness information**

Although there are ways to evaluate the quality of economic evaluations, still the debate about methodological problems of economic evaluation will continue. Lots of money is spend on research and on production of information. Channelling of information is just as important as performing research itself. Therefore it is necessary to develop an official way to present all CEA/CBA/CUAstudies. An international standard concerning economic evaluation of curation<sup>82</sup> and prevention is recommended; in order to make sure that a minimum of information is always available. Standardisation of presentation the cost-effectiveness information for people who are not familiar with cost-effectiveness research is a condition in order to make information accessible for policy makers. At the same time, an agreed standard for decision making in order to develop extensive policy on health is a condition for progression. Feasible information is a condition for structural comparison. Moreover, structural comparisons only make sense if the cost-effectiveness information is interpreted in the right way. Different research institutes and individual researchers have developed their own databases with information on cost-effectiveness<sup>83</sup>. It is recommended that databases will be linked and made public for policy makers who need available information. This might also improve the

<sup>&</sup>lt;sup>81</sup> Esping Andersen 2003. *Three worlds of welfare* 

<sup>&</sup>lt;sup>82</sup> In addition to the 'Richtlijnen voor farmaco-economisch onderzoek' see: http://www.xs4all.nl/~jannetvb/busschbach/Richtlijn.htm

http://www.xs4all.nl/~jannetvb/busschbach/publications.htm (database peer reviewed publications)

ZonMw, RIVM, University of York, NICE

quality of new research. The ministry asked in the past for studies concerning prevention with a scope of five year and from a health care perspective. For prevention studies a longer scope and a two perspective approach (health care and societal) would give the right information for making policy.

#### 11.6 Cost-effectiveness and intersectoral policy

There is an assumption that integral intersectoral health policy would cause more health gain which is also produced in a more cost-effective way. This is because the optimalisation of environmental and social factors causes a natural response (healthy behaviour). The intended healthy behaviour becomes a more natural response, because of better circumstances (housing, spatial planning and the environment, healthy food, education and sports). At present, there is no information available about the economics of intersectoral policy. Many instruments and policies used within the different policy areas will be in better harmony and might have better results. It appears that interdepartmental cooperation is a standard way of working in countries like Sweden and Denmark. These countries might serve as an example. To find out possible results of intersectoral policies and the comparison of intersectoral policies in different countries might be an interesting exercise.

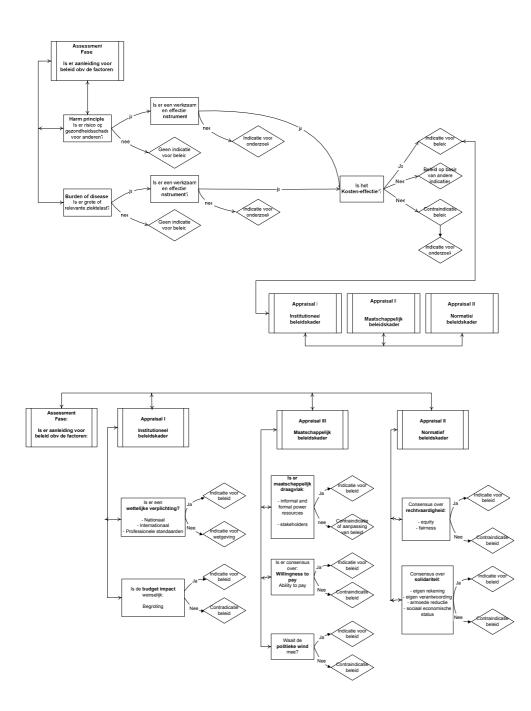
#### 11.7 Public health, policy and politics: a systematic perspective

This recommendation refers to a debate between public health scholars and policy makers. The policy context (cycle of public health, based on relevant acts, WCPV, WPG), the PHSF and other information available, serves as input for a systematic perspective on public health. Policy problems need to be described in a systematic way. This implies the decision making criteria, operationalisation, analysis of possible perspectives and description of the infrastructure. Based on the outcomes of all recommended studies, a systematic perspective on Public Health should be developed. The perspective needs to be acknowledged and accepted by relevant actors. Scholars in the field emphasise the need for such a perspective. Money is lost due to lack of consistency between policies on all levels. The debate about governmental and individual responsibility would be part of this perspective, as well as prioritization of criteria.

#### 11.8 A "prescriptive scheme" of decision making criteria in public health

In addition to a systematic perspective on public health, a prescriptive is suggested here. The descriptive scheme is based on logic and is completely iterative. The prescriptive scheme has an implicit logic and order. The prescriptive scheme is a possible application of the descriptive scheme, in order to aid decision making for a public health intervention. After answering every question of the prescriptive scheme a logic advice should evolve, based on multi-criteria priority setting, in which all criteria have been made explicit. This is an example of explicit decision making and explicit rationing.

<u>A Prescriptive Scheme for Decision Making Factors in Public Health Policy: decision making flow diagram (ex-post and ex-ante)</u>



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# 13 Appendices

#### 13.1 Description of decision making criteria for decision making in public health

All criteria will be described with a broad definition. Furthermore, the operationalisation is explained. Operationalisation stands for qualitative and quantitative methods to describe the criteria. In chapter 9 it will become clear how all factors are interrelated. The specific decision-making criteria concerning prevention policy decision making will be highlighted in chapter 9, 10 and 11.

#### 13.1.1 Epidemiological and demographic decision making criteria

Epidemiology is the study of the determinants and distribution of disease in a population. Demography is defined as the statistical description of social and political phenomenon's and characteristics of people. Measures of disease frequency involve prevalence and incidence of disease, mortality and morbidity. Examples of demographic measures are birthrate, fertility rate and infant mortality rate<sup>84</sup>. Both measures of disease frequency and demography are used and aggregated to calculate epidemiological characteristics of a population. This information is the foundation of policy aimed at controlling disease in a population.

#### Burden of disease

Burden of disease is a general term used in public health and epidemiological literature to identify the cumulative effect of a broad range of harmful disease consequences on a community, including the health, social, and economic costs to the individual and to society.

(DPH USA). The WHO describes burden of disease as the total significance of disease for society beyond the immediate cost of treatment.

Measures of burden of disease are:

- number of people affected, derived from diagnosis groups, handicaps
- use of resources and cost, like days in hospital, days of absenteeism, number of referrals
- mortality, morbidity, incidence, prevalence
- aggregated measures for health: years of potential life lost (YPLL) and disability adjusted life years (DALY)

Daly's provide information on the effect of disease on population health. Daly's are used to compare importance of different risk factors. They are used to compare burden between diseases and to estimate the effect of an intervention (as well a therapy as policy).

Burden of disease serves as a criterion for both curation and prevention. The expected burden of disease when the preventive programme should not have been implemented, is the measure for prevention<sup>85</sup>.

#### Quality of Life

Health related quality of life (HRQoL of QoL) is defined as physical, psychological and social functioning and expressed as personal values attributed to these aspects. There are generic instruments and disease specific instruments to measure QoL. Examples of generic instruments are Short Form 36 and EQ-6D. Respondents are asked about mobility, pain, cognitions, and physical and psychological well being. Health Related Quality of Life is a measure which is used to calculate Qaly's and Daly's. HRQoL, Qaly and Daly are somewhat subjective measures, because figures are based on preferences of respondents.

<sup>&</sup>lt;sup>84</sup> Coggon 2003

<sup>&</sup>lt;sup>85</sup> GR 2003. Contouren van het basispakket

#### QALY's and DALY's

A Quality Adjusted Life Year is a measure of health outcome which simultaneously captures reduced morbidity and mortality. It expresses healthier and longer years of life, a measure for *quality and quantity of life*. Disability Adjusted Life Years expresses the opposite. It expresses increased morbidity and mortality. DALY = years of life lost + years of life with a disease.

There is an enormous amount of literature about Qaly's, arguments in favour and against, about the relationship to rationing and underlying rationing principles<sup>86</sup>. The concept of the Qaly was first introduced in 1968 by Herbert Klarman and colleagues in a study on chronic renal failure. The World Bank and the WHO introduced Qaly's and Daly's in the Global Burden of Disease 1990-project. At that stage it became a generally accepted measure.

A Qaly and a Daly go hand in hand. Daly and Qaly have the sum of one. One minus a Daly is the weight of a Qaly. If a Qaly is equal to 1, this implies that the health of a person is 100%. If a Daly is equal to 1, the fact that a person had died stands. If the weight of a certain disease is valued as 0,4 and the duration of the illness was a year, the Qaly equals to 0,6 and the Daly equals to 0,4.

The most fundamental objection to Qaly's lies in the attempt to devise a common measure by which we assign a quantitative value to disparate ingredient factors. Loughlin expresses it as follows<sup>87</sup>: 'In addition to its bogus objectivity it disguises the incommensurability of many of the values involved in decisions about the allocation of health resources'.

#### **Necessity: need**

The first sieve of the Funnel of Dunning is the necessity criterion. Necessity is a criterion which is very difficult to quantify. Necessity or 'need' is expressed as 'benefit' or 'satisfaction'. Benefit or need have been expressed as a 'utility'. The way a utility is quantified should express the necessity of medical service or preventive programme. The quantification of a utility should be a Qaly, but not all experts agree that this is methodologically right<sup>88</sup>.

Egalitarian statements like 'equal treatment for equal need' and 'equality of access for equal need' run aground because of the elusiveness of the definition and operationalisation of 'need'. Because of the difficulty of quantification of the criterion necessity, the Health Council of the Netherlands prefers the criterion 'burden of disease'.

Doctors translate need of patients into treatments. Need is transferred into actual use of health care by doctors. This might be called a literal interpretation of supply induced demand. If the diagnosis and the prescribed treatment are fully effective, need is demand. This is because patients do not demand for health care but for health. When the government provides in extensive prevention policy, is this also an effective response to the demand for health of people?

#### **Medical effectiveness**

Medical effectiveness refers to the effectiveness of curative and preventive instruments. It refers to the quality of these instruments. Quality is described as having three dimensions: quality of input resources, (certification, and/or training of providers); quality of the process of services delivery (the use of appropriate procedures for a given condition), and quality of outcome of service use (actual improvement in condition or reduction of harmful effects).

Clinical trials are used to study effectiveness of medical treatments. Preventive programmes have to be evaluated in a different way. Because of the notion of prevention it is not possible to compare effects within a 'intervention group' and a 'control group' in the same way. The effects of preventive

<sup>&</sup>lt;sup>86</sup> See Druumond 2005, Hunter 1997, Cuyler 2000, many articles

<sup>&</sup>lt;sup>87</sup> Loughlin 1996 in Hunter 1997

<sup>&</sup>lt;sup>88</sup> Drummond ao 2005: 188/9. See appendix about conditions when a QALY may be explained as utility.

programmes may be observable after a long while (ten years for instance). It is difficult to determine causality: why didn't the illness occur to a certain person?

Quality of care is also the measure of the degree to which delivered health care services meet established professional standards and judgments of value by the consumer. Quality may be seen as the degree to which actions, taken or not taken, maximize the probability of beneficial health outcomes and minimize risk and other untoward outcome, given the existing state of medical science and art<sup>89</sup>.

Medical terminology concerning effectiveness of screening:

	Test	Disease		No disease	
	positive	Α		В	
	negative	С		D	
A=	True Positive (c	lisease)	C=	False Negative	
B=	False Positive		D=	True negative (	no disease)

Specifity = D/ (B+D) (probability that the test really shows that there is no disease) Sensitivity =A/ (A+C) (probability that the test really shows that there is a disease, it is sensitive to the presence of the disease)

Predictive value: test is positive, what is the probability that person has the disease indeed?

#### Harm principle

The harm principle is referring to the external effects of a disease. Because of the fact that infectious diseases were the main cause of death during the nineteenth century, collective action was indicated<sup>90</sup>. The only way to control infectious disease is by comprehensive, collective preventive provisions. Some say this is a governmental responsibility, because contagious diseases are a threat to all. In the Netherlands, the expenses on prevention of infectious disease are relatively high. The current policy on smoking is conducted because of the harmful effects of smoking to other people than the smokers themselves. Smoking is a determinant of lung cancer and lung cancer causes a substantial number of deaths.

When someone experiences a cost (or benefit) which is a side effect of someone else's economic transaction, this is called an externality (or diseconomy). An example of a positive externality is a vaccination campaign, which provides protection both for those immunized and for those with whom they come into contact. The most obvious example of a negative externality in production is the pollution caused by many industries. An example of negative externality in consumption is the effect of passive smoking on the health of non smokers<sup>91</sup>.

The herd community is the opposite of the harm principle: the collective immunity of a population, mainly because of vaccination.

#### **Target group**

Some times policy is based on a specific target group. This is for example a group with low social economic status or a specific disease group with certain identified characteristics. Low social economic status is related to a high burden of disease. The burden of disease might be the decisive criterion, but sometimes the target group has several characteristics at the same time which have been valued as very important. It is difficult to identify which is the specific criterion for a decision, especially if the characteristics (and therefore the different criteria) are all important and all interrelated.

<sup>&</sup>lt;sup>89</sup> USA Department of Public Health

<sup>90</sup> WRR 1997 Volksgezondheidszorg

<sup>&</sup>lt;sup>91</sup> Dror 2005 Hirilamic

#### 13.1.2 Economic decision making criteria

Health economy is a developed expertise because of many reasons. Health care expenditures are about 10% of GDP. In the Netherlands in 2003 it was about 57,5 billion euros. For prevention was spend about 12,5 billion euros<sup>92</sup>. Capital investments in health care are substantial and health care is a source of labor. Health economies are growing. Therefore it may be seen as an important part of macro economics. The value of health economics can also be found in the way solutions are studied and weighed. Economics is about decision making. Many ethical theories have been implemented in economics. Ethical values can be transformed in comparable quantities, although this needs to be done with many reserves in mind.

#### Efficiency

Technical efficiency occurs when the firm produces the maximum possible sustained output from a given set of inputs. Allocative efficiency refers to situations in which either inputs or outputs are put to their best possible uses in the economy so that no further gains in output or welfare are possible.

#### **Cost-effectiveness**

Cost effectiveness analysis needs to be distinguished from medical effectiveness and cost-utility analysis. Three methods of economic evaluation have been developed:

<u>Cost-benefit analysis</u>: costs are valued in money and compared with outcomes also valued in money. <u>Cost-effectiveness analysis</u>: costs are valued in money and compared with a single primary outcome (medical outcome). Cost-effectiveness ratio

<u>Cost-utility analysis</u>: a specific form of cost-effectiveness analysis in which outcomes are measured in terms of Qaly-gained. Qaly's are the utilities.

Economic evaluation stems form Paretian welfare economics. Welfare economics incorporates the principles that individuals are the best judges of their own wellbeing and that if one person can be made better of without another being made worse off there is global improvement in welfare. In policy terms it is practically useless because few policies benefit some individuals without affecting others. CBA translates welfare economics into something which can inform decision making<sup>93</sup>. Submission for a pharmaco-economic dossier is mandatory for all drugs claiming to have therapeutic value since January 2005 in the Netherlands<sup>94</sup>.

There are many methodological difficulties concerning economic evaluation of prevention:

- Discounting: there is a general debate about discounting: the level of discounting (3%, 5%, not at all), discounting costs and benefits at the same level or not. The issue concerning prevention is the fact that effects (benefits) of prevention will be noticeable after ten or twenty years.
- no possible control group to compare/ it is difficult to compare the targeted group with another representative group without the intervention (control group).
- difficult to compare something which did not really happen, it was prevented from happening
- costs of a programme are calculated, benefits are difficult to value
- consequences of preventive programmes are not always transparent or predictable, there are many side effects.
- Dilemma of the benefit of screening is the prevention paradox: individual burden of participation in a programme and societal benefit of early detection of disease

Side-effects:

<sup>&</sup>lt;sup>92</sup> Another estimate is about 14 billion and this was said to be an underestimation. Prevention is part of different sectors and therefore part of different budgets (Kosten van Preventie 2003 RIVM).
<sup>93</sup> Coast J is economic evaluation in touch with society's health values?

<sup>&</sup>lt;sup>94</sup> (penny and pound wise (oostenbruggen over effective treatment)

- Consciousness of people: because of the existence more preventive policies, people may become more conscious of the need of responsible healthy behaviour. This might be seen as the opposite of moral hazard: people tend to take more hazardous health risks because they know there is a cure if something happens
- Some preventive programmes have one target group or target policy and several positive consequences. An example of the domino effect of policies aimed at more physical exercise: more exercise → less overweight → less diabetes → less physical stress → less low back pain → less CVD → healthier diet → healthier babies → healthier effects on relatives and friends.

Because of prevention, the demand for cure might become more efficient. People get more and more healthy years of life. Finally, they will need more care because of conditions of elderly. Care is an expensive part of healthcare. The same can be said about curation. Every life extending intervention, causes a longer life and therefore a higher probability for costs of health care.

#### **Cost-effectiveness threshold**

The implementation of an official cost-effectiveness threshold would imply that the ratio of cost per gained Qaly is the decisive criterion concerning prevention and cure. A threshold in a Qaly league table is aimed at improving allocative efficiency. A cost-effectiveness plane is a way to show the results of an economic evaluation, a threshold can be implemented. These visual representations may help decision makers.

QALY League Table	
Intervention	\$/QALY
GM-CSF elderly with leukemia	\$235.958
EPO in dialysis patients	\$139.623
Lung transplantation	\$100.957
End stage renal disease	\$53.513
Heart transplantation	\$46.775
Didronel in osteoporosis	\$32.047
Statins in high cholesterol	\$18.151
PTA with Stent	\$17.889
terbinafine in onychomycosis	\$16.843
Breast cancer screening	\$5.147
Viagra	\$5.097
Congenital anorectal malformation	\$2.778

An example of a Qaly League Table:

An example of a cost-effectiveness plane<sup>95</sup>:

<sup>&</sup>lt;sup>95</sup> Drummond 2005:131

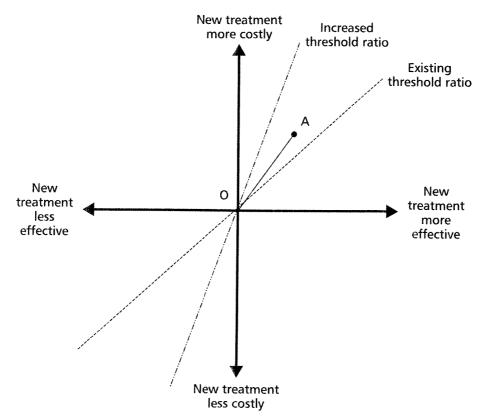


Fig. 5.7 Threshold cost-effectiveness ratios on the cost-effectiveness plane.

- (A) represents a new treatment or programme
- (O) represents the situation when there is no treatment of the current or older treatment
- (OA) represents the incremental cost-effectiveness ratio

The threshold represents the willingness to pay for a unit of effect (this is for example a life year or a Qaly). The two thresholds can be used to compare the effects of the level of a threshold (WTP), in relation to budget impact. Different options can be compared: treatment A falls outside the area of the existing threshold, after increasing the threshold treatment A will be rewarded.

The National Institute for Clinical Excellence of the UK appreciated a cost-effectiveness threshold of £ 42.000,- for cure as being 'good value for money'. The World Bank values the GDP per citizen times three as a cost-effectiveness threshold. The RVZ advised a cost-effectiveness threshold of  $\in$  80.000,- for cure. Based on the Cholesterol Guidelines a cost-effectiveness threshold for prevention was valued at  $\in$  20.000,-.

The level of the cost-effectiveness threshold may be differentiated, depending on severity or burden of disease. As a result, multi criteria priority setting might evolve. Economists argue about the right level of the cost-effectiveness threshold<sup>96</sup>.

#### **Budget impact**

Budget impact shows the financial consequences of a decision concerning the introduction of a certain medical or preventive programme. The budget impact may be acceptable or unacceptable. Severens describes that a cost-effectiveness ratio needs to be combined with the acceptable possibilities within the budget in order to make a decision<sup>97</sup>.

<sup>&</sup>lt;sup>96</sup> David D, P Neumann

<sup>97</sup> Severens JL 2002

Investments and savings combined with epidemiological characteristics of the patient population give input for the total costs of a programme. With this number, the budget impact can be predicted. This is possible either on a individual level and on population level.

The Budget Memorandum is an explanation to the national budget and provides a summary of the most important plans from the ministerial budgets and its financial consequences. Specified per ministry. The National Financial Annual Report states what has been realized in the previous year compared to the budget, submitted a year and half earlier on Budget Day. There are other documents like 'Cost of illness 2003' and the 'Dutch Healthcare Performance Report' about the performance of the Dutch health care system in 2004 which can provide insight in the financial consequences of certain diseases, treatments and healthcare settings.

#### Willingness to pay

Willingness to pay is derived from consumer purchasing behavior for risk reducing devices. Related is willingness to accept which stems from labor economic theory of compensating differentials. Willingness to pay is a method to express preferences: how much is somebody prepared to offer or to pay for something? It is a way to value public health interventions.

#### Individual responsibility

The extent of individual responsibility depends on the (political) choices which are made concerning governmental responsibility (public provision of a good) and solidarity. The responsibility is depending on ideas about whether something is a public good or a merit good.

A public good is one for which consumption is non rival and non excludable. Non rival implies that consumption by one individual does not reduce someone else's consumption. Non-excludable implies that a consumer cannot be excluded from consuming the good either by having to pay or through some other mechanism. Merit goods are commodities thought to be good for someone regardless of the person's own preferences. The debate about public provision of goods, public goods and merit goods is important with regard to prevention. The government chooses that a preventive programme is 'best for you'. Ideas about 'paternalism' or 'healthy policies' vary among policy makers.

#### 13.1.3 Policy decision making criteria

After describing the economic and epidemiological criteria, the probably most elusive criteria will be highlighted in this paragraph. Some terminology stems specific political science and science of public administration.

#### Institutional configurations

Institutional configuration is referring to regulation and structure of the health care system. The problem of decision making is also that rationing at some levels interferes with general principles of many health care systems. The regulation of a country may be seen as the frame work of the system and it possibilities. Rules and regulations may alter; even a law is dynamic. Interpretation and adjustments are part of a regulative system. International, European and national law are harmonized up to some extend. Therefore, this complex system of rules is influencing the national healthcare system and the decisions which are made within the system.

Important Dutch regulation concerning prevention:

- Public health act (collective prevention, local authorities);
- Contagious disease act;
- Tobacco act; Screening act;
- Guidelines, directions and rules concerning health protection of citizens (food safety, use of alcohol, dangerous situations, safe labour, etc).

Every four years the ministry produces a white paper concerning collective prevention. In 2006, the government made a reservation of almost five million euros for prevention policy as it was laid down in the policy document 'Opting for a healthy life'98.

An example of European regulation regarding prevention is the 'Programme of community action in public health 2003-2008'. This comprehensive action programme is an essential part of the European Community's health strategy. The programme concerns health promotion, cancer, AIDS, communicable diseases, drug addiction, health surveillance and pollution related diseases, injury prevention and rare diseases. All member states have to develop policy on these eight existing actions in the field of health.

## Equity and fairness

Equity is a system of justice based on conscience and fairness. Equality is a particular interpretation of equity, because it may be judged that it is fair to be unequal. Equity is a criterion as well as an underlying principle for other criteria. It is intertwined with many goals and objectives of healthcare systems<sup>99</sup>. Van Doorslaer defined horizontal and vertical equity in finance and in delivery (Table below). Equity is operationalised in an economic and econometric way, but because of the normative notion it is valued as a policy criterion.

Equity Table (v Doorslaer)	Finance	Delivery
Vertical	VEF: unequal payment for unequal ability to pay (ATP)	VED: unequal treatment for unequal need
Horizontal	HEF: equal payment for equal ATP	HED: equal treatment for equal need

Operational definitions of equity (Table from Donaldson & Gerard 1993):

Horizontal-equity criteria:

- Equal expenditure for equal need: e.g. equal nurse cost per bed ratios in all acute hospitals
- Equal utilization for equal need e.g. equal length of stay per health condition •
- Equal access for equal need; e.g. equal waiting time for treatment for patients with similar • health conditions, irrespective of factors such as location, age or ethnicity.
- Equal health/ reduced inequalities in health; e.g. equal age- and sex-adjusted standardized • mortality ratios across health regions

People on the same incomes should pay the same amount in income tax.

#### Vertical equity criteria:

Unequal treatment for unequal need; e.g. unequal treatment of those with treatable trivial complaints versus serious conditions, the last ones receive more resources.

Vertical equity means equal access irrespective of income or financial wealth. Progressive financing (progressive income tax rates and mainly income tax financed) is based on ability to pay. Vertical equity taxpayers with different resources must be treated differently. This can be done by introducing a tax structure with progressively rising tax rates.

#### Solidarity

<sup>&</sup>lt;sup>98</sup> Dit betreft uitvoering van de Wet op de Collectieve Preventie Volksgezondheid WCPV, de zogenaamde tweede 'Preventie Nota' Kiezen voor gezond leven. Richtlijnen voor nationaal, regionaal en lokaal beleid in het kader van de beleidscyclus voor Public Health. <sup>99</sup> Distinguish intrinsic and operational goals, see Murray and Frenk 2000: 718

As a moral concept, solidarity gives direction to how a society should be shaped, as a 'moral infrastructure'<sup>100</sup> of the modern welfare state. Income solidarity implies cross subsidies from high income groups to low income groups. Solidarity in health insurance is a redistributive arrangement. If the health insurance premium is unrelated to health risk, it is also called 'actuarial fairness'. When low-risk individuals cross-subsidize high-risk ones it is called risk solidarity (healthy to unhealthy). Furthermore there is solidarity of younger people with elderly people; solidarity of age<sup>101</sup>.

Esping-Andersen used the concept of solidarity in empirical analysis. He compared solidarity in welfare states. Based on this analysis he developed a typology of welfare states: conservative, liberal and social democratic.

The scope of solidarity is the ratio between the entitlements, based on the basic benefit package (coverage) and the membership, referring to the portion of the population which is covered by the public arrangement<sup>102</sup>.

It is difficult to know when you get ill. And if you will be ill, you don't know how much treatment would cost. To cover this risk, one could pool the risk with oneself over time or with a group. The risk pooling with smaller groups was the rise of the first health insurances. The problem of causality is important in relation to solidarity. Even though people have healthy lifestyle, they can get just as many diseases as people with unhealthy manners. On scale of a population, it is observable that a healthy lifestyle will improve health. In individual situations, it is difficult to draw conclusion about the right determinant, causality and the occurrence of illness or the absence of illness<sup>103</sup>.

#### Societal support

Societal support depends on the preferences the public has concerning the extent of solidarity, fear about getting diseased and the need for protection. If somebody is not aware of health risks or is not afraid of health damage, the willingness to pay for collective arrangements or supplementary health insurance is probably lower. It also has to do with trust: does the public trust the actions of the government. Is it valued trustworthy that if there is a public arrangement, that everybody will get what was promised and what they have been paying for through their tax money? Societal support also depends on willingness to pay.

In health care, patient organizations are important. They became even more important in the system of regulated competition in the Netherlands, because patient groups defend their interests to health insurance companies and towards the government. Societal actors are further specified in chapter 10.

#### **Political reality**

Political perspectives frame daily political reality. The political agenda can be swayed by the issues of the day. Therefore, it might be necessary that a minister makes a decision based on available information and insight at that specific moment. Pressure of societal actors and policy stakeholders is part of the situation. Rational decision making based on the 'right' assumptions and perceptions in the heat of the moment is the task. It is difficult to decide what is 'right'.

#### 13.1.4 Underlying rationing principles

This paragraph describes the principles which are underlying or intrinsic to decision making criteria. These principles have a philosophical nature, but they are also interpreted in an economic or legal way.

<sup>&</sup>lt;sup>100</sup> Hinrichts 1995 in Maarse and Paulus 2003

<sup>&</sup>lt;sup>101</sup> Hansen J, Verburg R ao 2005 Zonmw 2003, Dror 2002, WRR 2000

<sup>&</sup>lt;sup>102</sup> Maarse and Paulus 2003

<sup>&</sup>lt;sup>103</sup> Therefore one could argue whether premium differentiation related to lifestyle makes sense or not. Premium differentiation might also be called solidair to people with healthy lifestyle who take responsibility for healthy life.

#### Utilitarianism

The jurist and philosopher Jeremy Bentham (1748–1832) developed the concept of utilitarianism. The basic idea is that the greatest good for the greatest number needs to be achieved by means of maximization of the sum utilities of people. The social welfare function is the sum of individual utilities. As a result of the maximization of the sum of utilities, there is some harm for a few members in return for a greater good for the many. Donaldson and Gerard call it a 'misplaced theory of justice', because it ignores distributional aspects (equity, equality).

In healthcare it may be interpreted as the search for the best possible health outcomes for the greatest number of people. This is expressed as Qaly's or gained years of healthy life. Cost utility analysis implicates an utilitarianistic interpretation of justice. Therefore, decision making based on cost utility analysis (and on a cost-effectiveness threshold) is in fact an implicit choice for utilitarianism as a guiding principle. A utility is a measure of satisfaction Most economic theory is the assumption that people do things because doing so gives them utility. People want as much utility as they can get. However, the more they have, the less difference an additional unit of utility will make there is diminishing marginal utility. (Bishop 2000)<sup>104</sup>.

#### Theory of Social Justice and the Maximin principle

It is difficult to contemplate life in society without personal preferences obscuring ones perspectives. The Rawlsian 'veil of ignorance' is a hypothetical situation to practice to think in an unprejudiced, open minded way about social justice. Rawlsian social justice is justice according the Maximin principle. This principle implies that it is justice to maximize the position of people who are the least well off.

A negative implication of this principle is expressed by Arrow: "Thus there could easily exist medical procedures which serve to keep people barely alive but with little satisfaction and which are yet so expensive as to reduce the rest of the population to poverty". This may be regarded as loss of welfare. The Maximin principle as guiding principle in decision making is a strong presumption in favour of equality. It permits inequalities to arise only if they contribute to the lot of the worst off<sup>105</sup>.

#### Equity

The concept of equity is explained earlier. Equity is a system of justice based on conscience and fairness. Equity can serve as an underlying principle, but also as a decisive criterion. The operationalisation of equity to inform decision making is also explained in paragraph 8.1.3.

#### **Entitlement theory**

The libertarian Robert Nozick published his ideas in 'Anarchy, state and utopia' in 1974. The tenor of his theory is that the market mechanism is considered to be a fair rationing mechanism.

Only free market exchange would imply that people are equal parties. Even if a free market did not produce the most overall well being according to Nozick's view, it would be justified. The theory consists of three principles<sup>106</sup>:

- Transfer principle: Holdings (actually) freely acquired from others who acquired them in a just way are justly acquired.

- Acquisition principle: Persons are entitled to holdings initially acquired in a just way (according to the Lockean Proviso).

- Rectification principle: Rectify violations of the first two principles by restoring holdings to their rightful owners, or a one time redistribution according to the Difference Principle.

If people's current holdings are justly acquired, then the transfer principle alone determines whether subsequent distributions are just. Consequently, any taxation over the amount required to preserving

<sup>&</sup>lt;sup>104</sup> The methodological debate about the fact whether a Qaly is an utility is highlighted in the appendix, see Drummond 2005

<sup>&</sup>lt;sup>105</sup> Folland, Goodman and Stano 2004, Donaldson and Gerard 1994

<sup>&</sup>lt;sup>106</sup> Johnson 1995

institutions of just transfer, acquisition and rectification that is, preserving entitlements according to Nozick, are unjust. On the other hand, people frequently accept rules that restrict liberty somewhat because they expect some outcomes to improve life for themselves and others.

#### Egalitarism

Egalitarism is the striving for the utmost equality in health and healthcare. Patients with the worst health need to be cured first. Commodities or societal benefits have to be distributed in equal shares. The extent of decommodification<sup>107</sup> is a measure for the welfare state of a country<sup>108</sup>. The welfare state is developed in order to compensate people who are in need of financial help. This gives people more equal possibilities to live their lives.

#### The Rule of Rescue

In 1986, Jonsen developed the idea of the 'rule of rescue' as a rationing mechanism. Every possible action needs to be undertaken in order to safe a life or to avert a life threatening situation.

If the total social utility gained from the Rule of Rescue, including the utility gained from having reinforced within the community the belief that life is valuable and worth great effort to preserve, outweighs the utility sacrificed by not putting resources to the best alternative use, then the Rule of Rescue would be justifiable from a utilitarian point of view. On the other hand, fairness requires that we do not discriminate between individuals on morally irrelevant grounds. Being identifiable as the one who is being rescued does not seem to be a morally relevant ground for discrimination<sup>109</sup>.

#### The concept of Pareto Optimality

Vilfredo Pareto defined, in the early nineteenth century, an economically efficient outcome in society as one under which it is impossible to improve the lot of any person without hurting some one else. An efficient economy necessarily would have exhausted all means for mutual gains.<sup>110</sup> A Pareto improvement is the situation in which the level of welfare of one or more parties can be improved without hurting any other party.

#### Political ideology

The political spectrum may function as a framework for decision making. The ideas and principles of ideologies like social democracy, liberalism, libertarianism, social liberalism, socialism, the third way and others have been crystallized out in the past. There is an ongoing debate between people guided by their ideologies about the interpretation of the right to health care, governmental responsibilities, the welfare state and also about the right principles and criteria for decision making. Political ideology is not something which is about right or wrong, but about a process of thinking and learning. Political actors decide on the current limits and possibilities of policy issues. When considering policy issues, the windows of opportunity may depend on political coalitions. The structuring and financing of a health care system is depending on political choices. In the Netherlands, some political parties prefer to invest in prevention, other have different priorities.

#### Fair Innings concept

This concept is a kind of rationing by age, developed by Alan WIliams in 1997<sup>111</sup>. Everyone has the same amount of innings. People are entitled to a normal (average) span of life at a reasonable level of quality. This might be expressed as an amount of Qaly's, everybody is entitled to the same amount of Qaly's. If an older person has had his or her 'innings' or treatment before, the fair innings concept would require the treatment to go to a younger person. The central issue lies in how much society

Decommodification is the extend of which goods are subsidized by government money, it is also a way to express the government responsibility in a country – Based on Esping Andersen and others

Esping Andersen 2000 ao

<sup>&</sup>lt;sup>109</sup> Richardson and McKie 2003

<sup>&</sup>lt;sup>110</sup> Folland Goodman and Stano 2004: 378

<sup>&</sup>lt;sup>111</sup> Folland, Goodman and Stano 2004

prefers to help the one versus the other.

#### 13.2 Literature search for decision-making criteria in public health

In the following table, information about literature is ordered by author, identified criteria and type of source. As said in the methodological chapter, the criteria need to be defined in a explicit way (definition and operationalisation) or need to be described in relations to other criteria and for instance rationing principles. An implicit referral to a criterion is not taken into account.

Source	Decision making criteria (prevention/ cure / care)	Type of source
	Studies	
PHSF 2006	Health gain, burden of disease, quality of life, SES	study
Rutten & Brouwer	Efficiency, cost en clinical effectiveness, cost utility	Study
2004	threshold, cost sharing, budget impact	
Groot & Maassen	Comparison of cost per gained year of life for care and cure, efficiency	Study
Ottes and Rijen	Uninsurability, substitutability of cure programmes () pg 13	Study
Rijen & Ottes	Prioritisation by public, Societal support	Study
Bal & Lindeloof	Societal support	Study
Oortwijn 2005	CE-threshold, efficiency, equality, need, solidarity, individual responsibility (WTP& ATP), effectiveness	Study
Guideline cholesterol	Cost-effectiveness, effectiveness, efficiency	Study
Donaldson C	Efficiency, equity, effectiveness	Study
Stolk EA 2003	Equity, solidarity, efficiency	Study
Severens 2002	Cost-effectiveness and budget impact combined	Oration
Mayard	Efficiency, equity-fairness, WTP, ATP, benefit-need,	Study
•	Advisory studies	
Sensible and	Cost effectiveness, cost-effectiveness threshold, threshold	Advisory
sustainable care RVZ	follows burden of disease, societal support, and more	study RVZ
2006	implicit as consequence of CE: justice, solidarity	
Zorg in model CPB	Medical need versus economic demand, budget impact,	Advisory
2006	market mechanism (meso: expected production of hospital)	Study CBP
Preventie beleid RMO	Epidemiological characteristics like diseases incidence and	Advisory
2005	prevalence, risk populations, cost-effectiveness, SES,	study RMO
	effectiveness of prevention workers, of prevention in cure,	
Contouren van het	Criteria of a basic benefit package based on solidarity:	Advisory
basispakket GR 2003	burden of disease and cost-effectiveness, based on	study GR
	universal basic benefit package: SES, external effects,	
	efficiency effects on health care	
Gezond zonder zorg RVZ 2000	Health gain by means of facet policy	Advisory study RVZ
Volksgezondheidszorg	Public health responsibility: necessity, risk solidarity,	Advisory
WRR 1997	effectiveness, positive and negative external effects, solidarity	study
Kiezen en Delen 1990	In ranking order: necessity, clinical effectiveness, efficiency,	Advice of
	individual responsibility, out of pocket payments	government
		committee
	White papers	

Preventie brief 2006	Expectation of life, Healthy years of life, Health inequalities	White paper
Zorgbalans 2006	Quality, Accessibility,	Government
-	Budgetimpact/ affordability	Evaluation
		study
Nota Gezond en Wel	Efficiency and necessity	White paper
Zorg nota 2000	Burden of disease, Necessity: medical need	White paper
	Effectiveness: medical success	
	Opinion articles	
Dondorp W (HMF)	Critical about possibility of objective (quantitative)	Opinion
2006	prioritisation	article
Jakson J & de Beer P	CE analysis is necessary to weigh decisions, effectiveness,	Opinion
(NRC) 2006	efficiency, CE-threshold (level is disputable), further	article
	'normative questions'	
Verkerk M (NRC) 2006	Necessity, justice, solidarity, costs, burden of disease,	Opinion
	effectiveness, definition of cure based on ethics	article
Trappenburg M (NRC)	Disease, 'yardstick of public health' (CE-threshold), which	Opinion
2006	will lead to comparison of incomparable quantities	article
CHSRF Myth busters	Health gain, cost-effectiveness	Opinion
2003		article
Hartogh G den (Trouw)	Quantified qualitative measures is quasi exact –prefers	Opinion
	weighing several criteria by experts	article
Meerding WJ (Trouw)	Quantified qualitative measures are a tool for decision	Opinion
	making	article
iBMG manifest (iBMG	Patient focused cure and care: quality and cost effectiveness	Manifest
EUR) 2002	Healthcare market: solidarity and efficiency, right to health	
	care	
	International and other national publications	
NIH	Public health needs, scientific quality of research, probability	Advisory
	of success (effectiveness),	study
NICE	Additive to cost-effectiveness: equity (equal access, starting	Study UK
	point of health gain), budgetary effect, burden of disease	
	(prevalence, incidence, treatments, deaths), opportunity	
	costs	
Oregon, Medicaid	Cost-effectiveness, expert opinion, public opinion,	BBP decison
(1989)		
Lalonde (1974)	Population health: epidemiological characteristics,	White paper
	influencing biological, physical, social, lifestyle and health	Canada
	determinants	
McKee & Mossialos ea	Most countries use criteria implicit. Netherlands: funnel of	International
DM in PH	Dunning. France is explicit: burden of disease, societal	Study
	values and priorities, inequalities in health outcomes, current	OEHSP
	state of knowledge about the conditions/ health problems	
	etiology, determinants or risk factors, treatment options and	
	effectiveness of actions (pg 30)	

#### 13.3 Interviews: Questions and answers

#### 13.3.1 Questions

- What decision making criteria for public health do you think are important? What decision making criteria for prevention do you think are important? -
- -

- What is the role of economic evaluation in decision making in health and public health?

- What do you think of a cost-effectiveness threshold?

- What are the problems of decision making in public health policy and more specific in prevention? After findings of literature research, a stage before the final raw list of criteria:

Do you know any other decision making criteria?

#### 13.3.2 Answers

#### I Preferences about a cost-effectiveness threshold and other decision making criteria

Statements about cost-	Suggested alternatives and preferences	Respondent
effectiveness threshold		
<i>Disapproval</i> of the use of a cost- effectiveness threshold	Equity, qualitative aspects of health, social economic status	RIVM
Does a cost-effectiveness threshold offer the right consensus you are looking for?	Cost effectiveness may not prevail against alternative criteria like equity How do you weigh qualitative criteria next	
	to the 'number'	
Preference for other criteria	Solidarity poor/ rich, necessity and efficiency preference for specific preventive measures Balancing cure and prevention	RIVM
A cost-effectiveness threshold	Own responsibility	RIVM
should not be the only measure		
Prefer other criteria	Social economic status	RIVM
Cost effectiveness threshold is preferable	Preference for clear and effective measures, other wise it is waste of money	VWS
A cost effectiveness threshold concerning prevention or public health will be <i>difficult</i> to maintain	Difficult underpinning of criteria, there fore difficult agreement and difficult decision making	VWS
It is the question which incentive you want to use, in order to get the wanted results: steering with <i>financial incentives</i> evokes certain responses	It is not right if the position of the weak is the leading principle in decision making on macro level	VWS
If a cost-effectiveness threshold will lead to efficient demand for cure, sustainability of the system and support for solidarity is promoted		VWS

## II Integrated healthcare: prevention, cure and care

Statements about integration of prevention and cure	Respondent
More prevention in <i>protocols</i> is preferable	VWS
Integration of prevention and cure both on level of <i>local authorities</i> and on level of	VWS
national authorities: influencing behaviour on both levels together, probably more	2x
impact	
Because of integration of prevention and cure, more health gain is achievable	VWS
especially while having direct patient contact: infant welfare centre, gp-care,	

nursing assistance, elderly care	
Integrated perspective: prevention may cause savings of AWBZ-expenses,	VWS
integration of cure and prevention may decrease demand for care	
Currently, there is no integrated prevention policy	VWS
The VTV indicates the need for intersectoral public health policy. The VTV might	RIVM
be agenda setting in this way.	
Until now, policy of infectious disease cover a main part of prevention budget.	RIVM
This is not according the available information about public health, there should	
be more integrated and intersectoral policy.	

#### III Prevention and demand for cure

Statements about decision making criteria and comparison between	Respondent
prevention and cure	
Integration of prevention and cure or more spending on prevention might be	VWS
important for the sustainability of solidarity: less unnecessary spending on cure	
because of a more efficient demand for cure – more support to show solidarity	
(also willingness to pay)	
More efficient demand for cure will cause less unnecessary spending on cure, this	VWS
will cause more productivity (societal benefit). Absenteeism may decrease. (if	
prevention is preferred more)	
More prevention will lead to an efficient demand for cure	VWS
Own responsibility needs to be emphasized in order to achieve responsible	VWS
behaviour. By means of premium differentiation people are forced to take	
responsibility, but this has several positive and negative consequences. It is	
important to find the <i>right combination of incentives</i> in order to promote healthy	
life, which eventually may lead to a more efficient demand for cure	
Cost-effectiveness of prevention seems to be unattractive according to studies of	VWS
the RIVM, because of deferring health care costs to a later stage of life. To	
prevent sickness may cause more costs. The same can be said about cure:	
curation of a disease may cause a longer life and therefore more demand for cure	
and care.	

### IV

Statements about prevention and intersectoral public health policy	Respondent
Intersectoral public health policy is like a car with eight wheels standing in a	VWS
different direction	
It should be interesting to <i>compare what each department spends</i> for one Qaly gained, in order to get the impression of unofficial spending thresholds	VWS
There is <i>no incentive</i> for average employers to buy insurance including prevention, they don't see what it will add to their company or business. Investing in maintenance of machines makes sense, it is shown as depreciation values on the balance. Machines don't run. There is also the dilemma of a very good employee with very bad habits. An employer is not going to deal with these bad habits as long as the employee is functioning very well	МКВ
The government has the responsibility to cultivate healthy habits in a broader sense, by means of media. Consumers don't know about healthy food any more: they buy things which are wrapped practical and not outdated. If the consumer wants it, retail and chains of shops will adjust to this demand. If children appreciate healthy food, parents buy healthy food more easily. Integrated and intersectoral public health policy might promote a change in this direction. When this will happen, negotiation between insurance companies and employees might	

occur more.	

## v

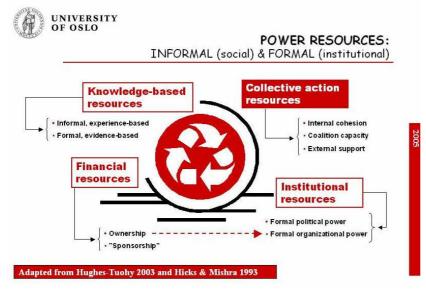
Statements concerning public health policy and decision making	Respondent
If the government would like to have support for its decisions, policies should be	Hospital policy
motivated. The decision making criteria and motives should be made explicit.	maker
The most important thing is that it is <i>legitimized</i> what is chosen. Now it gives the	МКВ
impression of 'pick and choose policy'.	
Is policy following information or is information following policy?	RIVM
Aversion against incidental policy	

Elements of policy making<sup>112</sup>

# **Elements of public policy-making**

"Who"	Participants in the policy process (policy actors) – responsibilities, authority, competences
"What"	What is it that they want to achieve, and is it realised? – policy motives, goals, objectives and effects
"How"	How can they realize their policy goals? – resources & policy instruments
Policy context	Conditions for policymaking – broader societal environment – governance structure and culture – stakeholders, social support & resistance

#### **Power of Resources**



#### Policy cycle

<sup>&</sup>lt;sup>112</sup> van der Grinten 2005, sheets EUR

Beleidscyclus	Applied problem solving	Policy stages
1 Detectie van het beleidsprobleem	Problem recognition	Agenda setting
2 Bepalen van de beleidsdoelen, tijd en plaats	Proposal of solution	Policy formulation
3 Keuze van beleidsinstrumenten 4 Analyseren van de beleidsalternatieven 5 Nemen van een beslissing	Choice of solution	Decision making
6 Implementatie van de beslissing	Putting solution into effect	Policy implementation
7 Evaluatie van de beleidsuitkomsten	Monitoring results	Policy evaluation