

## Summary

The summary of my PhD thesis is structured as follows:

- I. Introduction
- II. Research description
- III. Assessment of cases from day-to-day practice
- IV. Presentation of the assessment model
- V. Consideration of the research and assessment model

### I Introduction

Lifestyle-related diseases are increasingly posing a risk to public health across the globe in both relative and absolute terms. In relative terms because today the majority of infectious diseases which in the past posed a threat to public health can be successfully controlled, and in absolute terms because a large proportion of the population is leading an increasingly unhealthier lifestyle in part as a consequence of growing prosperity. An unhealthy lifestyle includes for instance smoking, overconsumption, an unhealthy diet, insufficient physical exercise and excessive alcohol consumption.

The prevention of lifestyle-related diseases can be carried out in a variety of ways. Obesity, for instance, could be prevented, by:

- encouraging or obliging people to take more physical exercise;
- encouraging or obliging people to follow a diet;
- encouraging or obliging manufacturers to reduce the quantity of sugar and fats, particularly unhealthy fats in food;
- introducing compliance regulations for the size of portions available in supermarkets and provided by the catering industry;
- imposing restrictions on advertising food, drinks, and stimulants
- etc.

While the effectiveness of several of the above measures is debatable, on the other side of the coin it is becoming increasingly clearer that the provision of information alone usually fails to spur people to lead healthier lives. A growing number of scientists are therefore advocating that various means be employed *to*

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*force or pressurise* the public into developing healthier behaviour and to spur the food industry to offer a healthier range of products and curtail their marketing ploys in luring people to over-consume. Prevention measures aimed at influencing or even prohibiting the production, distribution and consumption of food, drinks and stimulants, however, encroach on the population's freedom of choice and on free enterprise. To what extent is the application of such measures justified and how can this be assessed? The question prompted me to develop a model for the purpose of assessing the justification of lifestyle-influencing interventions aimed at controlling lifestyle-related diseases.

## II Research description

### II.1 Definition of the problem and research question

The risks of prevention measures aimed at controlling lifestyle-related diseases for the population's freedom of choice, the financial interests of the business community, and the free movement of goods and services, raise a key question and that is: to what extent are prevention measures justified? On the basis of the definition of the problem, I formulated a research question when I commenced my research in 2005. On the basis of having gained enhanced understanding, I fine-tuned the research question on a number of occasions while performing the research (§1.2). The fourth and final version of the research question is as follows:

#### *Final version of the research question (2008)*

Can a model be developed for the purpose of assessing the justification of prevention measures that seek to influence people's lifestyles in an effort to control lifestyle-related diseases?

### II.11 Focus on justification of the line of reasoning

In my view two pillars underpin the justification of applying a prevention measure as follows:

1. justification of the *line of reasoning* leading to the decision to apply the prevention measure;
2. justification of the *procedure* (what influence can be exerted on decision-making by what parties and when?) leading to the decision to apply the prevention measure.

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My assessment model focuses on justifying the line of reasoning. Depending on the case, consideration should be given to the extent to which procedural aspects are relevant for substantively assessing justification of the prevention measure. The assessment of the procedural justification in itself falls outside the scope of my assessment model (§12.4.4).

### *II.III Research approach and methods*

#### ***Research approach***

In order to answer the research question, I conducted research, which comprised two parts:

- developing the assessment model on the basis of a ***literature search*** (Chapters 1-4);
- empirical testing of the assessment model on the basis of ***cases from day-to-day practice*** (Chapter 5-14).

In terms of content, the literature search was broken down into three parts:

- research into established assessment models which can be used to assess the development of the proposed model (Chapters 2 and 3);
- research into the assessment principles underlying the proposed model (Chapter 4);
- research into examples of the prevention of lifestyle-related diseases in day-to-day practice (Appendix 6).

I tested the accuracy, completeness and practical application of the model I developed on the basis of two cases from day-to-day practice:

- the prevention plan of Clarion Health Partners, one of the largest collaborative hospital organisations in the USA (Chapters 5-9);
- the statutory smoking ban in the Dutch catering industry (Chapters 10-14).

Why these cases are chosen, is explained at the beginning of Chapter 5 (Clarion) and at the beginning of Chapter 10 (smoking ban in the catering sector).

While empirically testing my model on the basis of cases from day-to-day practice, I operationalised the criteria for the model and determined the assessment method for each criterion. For the purpose of operationalising the criteria and determining the corresponding assessment method, I used the literature that I had studied as well as the cases referred to above.

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*Description of the Clarian Health case*

In 2007 the collaborative US Hospital organisation Clarian Health announced plans to launch a completely new approach to reduce the annual health-care costs of its employees in 2009. Clarian's plan entailed imposing a financial penalty on its employees for leading an unhealthy lifestyle. To that end Clarian had established the following unhealthy life-style indicators: smoking, seriously overweight, high blood pressure, high cholesterol and glucose levels, on the basis of which employees would be penalised each month. Clarian's prevention plan generated much consternation in the media, with news pages and weblogs on the Internet devoting an enormous amount of coverage to the plan. The numerous written responses to the prevention plan afforded me a unique opportunity to test the accuracy, completeness and practical application of my model empirically. To that end I assessed the justification of Clarian's prevention plan on the basis of the criteria applied in my model.

*Description of the case of the statutory smoking ban in the Dutch catering industry*

'The proof of the pudding is in the eating'. That's why I tested the accuracy, completeness and practical application of my model once again by assessing the justification of the statutory smoking ban in the catering industry on the basis of my model. The Dutch government imposed the statutory smoking ban on the Dutch catering industry, which entered into force on 1 July 2008. I have therefore based the assessment of the justification of the smoking ban on the official documents which the Dutch government has used to date to substantiate the formulation and application of the smoking ban. My literature search into the government's reasons for substantiating the introduction and enforcement of the smoking ban covers a period of over 25 years (November 1984 - June 2011). The meeting documents of the Lower House and Upper House of Dutch Parliament, news messages on the Ministry of Health, Welfare and Sport website and relevant laws and regulations (§10.2) formed the core of my literature search.

**Research methods**

I used three research methods (§1.5) to perform my research as follows:

- literature search;
- argumentative text analysis;
- reasoning.

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### III Assessment of cases from day-to-day-practice

#### *III.I Justification of the Clarian Health prevention plan*

On the basis of the information available on the Internet about the Clarian Health prevention plan, the design (first filter of my model), the effects and side effects (second filter) and the implementation method (third filter) of the prevention plan **are unjustifiable** according to my model. Firstly, this is because insufficient information is available on many of the criteria in my model for the purpose of making a reliable assessment. And secondly, because based on the information that is available, the conclusion can be drawn that the application of the Clarian Health prevention plan in its present form is unjustifiable. The main points of criticism in terms of substance are as follows:

- I consider the US federal government’s decision to give employers – albeit within a finite financial framework<sup>1</sup> – the opportunity to impose at their discretion a financial penalty on their own employees for leading an unhealthy lifestyle inside and outside working hours as highly disputable. In my view employers are not qualified to design and implement prevention measures of this nature. To avoid the inequality of rights among different employers’ employees and employer arbitrariness, it would in my view be better for the democratically elected central government to decide on the design of such prevention measures. I believe it would be preferable to leave the implementation of such prevention measures to a trusted third party, such as a health insurer. (§6.7) In my view the intrusive nature of the prevention measure (structural infringement of physical integrity and privacy) cannot be justified for employees who do in fact conform to Clarian’s health criteria. (§7.7)
- The fact that the prevention plan could create serious financial difficulties for Clarian employees (and their families) or make them default on the payment of their health insurance premium I regard as unjustifiable. A hardship clause may perhaps help resolve this situation (§7.7).

#### *III.II Justification of the statutory smoking ban in the catering industry*

##### ***Lack of clarity on the objective***

The introduction of the smoking ban in the catering industry involved extensive public political debate. For this reason I find it odd that after having studied the parliamentary documents I found that the debate failed to create clarity on the

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1. See Appendix 8: Explanatory notes to §f of the HIPAA.

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objectives underlying the statutory smoking ban in the catering industry. The successive Ministers of Health, Welfare and Sport adopted different views on the objective underlying the catering industry smoking ban (§10.5).

In my view, in June 2007 the Lower House of Dutch Parliament should not have concurred with the statement made by Ab Klink, former Minister of Health, Welfare and Sport, who affirmed that visitor protection is a secondary objective of the statutory smoking ban in the catering industry. It emerged that the term ‘secondary objective’ could be interpreted in multiple ways. In July 2007 Mr Klink regarded ‘a secondary objective’ as an objective, in which case protecting visitors against passive smoking falls under the criterion ‘risk of harm’ in the first filter of my model. In July 2009 Mr Klink regarded ‘a secondary objective’ merely as a ‘positive side effect’, in which case protecting visitors against passive smoking falls under the criterion ‘cost-benefit ratio’ in the second filter of my model. I believe Mr Klink failed to adequately substantiate the change in views on the objective underlying the statutory smoking ban imposed on the catering industry.

In terms of the clarity of the objectives underlying the statutory smoking ban in the catering industry, the ban *cannot pass* through the *first filter* of my assessment model (logic of the design) during Mr Klink’s reign as Health Minister. I regard the introduction of a statutory smoking ban in the catering industry without having clear underlying objectives as reflecting *a lack of clarity*.

Considering that public amenities should be freely accessible to all members of the public, I believe that people visiting catering outlets should be given statutory protection against smoking. I therefore disagree with the position taken by the current caretaker Minister of Health, Welfare and Sport Edith Schippers who says that the objective of the statutory smoking ban in the catering industry should be confined to protecting catering industry employees against passive smoking. The position adopted by Ms Schippers fails to conform to the spirit (see under the criterion ‘legitimacy’ in §12.4.2) of:

- the Tobacco Act;
- the WHO Framework Convention on Tobacco Control (2003);
- the agreements made by Hans Hoogervorst, former Minister of Health, Welfare and Sport, with Koninklijk Horeca Nederland, the trade association for the catering industry in the Netherlands, concerning the action plan aimed at the self-regulation of smoking policy in the catering industry (2004);
- the Recommendation formulated by the Council of Europe on smoke-free environments (2009).

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My personal view on the need to ensure the statutory protection of visitors to catering outlets against passive smoking, however, is irrelevant in the context of my model. I regard the fact that the position adopted by Dutch Health Minister Edith Schippers does not conform to the spirit of the above four documents as an inadequate reason for acknowledging that her position is unjustifiable. In a formal legal sense, in my view the above documents do not – insurmountably – impede the position adopted by the Health Minister Edith Schippers.

In terms of the clarity of the objectives underlying the statutory smoking ban in the catering industry, the ban **can in fact pass** through the **first filter** of my assessment model (logic of the design) during the reign of Edith Schippers as Health Minister. The Health Minister's view is **clear** (transparent) and cannot be interpreted in multiple ways. According to Ms Schippers the objective of the statutory ban in the catering industry should, and is in fact confined to protecting employees against passive smoking.

***Formal wording of the Act as a starting point for assessing the statutory smoking ban***

*Employee protection as a starting point for the assessment*

Due to the lack of clarity on the objective of the statutory smoking ban in the catering industry during Ab Klink's reign as Health Minister, I assessed the justification of the statutory ban on the basis of my model, taking the formal wording of the Act as a starting point. The formal wording of the Act only offers employees protection against passive smoking (§10.5). From the perspective of my model, the limited objective of the statutory smoking ban in the catering industry in itself is not unjustifiable (§10.6.4).

*Logic of the design (first filter of the model)*

The statutory smoking ban in the catering industry **can pass through** the first filter with the objective of protecting employees in the catering industry against passive smoking: the design is logical. It is not moralistic, it is not perfectionistic nor is it paternalistic.

*Effects and side effects (second filter of the model)*

The statutory smoking ban in the catering industry as introduced by the former Health Minister Ab Klink on **1 July 2007 cannot pass through** the second filter: one of the possible or actual side effects is unfair. It is important to note that the observed unfairness relates only to a **minor** part of the catering industry – the small cafés which have no staff. The aspect of 'hardship in specific cases' under the

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‘justification’ criterion serves as the breaking point for justifying the smoking ban in small cafés which have no staff. In relation to the objective of the smoking ban for small cafés which have no staff – i.e. the prevention of unfair competition with cafés with staff – the financial implications for these types of cafés could possibly be disproportionate. I have said ‘possibly’ because no financial validation is available. I have taken into account that there is less unfair competition in day-to-day practice than expected. As soon as small cafés that have no staff attract more visitors on account of the fact that visitors are allowed to smoke in these establishments, the small cafés will indeed need to employ staff. This, in turn, means that the smoking ban will apply with immediate effect.

The current statutory smoking ban in the catering industry, which excludes small cafés which have no staff, **can pass through** the second filter (effects and side effects).

*Implementation method (third filter of the model)*

The statutory smoking ban in the catering industry **cannot pass** through the third filter. The manner in which the ban was implemented is unreasonable and unfair in certain areas.

In implementing the statutory smoking ban in the catering industry, in my view the former Health Minister Ab Klink bungled on too many occasions, which makes it difficult to acknowledge that the implementation method is justifiable. On the one hand he had little consideration for ensuring continued and increasing support for the statutory smoking ban in the catering industry from *Koninklijk Horeca Nederland*, the trade association for the catering industry in the Netherlands, and from catering businesses. For more information, see the criteria ‘timing’ (§13.1.3) and ‘support’ (§13.2.3) under the heading ‘Conclusion’. On the other hand, he paid little attention to the supposed unfavourable financial consequences of the implementation of the ban for small cafés which have no staff. For more information, see the criteria ‘complementary policies’ (§13.3.3) and ‘verifiability’ (§13.4.3) under the heading ‘Conclusion’.

In respect of the implications for enforcing the smoking ban, in my view by exempting small cafés which have no staff from the smoking ban the Dutch Health Minister Edith Schippers was **careless and negligent** in relaxing the statutory smoking ban in the catering industry. For more information, see the criterion ‘enforceability’ (§13.4.3) under the heading ‘Conclusion’. It is important to note that the carelessness and negligence observed relates only to part of the catering industry - the cafés. The carelessness and negligence, however, form an



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inadequate reason for acknowledging that the relaxation of the statutory smoking ban implemented by the Health Minister Edith Schippers is unjustifiable. However, what does apply is the *sub-optimal implementation of relaxing* the statutory smoking ban by the Health Minister Edith Schippers.

## IV Presentation of the assessment model

The definitive research question I have endeavoured to answer is as follows (§1.4):

Can a model be developed for the purpose of assessing the justification of prevention measures that seek to influence people's lifestyles in an effort to control lifestyle-related diseases?

I have answered the research question by presenting the definitive version of my model in §15.1.

The model comprises three components:

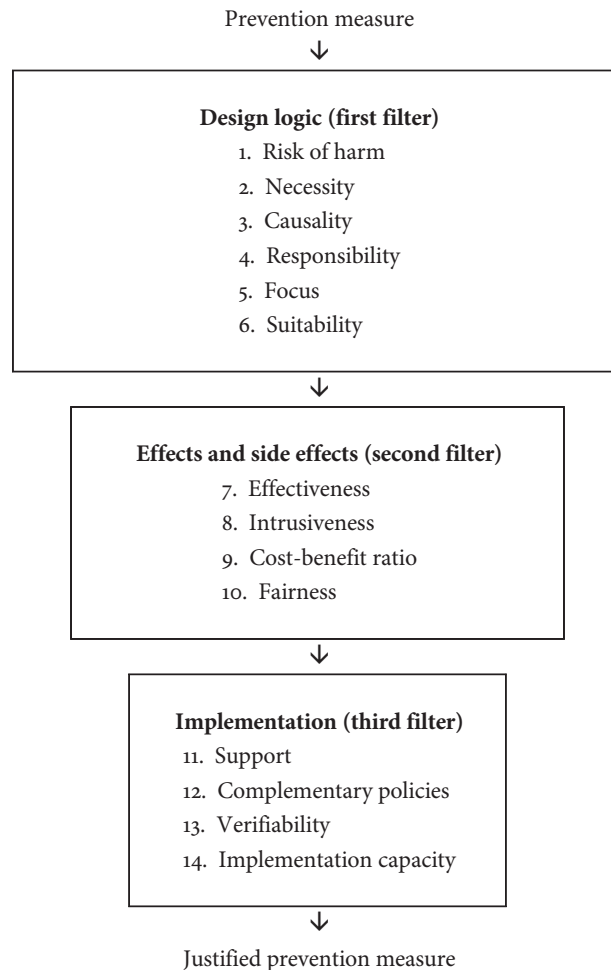
- **assessment criteria:**
  - operationalisation of the criteria (§15.1.1).
- **assessment structure:**
  - assessment filters (explicit assessment structure) (§15.1.2);
  - assessment clusters (implicit assessment structure) (§15.1.2);
- **assessment method:**
  - assessment method in broad outline (§15.1.3);
  - assessment method detailed by criterion (§15.1.1).

### IV.1 Assessment criteria

The development of versions 1-6 of my model is primarily based on literature relating to established assessment models (Chapters 2-4) whereas the development of versions 7-9 is based on testing my model against cases from day-to-day practice (Chapters 7-14). The definitive assessment criteria are shown in Figure 28 below.

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**Figure 28: Definitive assessment criteria of my model**



The operationalised criteria are set out below in key words (for a detailed description, see §14.2.1).

**1. Risk of harm criterion**

- What harm, disturbance or nuisance or infringement of moral views does the prevention measure endeavour to control?

**2. Necessity criterion**

- To what extent is the prevention measure necessary?
- To what extent is the prevention measure moralistic or perfectionistic?
- Are penalties imposed on the persons or organisations causing the risks?

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### **3. Causality criterion**

- To what extent do the lifestyles targeted by the prevention measure form the driver of the risks that one seeks to control?
- What are the driving factors behind the lifestyles targeted by the prevention measure and to what extent are they determinant?

### **4. Responsibility criterion**

- What parties are held responsible for creating or maintaining the risks that one seeks to control?
- In determining responsibility, have all known risk drivers (third criterion) been taken into account?
- To what extent is the prevention measure paternalistic?

### **5. Focus criterion**

- Is the choice of target group and life-style influencing factors logically related to the risk drivers (third criterion) and responsibility (fourth criterion) for these risks?
- Have people in the target group been overlooked by the prevention measure or have they fallen outside the target group by the prevention measure?

### **6. Suitability criterion**

- Does the choice of parties implementing the prevention measure relate logically to the focus (fifth criterion) of the prevention measure?
- Are the parties implementing the prevention measure competent, authorised and suitable for doing so?
- Will implementation of the prevention measure not harm the nature or the reputation of the parties that are implementing the measure?

### **7. Effectiveness criterion**

- To what extent have the intended effects of the prevention measure been achieved?

### **8. Intrusiveness criterion**

#### **I. General assessment:**

1. To whom does the intrusion of private life apply?
2. Who is responsible for the intrusion of private life?
3. To what extent does the intrusion of private life apply?
4. How significant is the intrusion of private life?
5. Is allowing the intrusion of private life creating a precedent?
6. How inconvenient is the intrusion of private life?

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II. Assessment of various aspects:

- a. infringement of physical integrity;
- b. violation of liberties;
- c. infringement of privacy;
- d. infringement of perceived safety;
- e. discrimination;
- f. stigmatisation.

III. Assessment of the degree of pressure or force applied.

**9. Cost-benefit ratio**

- What are the costs and benefits of the prevention measure and what is the cost-benefit ratio (ratio of burdens to benefits)?

**10. Fairness criterion**

- Are the costs distributed across the parties in proportion to their level of responsibility for the risk of damage?
- Are the parties treated equally in the same cases?
- Have people's means been taken into account?
- Has account been taken of people's personal circumstances or the specific circumstances of organisations?
- Have the equal opportunities of the parties involved been affected in respect of their access to health care and prevention?
- Has the distribution of the available health-care and prevention funds been influenced in line with needs?
- Does the prevention measure not violate the current Act or legally effective agreements?

**11. Support criterion**

- Is it the right time to apply pressure or force?
- Have people and organisations been gradually prepared for the prevention measure?
- To what extent has emphasis been placed on garnering support for the prevention measure?
- Are the current political, economic and social circumstances appropriate for implementing the prevention measure?
- Is the prevention measure consistent with the policies pursued by stakeholders?
- How much support is there for the prevention measure?

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## 12. Complementary policies criterion

- Has the prevention measure been anchored in broader prevention or other policies?
- Is there no policy that conflicts with the prevention measure?
- How is information provision concerning the prevention measure organised?
- How is enforcement of compliance with the prevention measure organised?
- Will constraints be identified and resolved during implementation?

## 13. Verifiability criterion

- Are the 'design', the 'effects and side effects' and 'implementation' of the prevention measure monitored and evaluated?

## 14. Implementation capacity criterion

- Have a sufficient number of people and funds been made available to ensure that implementation of the prevention measure is feasible and sustainable?

### *IV.1 Structure of the assessment model*

I derived the concept of the filter structure from the 'Trechter van Dunning', an assessment model based on the concept of a 'funnel' with successive filters (the literal translation of 'trechter' is 'funnel') developed in 1991 by the Committee on Choices in Health-Care (*Commissie Keuzen in de Zorg*) headed by the late Dutch cardiologist A.J. Dunning.

The first reason for applying the principle of a 'funnel' with successive filters is that the **sequence** in which the assessment criteria in my model are used has a huge impact on the substance, and consequently the **validity** of the assessment process. The clustering of the assessment criteria in filters clearly shows why the sequence of the criteria is vital.

The second reason for applying the principle of a 'funnel' with successive filters is that it is easier to manage the total number of 14 criteria. If information fails to pass through a certain filter, the underlying criteria need no longer be examined.

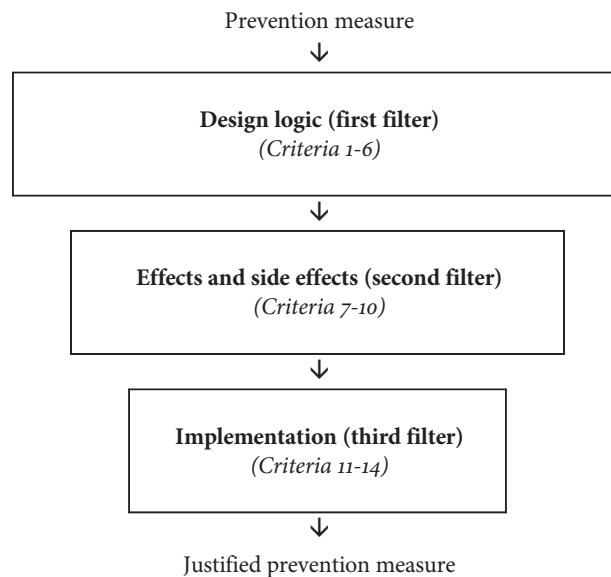
The third reason for applying the 'funnel' principle with successive filters is as follows. **The criteria in a filter may be weighed against each other.** This means that a good score for a certain criterion will help compensate for a poor score on another criterion. **The criteria originating from the various filters are not permitted to be weighed against each other.**

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The following two examples serve to illustrate the above:

- If prevention is unnecessary (first filter), it is irrelevant to subsequently assess effectiveness (second filter).
- If the prevention measure is ineffective (second filter), implementation of the prevention measure no longer applies (third filter).

**Figure 29: Filter structure of the assessment model**

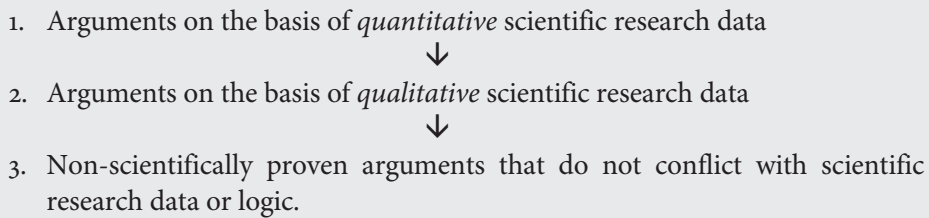


***Explanatory notes on the sequence of the assessment criteria (§3.3)***

The assessment model that has been developed is an argumentative model. To ensure the rationality of the assessment, as much scientific data as possible should be used in the model to substantiate reasoning. Taking the objectiveness, comparability and the ability to generalise the assessment into consideration, it would preferable to use quantitative rather than qualitative research data. Figure 30 reflects my views on the correct sequence of the reasoning in a rational assessment process.

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**Figure 30: Stages of reasoning in a rational assessment process**



To quantify or express intangible matters, such as disturbance, the intrusion of private life and the infringement of moral views, concepts such as the ‘Willingness to Pay’ and the ‘Willingness to Accept’ (§6.6.1) may be used.

Non-scientifically proven arguments, for instance, are those of a moral nature or relating to political ideologies, such as prohibiting the use of hard drugs because the use of hard drugs is deemed morally reprehensible.

Two classification systems are used to determine the sequence of the assessment criteria in the model as follows:

- the stages of reasoning in a rational assessment process, as reflected in the diagram in Figure 30;
- the logical sequence of the assessment criteria in terms of substance.

I consider the logical sequence of the assessment criteria in terms of substance as the most important in ensuring the rationality of the assessment model. To comply with both classification systems, I have clustered the criteria in the model as follows:

- the sequence of the clusters and the criteria within each cluster is based on the logical sequence in terms of substance;
- in terms of substance the criteria in a cluster are logically coherent;
- the sequence of the criteria in the clusters aims to reflect the sequence set out in Figure 30.

My endeavour to use the sequence of the criteria in a cluster as set out in Figure 30 prompted me to split up the criterion ‘necessity’ in cluster 1 in the scientifically

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objectifiable criterion ‘risk of harm’ and the scientifically non-objectifiable criterion ‘necessity’<sup>2</sup>.

My model *implicitly* features seven clusters each containing two criteria as follows:

- Cluster 1:
  1. Risk of harm
  2. Necessity
- Cluster 2:
  3. Causality
  4. Responsibility
- Cluster 3:
  5. Focus
  6. Suitability
- Cluster 4:
  7. Effectiveness
  8. Intrusiveness
- Cluster 5:
  9. Cost-benefit ratio (ratio of burdens to benefits)
  10. Fairness
- Cluster 6:
  11. Support
  12. Complementary policies
- Cluster 7:
  13. Verifiability
  14. Implementation capacity

I used the breakdown of my assessment model into seven clusters with two criteria each to determine the correct sequence of the assessment criteria when building my model. To avoid making my model too complicated for the user, I explicitly opted not to make these clusters visible in the model.

The *imperative structure* of the assessment model – which requires assessment of the criteria in a fixed sequence – helps the assessor to assess the logical relationship between the assessment criteria.

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2. Contrary to my model, in the ‘*Trechter van Dunning*’ (‘funnel’ assessment model developed by the Committee on Choices in Health-Care) for example, ‘risk of harm’ is not a separate criterion but forms part of the criterion ‘necessity’.



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## IV.II Assessment method

### ***Justification of the line of reasoning***

Two pillars underpin the justification of applying a prevention measure as follows:

- justification of the ***line of reasoning*** leading to the decision to apply the prevention measure;
- justification of the ***procedure*** (what influence can be exerted on decision-making by what parties and when?) leading to the decision to apply the prevention measure.

My assessment model focuses on justifying the line of reasoning. Depending on the case, consideration should be given to the extent to which procedural aspects are relevant for substantively assessing justification of the prevention measure. Assessment of the procedural justification in itself falls outside the scope of my assessment model (§12.4.4).

In pluralist societies, it is impossible to determine measurable testing criteria to assess the justification of generally accepted lifestyle-influencing prevention measures. To avoid implying that the justification of a prevention measure with the aid of my model is tested on the basis of firm, measurable criteria, I refer to ‘assessing’ justification rather than to ‘testing’ justification for the purpose of my model. (Chapter 4).

Assessment of the justification of a prevention measure in my model is based on the principles of ***reasonableness and fairness*** of the line of reasoning underlying the application of the prevention measure. It is difficult to strictly separate the terms ‘reasonableness’ and ‘fairness’. ‘Reasonableness’ refers primarily to rationality’, i.e. reason = ratio = power of reason, while ‘fairness’ refers to fair = honest.

### ***The reasonableness and fairness of the line of reasoning***

The reasonableness and fairness of the line of reasoning underlying the application of the prevention measure have been assessed for each criterion. The assessment actually represents a quest to uncover the ***falsification*** of the reasonableness and fairness of the following aspects of the line of reasoning (§4.5) as follows:

1. ***Accuracy*** of the line of reasoning (does the line of reasoning not conflict with scientific information or is it illogical?);
2. ***Completeness*** of the line of reasoning (have any relevant arguments and available scientific information been overlooked or ignored?);

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3. Robustness of the *evidence* (is the evidence of the line of reasoning sufficiently strong?);
  4. *Clarity* of the evidence (is the line of reasoning freely and easily available to all parties?);
  5. *Internal consistency* of the line of reasoning (does the prevention measure conform to the relationship established between the criteria of my model?);
  6. Relation to the *harm principle* (is the prevention measure not moralistic, perfectionistic or paternalistic?);
  7. The possibility of providing *better alternatives* (whether there are any better alternatives is assessed on the basis of the optimisation principle described in detail below).

### ***Optimisation principle***

If the line of reasoning that is used to substantiate the prevention measure concerning aspects 1-6 seriously fails, the application of the prevention measure is unjustifiable. If better alternatives are possible (seventh aspect), this does not automatically imply that the application of the prevention measure is unjustifiable. The fact that the design (first filter) and the effects and side effects (second filter) or the implementation (third filter) of the prevention measure are sub-optimal does not necessarily imply that they are not good enough. The sub-optimal application of a sub-optimally designed prevention measure might occasionally be preferred above non-application of the prevention measure, i.e. 'half a loaf is better than none'. If a prevention measure is found to be sub-optimal, this will always *help spur improvement*. Assessment of the prevention measure by means of the optimisation principle involves assessing whether *carelessness* (wrongly not taking aspects into account) or *negligence* (wrongly failing to act) are found to have been the case. By taking the *given possibilities* as the starting point (e.g. the available people and funds), I have endeavoured to avoid shaping the assessment in a perfectionistic manner (§13.3.1 and 15.2.9).

### ***Harm principle***

Freely translated the harm principle entails that people's liberties may only be curtailed to avoid them inflicting harm on third parties. This is quite a liberal starting point, which many people may feel is pushing the limits. I have assumed a *relative view on the harm principle*. This means that I have not unscrupulously rejected the paternalistic and moralistic restriction of liberty but merely wish to point out that this is less strongly justifiable than the restriction of liberty to prevent harm. Taking a relative view of the harm principle I have arrived at the following *generally accepted starting points* for the purpose of assessing the justification of the restriction of liberty (§4.3.5):

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- preventing harm to lawful interests justifies a lifestyle-influencing intervention more strongly than promoting lawful policy targets;
  - Preventing harm or disturbance justifies a lifestyle-influencing intervention more strongly than preventing the infringement of moral views;
  - preventing harm inflicted on third parties justifies a lifestyle-influencing intervention more strongly than preventing harm inflicted on oneself (if this involves the 'same' type of harm);
  - preventing harm inflicted by children on themselves justifies a lifestyle-influencing intervention more strongly than preventing harm inflicted by adults on themselves (if this involves the 'same' type of harm);
  - as people's autonomy, freedom of choice, competency to express their will grows and as they acquire more information, there is less justification for paternalism.

***Retrospective assessment (evaluation)***

A retrospective assessment takes a retrospective view of the effects and side effects (second filter) and implementation (third filter) of the prevention measure in the situation in which these actually took place. A retrospective assessment can therefore only be performed during or after a prevention measure has been implemented. The influence of implementation has automatically been incorporated in the effects and side effects that occurred. If the assessment relates to a period after the implementation phase, the criteria in the third filter (implementation) are still relevant to the assessment (§13.7.2).

***Prospective assessment (prediction)***

A prospective assessment takes a predictive view of the effects and side effects (second filter) and implementation (third filter) of the prevention measure which have yet to take place. A prospective assessment can only be performed on the basis of assumptions on the 'effects and side effects' and 'implementation'. Assumption-based assessment offers the option to work with implementation scenarios (such as putting a great deal of effort versus little effort into 'enforcement'). It is also feasible to trial and research the 'effects and side effects' and 'implementation' of a prevention measure in a controlled and/or defined environment by performing experiments or pilot studies (§13.7.2).

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## V Summary of the discussion

### V.1 Consideration of my research and assessment model

In the discussion (§15.2) I discussed the following aspects of my research and the assessment model:

- objectiveness and completeness;
- neutrality;
- validity;
- reliability;
- practical application;
- universality;
- scope.

Please find below the main conclusions:

- The objectiveness of developing the model (§15.2.1), the completeness of the model (§15.2.1) and the neutrality of the assessment method (§15.2.2) are prerequisites for ensuring the assessment process is fair and therefore are prerequisites for ensuring the validity of the assessment model (§15.2.3). I consider it plausible that the model meets the above prerequisites.
- The fact that an assessment performed with the model is based on the falsification of arguments put forward, rather than on proving the accuracy of arguments put forward, to a certain extent guarantees the reliability of the assessments performed on the basis of the model. To make a statement about the aspect of reliability with greater certitude many prevention measures should be assessed by a range of different assessors (§15.2.4).
- I managed to actually assess the justification of two cases from day-to-day practice (the Clarian Health prevention plan and the statutory smoking ban in the Dutch catering industry) using my model. On the basis of the above, I consider it plausible that the model can be applied in practice (§15.2.5).
- I consider the universality of the model plausible. I consider it unlikely that testing the model against new cases from day-to-day practice will lead to fundamental changes in the model (§15.2.6).
- I presume that the scope of the model covers all situations in which parties seek to influence people's lifestyles or behaviour by exerting *pressure or force* (including imposing or enforcing compulsory education or banning the burqa, for instance).
- I believe that the scope or relevance of the model is limited to situations in which parties seek to influence people's lifestyles or behaviour by exerting *pressure or force* (§15.2.7).

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## V.II Consideration of my research and the assessment model

### To my knowledge no model currently exists (§15.3.1):

- which enables assessment of the justification of lifestyle-influencing prevention measures aimed at controlling lifestyle-related diseases in a generally accepted manner, and
- the criteria of which have been operationalised such that they can be applied in practice, and
- the accuracy, completeness and practical application of which have been demonstrated by applying the model to cases from day-to-day practice.

I now hope to provide such a model.

The model can be used by the following parties (§15.3.2):

- the national and municipal authorities (Ministry of Health, Welfare and Sport, the Council for Public Health and Care (RVZ), the Municipal Health Services (GGD) and in political circles;
- the public;
- companies (employers and health insurers, for instance);
- health-care institutions and care providers;
- research institutions (the National Institute for Public Health and the Environment (RIVM) and the Netherlands Institute for Health Promotion (NIGZ);
- the judiciary and the legal professional (an example is the legal proceedings instituted against the statutory smoking ban for small cafés which have no staff).

The above parties can use the model for the following purposes:

- assessing justification,
- comparative analysis,
- designing,
- examining and
- substantiating reasons or criticising

lifestyle-influencing prevention measures in situations where pressure or force is exerted.

To conclude the discussion, I have formulated *recommendations* for policy (§15.3.3) and scientific purposes (§15.3.4).