



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

## **Policy Framework for Population Screening for Cancer**

RIVM Report 2018-0042  
A. Klein | R. van Velzen





Rijksinstituut voor Volksgezondheid  
en Milieu  
*Ministerie van Volksgezondheid,  
Welzijn en Sport*

## **Policy Framework for Population Screening for Cancer**

RIVM Report 2018-0042

## Colophon

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A. Klein (author), RIVM  
R. van Velzen (author), RIVM

Contact:  
Anne Klein  
Centre for Population Screening, National Institute for Public Health and  
the Environment  
[anne.klein@rivm.nl](mailto:anne.klein@rivm.nl)

This investigation has been performed by order and for the account of  
Dutch Ministry of Health, Welfare and Sport (VWS) within the framework  
of defined legal and policy frameworks

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P.O. Box 1 | 3720 BA Bilthoven  
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[www.rivm.nl/en](http://www.rivm.nl/en)

## Synopsis

### **Policy Framework for Population Screening for Cancer**

The Policy Framework for Population Screening for Cancer provides an overview of the legal and policy frameworks for the three population screening programmes for cancer in the Netherlands, namely for breast, cervical and bowel cancer. In addition, it describes the cooperation and the various relationships between the parties who are involved in the preparation, decision-making and implementation of the population screening programmes. This optimises the way in which the parties involved can work together. The Policy Framework has been drawn up by the National Institute for Public Health and the Environment (RIVM) and formalised by the Ministry of Health, Welfare and Sport (VWS). The document is regularly checked and updated when necessary to reflect the actual situation.

The RIVM has the nationwide coordinating role, meaning that they monitor to ensure that high-quality population screening is provided for the participants and that it is easily accessible and affordable. This creates the optimum 'offering' for those participating in population screening. The Policy Framework is a tool for coordinating the programmes. It is also part of what are known as the 'implementation frameworks' in which the exact method is described for each population screening programme, along with who performs it.

The population screening programme consists of a sequential series of actions that are carried out and coordinated by various parties (the invitation to take part in the programme, the investigation itself, the assessment of the results, the communication of the results and any referrals that may be needed). These activities must be aligned with each other well and must be efficiently structured in order to guarantee the quality of the population screening.

Keywords: population screening, cancer, breast cancer, cervical cancer, bowel cancer, screening, subsidy, quality



## Publiekssamenvatting

### **Beleidskader Bevolkingsonderzoeken naar Kanker**

Het Beleidskader Bevolkingsonderzoeken naar Kanker (BBK) geeft een overzicht van de wettelijke en beleidsmatige kaders voor de drie bevolkingsonderzoeken in Nederland naar kanker: borst-, baarmoederhals- en darmkanker. Daarnaast beschrijft het de samenwerking en onderlinge verhoudingen van partijen die betrokken zijn bij de voorbereiding, besluitvorming en uitvoering van deze bevolkingsonderzoeken. Op deze manier werken de betrokken partijen optimaal samen. Het Beleidskader is opgeteld door het RIVM en is vastgesteld door het ministerie van Volksgezondheid, Welzijn en Sport (VWS). Het document wordt regelmatig getoetst en zo nodig aangepast aan de actualiteit.

Het RIVM ziet er als landelijke regiehouder op toe dat de bevolkingsonderzoeken voor de deelnemers een hoge kwaliteit hebben, en goed bereikbaar en betaalbaar zijn. Op die manier ontstaat een optimaal 'aanbod' voor de deelnemers aan de bevolkingsonderzoeken. Het Beleidskader is een instrument om de regie te voeren. Het vormt ook de basis voor de zogeheten uitvoeringskaders, waarin per bevolkingsonderzoek de precieze wijze waarop en door wie de bevolkingsonderzoeken worden uitgevoerd, is uitgewerkt.

De bevolkingsonderzoeken bestaan uit een reeks van opeenvolgende handelingen die door verschillende partijen worden uitgevoerd en gecoördineerd (de uitnodiging voor het onderzoek, het onderzoek zelf, de beoordeling van de uitslag, de communicatie, en de eventuele doorverwijzing). Deze handelingen moeten goed op elkaar aansluiten en efficiënt gestructureerd zijn om de kwaliteit van het bevolkingsonderzoek te waarborgen.

Kernwoorden: bevolkingsonderzoek, kanker, borstkanker, baarmoederhalskanker, darmkanker, screening, subsidie, kwaliteit



## Definition letter, VWS

> Return address PO Box 20350, 2500 EJ The Hague (NL)

National Institute for Public Health and the Environment  
For the attention of A.M.P. van Bolhuis, MBA  
Director of Public Health and Health Services  
PO Box 1  
3720 BA Bilthoven (NL)

**Public Health Directorate**  
Public and Youth Healthcare Services  
Address:

Parnassusplein 5  
PO Box 20350  
2500 BP The Hague (NL)  
[www.rijksoverheid.nl](http://www.rijksoverheid.nl)

**Information available from**

D.M.A. Onderstal  
(Senior) Policy Officer  
T +31 (0)70-340-7597  
M +31(0)6-5244-7140  
[dm.onderstal@minvws.nl](mailto:dm.onderstal@minvws.nl)

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*Correspondence must be addressed exclusively to the return address along with the statement of the date and the reference of this letter.*

Date 21 Oct. 2016  
Subject Determination of the policy framework for population screening for cancer

Dear Ms van Bolhuis,

The Policy Framework for Population Screening for Cancer provides an overview of the legal and policy frameworks for the three population screening programmes for cancer in the Netherlands, namely for breast, cervical and bowel cancer. In addition, it describes the cooperation and the various relationships between the parties who are involved in preparation, decision-making and implementation work for the population screening programmes. The policy framework acts as a foundation for further detailing of the implementation frameworks for the population screening programmes.

The policy relating to population screening for cancer aims to achieve health gains at the group level. This means that individuals from the target groups must be able to make properly informed choices as to whether they wish to take part or not.

A clear overview of the policy frameworks and the underlying relationships among the parties concerned is something I believe to be very important for high-quality setup and implementation of the cancer population screening programme. I am convinced that the Policy Framework for Population Screening for Breast Cancer will contribute to this and I am formally defining it by means of this letter and giving RIVM instructions to make use of the policy framework in the nationwide management of population screening for cancer.

Yours sincerely,  
Director of Public Health  
Dr M.C.H. Donker



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## 1 Introduction

### 1.1 Purpose of this policy framework

This policy framework for population screening for cancer gives an overview of the legal and policy frameworks determined by the Dutch Ministry of Health, Welfare and Sport (VWS) relating to population screening programmes for breast cancer, cervical cancer and bowel cancer. This document also describes the cooperation between the parties who are involved in the preparation, decision-making and implementation of the population screening programme for cancer.

This policy framework is thus the foundation for further detailing of the implementation frameworks for the population screening programmes. The implementation frameworks focus above all on implementing the population screening programmes.

This policy framework has been put together for the governmental authorities, executive organisations and professionals involved in the preparation, management, coordination and implementation of the population screening programmes for cancer, including those involved in quality assurance, nationwide monitoring and nationwide evaluation.

Appendices 1 and 2 contain an overview of the concepts and abbreviations that are used in this policy framework.

### 1.2 Accountability

This policy framework for population screening for cancer has been drawn up by the Centre for Population Screening of the National Institute for Public Health and the Environment (RIVM-CvB) on instructions from the Ministry of Health, Welfare and Sport (VWS). This document has been formally defined by VWS, taking due note of Article 26, paragraph 2 of the grant scheme for public healthcare.

### 1.3 Distribution and updating

This policy framework for population screening for cancer has been published by the RIVM-CvB. It can be downloaded from <http://www.rivm.nl>. The policy framework is checked annually to confirm it is up to date and amended if necessary. An update to this policy framework will appear at least once every four years.



## 2 Population screening programme

### 2.1 Constitutionally defined task of the government: public health

Article 22 of the Dutch constitution charges the national government with taking measures to promote public health. The Minister of Health, Welfare and Sport is responsible for formulating policy objectives and deploying the tools needed for promoting public health. In addition to legislation that keeps the care itself accessible and affordable, a key legal framework for promoting or protecting the health of the public at large is defined by the Public Health Act (Wpg) and the Population Screening Act (WBO).

In addition, a large number of laws and implementation measures define the conditions under which care may be offered in the Netherlands. This applies equally to public health and covers inter alia the Medical Treatment Agreement Act (WGBO), the Individual Healthcare Professions Act (Wet BIG), the Act on the Use of the Citizen Service Number in Healthcare (Wbsn-z) plus quality legislation, including the Healthcare Quality, Complaints and Disputes Act (Wkkgz).

Appendix 3 gives an overview and brief explanation of the legislation and regulations that apply specifically to population screening for cancer.

### 2.2 Prevention through programmes

Under the Public Health Act, public healthcare is a joint responsibility of the local and national authorities. The Public Health Act describes public healthcare as “measures to protect and promote health among the population or specific subgroups of it, including prevention and early detection of (treatable) diseases”. The national government fulfils that responsibility inter alia through prevention programmes (including population screening for cancer). A population screening programme is a systematic offer of medical examinations among a population who are in principle not affected. The initiative comes from the provider (the government). The Population Screening Act (WBO) applies to population screening programmes. The WBO offers protection against unnecessary or harmful population screening programmes. A WBO permit is required for carrying out the population screening for cancer.

### 2.3 National Population Screening Programme

The National Population Screening Programme (NPB) consists of the national programmes financed by the State, namely the three population screening programmes for cancer (breast cancer, cervical cancer and bowel cancer) and the five prenatal and neonatal screening programmes (blood test for pregnant women, prenatal screening for Down's, Edwards' and Patau's syndromes, the ultrasound anomaly scan for unborn babies, the blood spot test for neonates and the hearing tests for neonates). A policy framework is required for the five prenatal and neonatal screenings (PNS), just as it is for this policy framework for population screening for cancer. The policy frameworks for PNS and for

population screening for cancer together constitute the policy framework of the NPB.

This policy framework focuses on population screening programmes for cancer, such as:

- *National Programme for Breast Cancer Screening*  
The objective of breast cancer screening is to lower the mortality rate by detecting breast cancer at an early stage, before women have symptoms. Early detection often offers more options for dealing with it, in terms of the available treatment methods. In the population screening programme for breast cancer, women aged between 50 and 75 are invited every two years to have a mammogram.
- *Cervical Cancer Screening*<sup>1</sup>  
The objective of the cervical cancer screening programme is in particular to detect and treat the precursor stages so that cervical cancer can be prevented. In the population screening programme for cervical cancer, women aged between 30 and 60 are invited every five years to have a smear test done that is checked for HR-HPV. The invitations at ages 45, 55 and 65 are only sent to women who tested positive during the previous round of screening.
- *Bowel Cancer Screening Programme*<sup>2</sup>  
The objective of the bowel cancer screening programme is in particular to detect and treat the precursor stages so that bowel cancer can be prevented. In the population screening programme for bowel cancer, men and women aged between 55 and 75 are invited every two years. They receive a stool test at home that they can send back to a screening laboratory after taking a faecal sample.

## 2.4 Principles of population screening

### 2.4.1 *The Wilson and Jungner criteria*

The government's responsibility is fulfilled inter alia by careful checks against the criteria for responsible population screening that were formulated in 1968 for the World Health Organization (WHO) by Wilson and Jungner, with additions made in 2008. This normative framework is widely accepted and supported internationally; see Appendix 4 for a summary of these criteria. The criteria are examined by the Health Council of the Netherlands to assess whether a new population screening programme (or an innovation within an existing one) is a responsible thing to do. If the developments give cause to do so, the Health Council checks if so requested whether the population screening still meets the criteria imposed. The Health Council presents these considerations in a recommendation to the Minister of Health, Welfare and Sport, who takes the final decision.

<sup>1</sup> This description refers to the new population screening programme as implemented since 1 January 2017.

<sup>2</sup> This population screening programme is being phased in from 2014. It is expected that this population screening will be fully rolled out by 2020.

### 2.4.2 *Public values*

Population screening must be carried out in a way that complies with the public values adopted by the government authorities: quality, accessibility and affordability. The public values must be brought carefully into equilibrium, creating the optimum situation in terms of the setup and the execution of the population screening programme. See Appendix 5 for details of how the public values are applied.

The public values have been translated into indicators that can be quantified and assessed using monitors and evaluations. For further explanation of this, see Chapter 5 (“Quality assurance and quality improvement of population screening for cancer”).

### 2.4.3 *Cooperation in the care chain*

A population screening programme is not an independent task but part of a care chain. The aim is to have all elements of the care chain aligned with each other. In particular, the transition from population screening to further diagnostic tests (medical investigations after an unfavourable test result) and treatment is a key step for which the parties within the population screening programme and the care chain bear joint responsibility. This requires not only optimum cooperation but also detection of bottlenecks in the subsequent care process and getting them onto the agenda as early as possible.

The figure below shows the general steps that are part of the care chain for a population screening programme and the care process it is linked to.

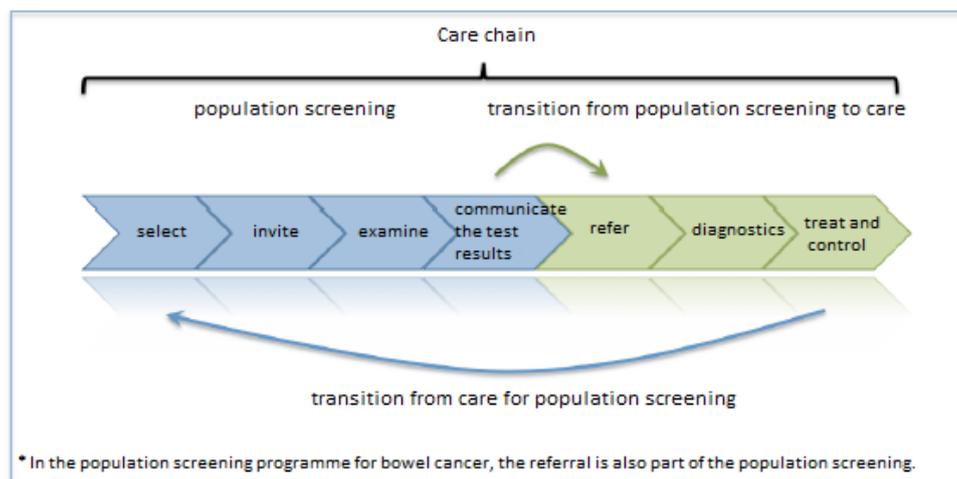


Figure 1: Representation of the care chain of the population screening programmes for cancer showing steps from the screening to the adjacent care delivery.

The chain starts with the selection of participants and invitations to take part. The screening examination then takes place and the test result is communicated to the participant. The population screening is completed once the participants have received the test result of the screening. If necessary, they can be referred to the care process in which further diagnostic tests and any necessary checks and treatments can take place. In the population screening programme for bowel cancer, the

referral is also part of the population screening. The steps in the care chain are described briefly below for each population screening programme.

*National Programme for Breast Cancer Screening:*

Women aged between 50 and 75 are invited every two years to have a breast image (mammogram) made. The screening examinations are mostly held in mobile mammography units. This examination involves taking mammograms. The images are assessed within a few days by two radiologists independently. The women receive a letter from the screening organisation<sup>3</sup> stating the test result. If there is a suspicion of breast cancer or if the image material is not sufficiently clear (BIRADS 0), the GP contacts the women for a follow-up examination in a hospital.

*Cervical Cancer Screening:*

Women aged between 30 and 60 are invited every five years to have a smear test done. The cervical smear is done at the GP practice by the GP or more commonly by the practice assistant. Women who do not respond to the invitation will receive a self-sampling device. The sampled material (cells) is sent to the laboratory and first examined for the presence of HR-HPV by means of an HR-HPV test. If the HR-HPV test is positive, a cytological assessment follows. The laboratory sends the test results to the GP and to the screening organisation. Depending on the cytological assessment, the woman will receive a recommendation for follow-up diagnostic testing after six months or a referral to a gynaecologist. The women receive a letter from the screening organisation stating the test result. In the event of a severely anomalous test result for which referral to a gynaecologist is needed, the GP contacts the woman.

The follow-up diagnostic testing after six months is also part of the population screening programme.

*Bowel Cancer Screening Programme:*

Men and women aged 55 to 75 are invited every two years to take part in the population screening programme. They receive a stool test at home (iFOBT, immunochemical faeces occult blood test) that they can send back to a laboratory after taking a faecal sample. The laboratory sends the test results to the GP and to the screening organisation. The participants receive a letter from the screening organisation stating the test result. In the event of an unfavourable test result, the GP is notified by the screening organisation and the participant is referred for further diagnostics (colonoscopy) and treatment if necessary.

<sup>3</sup> A screening organisation is a legal entity that has been given a permit to carry out the population screening under the Population Screening Act.

### 3 Involvement of government authority parties in population screening for cancer

#### 3.1 Key players among the authorities

Various governmental bodies are involved in the preparation or amendment and reassessment of population screening for cancer. The Health Council of the Netherlands and the Netherlands Organisation for Health Research and Development (ZonMw) have a task that is primarily preparatory, for new population screening programmes and far-reaching changes to the existing programmes. The RIVM-CvB issues advice about the setup and aspects of the implementation. Final decision-making is done by the Ministry of Health, Welfare and Sport (VWS). The Healthcare Inspectorate (IGZ) has a supervisory role.

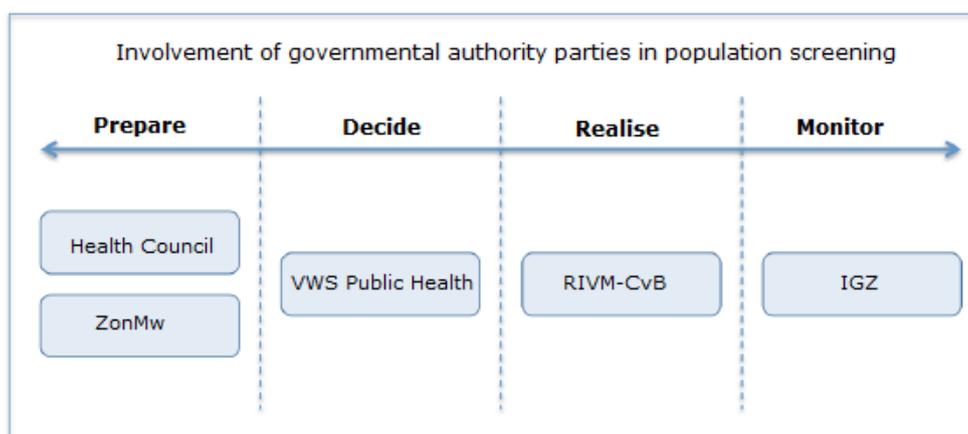


Figure 2: Involvement of governmental authority parties in population screening

The involvement of the authorities in the population screening programmes for cancer is explained in more detail below.

#### 3.1.1 Ministry of Health, Welfare and Sport – Public Health Directorate

The Minister of Health, Welfare and Sport (VWS) is politically responsible for population screening for cancer and defines the policy relating to these screening programmes.

In addition, the ministry ensures that the RIVM-CvB (the Centre for Population Screening at the National Institute for Public Health and the Environment) is able to direct matters nationally.

Tasks of VWS in population screening for cancer:

- a. The Ministry of Health, Welfare and Sport defines the legal and policy frameworks for population screening for cancer.
- b. VWS gives the RIVM-CvB instructions for directing and managing the implementation of population screening for cancer nationwide. These instructions define the context and the preconditions for the directing and managing activities for population screening programmes for cancer. Population screening must comply with the legal and policy frameworks and the public values, as well as being aligned with the care itself.

The RIVM-CvB provides financial and substantive accountability reports to VWS periodically.

- c. The Minister of Health, Welfare and Sport provides funding<sup>4</sup> for the National Population Screening Programme and gives the RIVM-CvB the task of acting as the money manager.
- d. VWS issues permits to the screening organisations under the Population Screening Act for carrying out population screening programmes for cancer and defines the grant scheme for public healthcare.
- e. VWS gives ZonMw instructions for tendering, funding and facilitating research into population screening for cancer.
- f. VWS can ask the Health Council of the Netherlands to make recommendations about possible new population screenings (and the desirability thereof), innovations<sup>5</sup> or reassessment of current population screening.
- g. The Minister of Health, Welfare and Sport decides about innovations in population screening for cancer.

### 3.1.2 *The Health Council of the Netherlands*

The Health Council of the Netherlands (GR) is an independent scientific advisory body. Pursuant to the Public Health Act, the Council has the task of advising ministers and parliament on public health and research into health and healthcare. Ministers ask the GR for advice that they can use for underpinning policy decisions. In addition, the GR has a signalling function and can also issue recommendations proactively.

Tasks of the GR in the population screening programmes for cancer:

- a. The Health Council advises the VWS minister both on request and spontaneously about the current state of knowledge and innovations in population screening for cancer.
- b. The Health Council advises the VWS minister on permit applications based on the Population Screening Act (WBO).

### 3.1.3 *ZonMw*

ZonMw is an independent executive body that finances research into health. ZonMw also encourages utilisation of the knowledge that is developed in order to improve health and healthcare. ZonMw encourages health research and health innovation throughout the knowledge chain, ranging from fundamental research to implementation.

Tasks of ZonMw in the population screening programmes for cancer:

- On instructions from the Minister of Health, Welfare and Sport, ZonMw defines the basic outlines of health research (insofar as this is financed by the government) and monitors how it is carried out. This includes pilots, further scientific and other research and cost-effectiveness studies. The research itself is carried out by third parties.

<sup>4</sup> The national direction and coordination by the RIVM-CvB is financed from the State budget of the Ministry of Health, Welfare and Sport (VWS). The regional coordination and implementation is funded via the grant scheme for public healthcare.

<sup>5</sup> Refer to Section 5.1.4 and Appendix 1 for further explanation of the concepts of "innovation" and "optimisation".

### 3.1.4 *The RIVM-CvB*

Since 1 January 2006, the Minister of Health, Welfare and Sport has charged RIVM (the National Institute for Public Health and the Environment) with the nationwide direction and supervision of prevention programmes. RIVM set up the Centre for Population Screening (CvB) in 2006 to carry out that task. The RIVM-CvB is the link between policy and practice.

Tasks of the RIVM-CvB in the population screening programmes for cancer:

- a. On instructions from the Dutch Ministry of Health, Welfare and Sport, the RIVM-CvB directs the population screening for cancer and manages the implementation, so that the legal and policy frameworks, the public values and alignment with regular care are assured.
- b. The RIVM-CvB provides signals and advises the ministry and other governmental parties about developments and innovations that are important for population screening for cancer and demand measures and/or policy changes.
- c. The RIVM-CvB finances the implementation of population screening for cancer on behalf of the national government. The parties contracted to do the work are the screening organisations and professionals.
- d. The RIVM-CvB defines the outline of how the implementation will progress and assures the quality by setting demands and monitoring them (e.g. implementation frameworks and training and accreditation requirements).
- e. The RIVM-CvB encourages and facilitates activities that promote quality and expertise for and among the relevant parties.
- f. The RIVM-CvB ensures that population screening for cancer is monitored and evaluated with the aim of assuring the public values, nationwide uniformity and alignment with care processes.
- g. The RIVM-CvB encourages or ensures the provision of a suitably equipped infrastructure (including the information management).
- h. The RIVM-CvB communicates with the public, the target group, professionals and stakeholders. The RIVM-CvB is responsible for the nationally distributed informational materials. The target group must be able to make an informed choice.
- i. The RIVM-CvB handles the preparation and implementation of new population screening programmes and adapts existing ones.
- j. The RIVM-CvB makes agreements with VWS and if necessary the IGZ and/or other governmental authority bodies in the event of calamities relating to population screening for cancer.
- k. The RIVM-CvB encourages cohesive implementation of the population screening programmes for cancer as far as possible.
- l. The RIVM-CvB informs VWS about developments that are important for the programmes and that require measures and/or policy changes in them.
- m. The Programme Committees advise the RIVM-CvB throughout. These committees contains experts from relevant professional groups and organisations that have authority within their profession or network and that have contacts in the field.

### 3.1.5 *The Healthcare Inspectorate*

The Dutch Healthcare Inspectorate (IGZ) is a governmental authority that is part of VWS. The IGZ monitors compliance with a number of quality-related healthcare laws, can give instructions, submit disciplinary complaints and can take measures (including emergency measures) if necessary.

Tasks of the Healthcare Inspectorate in population screening for cancer:

- The Healthcare Inspectorate investigates calamities and incidents, assesses the measures taken by the healthcare provider, takes measures itself if necessary, and advises the Minister of Health, Welfare and Sport about the observance of applicable legislation about population screening for cancer.

## 4 The parties involved in the implementation of the population screening for cancer

### 4.1 Key players in the implementation

The implementation involves many different parties with tasks as part of the chain, from determining policy through to actually offering the population screening to the target group.

Cooperation in this chain is essential for a successful implementation.

The figure below shows the main parties involved in the implementation of the population screening programme for cancer: on the left are the parties involved and on the right the main tasks of these parties in the cancer screening programmes.

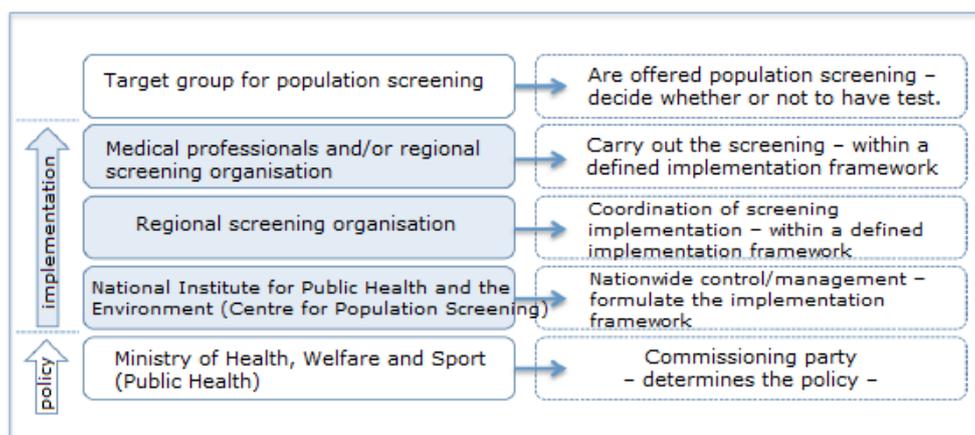


Figure 3: Cooperation between parties involved in the implementation.

The sections below give the frameworks for the parties involved in the regional coordination and implementation of population screening for cancer. These frameworks form the preconditions and guiding principles for the further design and implementation of the population screening in question. An implementation framework is drawn up for each population screening programme.

#### 4.1.1 Regional coordination and implementation of the population screening programme.

The screening organisations (SOs) organise and coordinate the implementation of population screening programmes for cancer in their region, on instructions from the RIVM-CvB, within the defined national implementation frameworks.

Tasks of the screening organisations in the population screening programmes for cancer:

- a. The screening organisations provide the regional coordination for managing activities for population screening programmes for cancer.
- b. The screening organisations enter into cooperation agreements or make similar agreements with the executive and quality assurance parties in population screening for cancer.

- c. The screening organisations ensure that the implementation complies with the legislation and regulations and the national framework for the implementation as set by the RIVM-CvB (the implementation frameworks).
- d. The screening organisations maintain an appropriate regional network for carrying out the population screening programmes and in that context have meetings with the parties in their region (including care institutions and professional practitioners) and – where relevant for the population screening – encourage cooperation between the parties involved in the screening and the adjacent parts of the care chain.
- e. The screening organisations<sup>6</sup> monitor the quality of the implementation by the implementation parties.
- f. The screening organisations also make data available for the referral function and the monitoring and evaluating party for the purposes of quality assurance, nationwide monitoring and evaluation of the population screening programmes for cancer. The organisations are also responsible for the quality of this data.
- g. The screening organisations exchange best practices so that the implementation of the programmes can be made more effective and targeted better. This means that they are always looking for a balance between aspects such as effectiveness, continuity, regional embedding and nationwide uniformity. Joint initiatives by the screening organisations are agreed with the RIVM-CvB

Frameworks for population screening programmes for cancer:

- a. The regional coordination and implementation activities for population screening programmes for cancer are handled by the five regional screening organisations: Stichting Bevolkingsonderzoek (Population Screening Foundation) Noord (North), Stichting Bevolkingsonderzoek Midden-West (Mid-West), Stichting Bevolkingsonderzoek Zuid (South), Stichting Bevolkingsonderzoek Zuid-West (Southwest) and Stichting Bevolkingsonderzoek Oost (East).
- b. The screening organisations are required to have a permit under the Population Screening Act.
- c. Because they are Population Screening Act permit holders under the grant scheme for public healthcare, the screening organisations are entitled to a grant as long as they comply with the regulations stated in the permit and observe the obligations imposed when the subsidy is granted. The SOs are accountable to the RIVM-CvB both financially and in terms of the substantive content.
- d. The screening organisations are independent organisations whose task and focus is on the regional coordination and implementation of population screening for cancer. They do not carry out any commercial activities.

<sup>6</sup> In the population screening programme for breast cancer, an external organisation monitors the quality of the implementation. The implementing party is in this case the screening organisation itself.

#### 4.1.2 *Carrying out population screening*

Various professionals and organisations are involved in carrying out population screening and the adjacent parts of the care chain; these include screening organisations, radiologists, GPs, laboratories, hospitals and so forth. They work together in accordance with the national implementation frameworks for population screening for cancer.

Frameworks for population screening programmes for cancer:

- a. The professional groups and organisations are responsible for the implementation of the quality assurance policy within their discipline, and ensuring sufficient expertise and the high-quality, responsible performance of their tasks.
- b. The professional associations for the various professionals are responsible for developing and maintaining guidelines. When developing the guidelines, the associations make sure there is proper coordination with the other professional associations.
- c. The RIVM-CvB states the relevant guidelines that apply wholly or in part to population screening programmes and (if necessary) imposes additional requirements in consultation with the professional groups. The permits and/or agreements/contracts oblige the parties to keep to the national implementation frameworks and the associated guidelines and/or quality requirements.
- d. The implementation parties make data available to the screening organisations for the purposes of assessing the quality of the implementation, and for monitoring and evaluating population screening for cancer. The organisations are also responsible for the quality of this data.



## 5 Quality assurance and quality improvement of population screening for cancer

The quality assurance, nationwide monitoring and nationwide evaluation are important instruments that ensure that the implementation of population screening for cancer satisfies the quality requirements that have been set and can continually be improved. The details of the quality assurance, monitoring and evaluation of the population screening programmes for cancer are worked out in the implementation frameworks for population screening.

### 5.1 Reference function

A reference function (an assessor) can be set up for assessing and optimising the implementation of the population screening programmes for cancer.

Frameworks for population screening programmes for cancer:

- a. The assessor focuses on the optimisation and safeguarding of the substantive medical quality and physical/technical quality of the implementation of the population screening programmes for cancer or parts of such programmes. The assessor must be independent of the organisations/professionals who carry out the population screening programmes.
- b. The assessor has sufficient relevant expertise and enjoys the broad support of the professional groups involved.
- c. The assessor evaluates the performance of the organisations and professionals involved in implementing population screening for cancer, monitors the quality and helps improve the implementation.
- d. The screening organisation<sup>7</sup> enters into an agreement with the reference function (the assessor) for evaluation of the implementation. The reference function reports back to the screening organisation, as defined in its terms of assignment.

### 5.2 Nationwide monitor

The nationwide monitor is used for monitoring the public values in the population screening programmes for cancer, identifying issues (in the healthcare chain), allowing adjustments to be made and providing accountability to VWS, the Inspectorate, other partners and the general public.

Frameworks for population screening programmes for cancer:

- a. The monitoring organisation must be an authoritative party that has an independent position with respect to the RIVM-CvB and the organisations/professionals who carry out the population screening for cancer and the adjacent parts of the care system.

<sup>7</sup> For the population screening programme for breast cancer, this is an agreement between the RIVM-CvB and the reference organisation. Part of this agreement is the accountability for the reference tasks and reporting other tasks and activities.

- b. The nationwide monitoring is based on the indicators and norm values. The data required for this is defined in a minimum dataset as established by the RIVM-CvB and the set of indicators. The organisations involved in the implementation undertake to make the data available and are responsible for the quality of that data.
- c. The monitoring organisation complies with the Medical Treatment Agreement Act (WGBO), the Personal Data Protection Act (Wbp), the applicable codes of conduct and the applicable guidelines on scientific integrity.
- d. The monitoring party must deliver national monitoring data (under the auspices of the RIVM-CvB) about the population screening programmes for cancer at least once a year.
- e. RIVM enters an agreement with the monitoring organisation for the purposes of nationwide monitoring. The monitoring organisation reports back to RIVM based on its assignment.

### 5.3 Nationwide evaluation

Evaluation studies consider specifically whether and to what extent the objectives of the policy (or programme) have been achieved. The range of subjects for evaluation includes both standard elements and more variable elements. Important elements are the effect evaluation (incidence/mortality reduction) and cost effectiveness study. Additional questions, which may originate from the findings from the nationwide monitors, are also answered.

Frameworks for population screening programmes for cancer:

- a. The evaluating organisation must be an authoritative party that is independent with respect to the RIVM-CvB and the organisations/professionals who carry out the population screening programmes for cancer and the adjacent parts of the care chain.
- b. The evaluation party complies with the Medical Treatment Agreement Act (WGBO), the Personal Data Protection Act (Wbp), the applicable codes of conduct and the applicable guidelines on scientific integrity.
- c. RIVM enters into an agreement with the evaluation organisation for the purposes of national evaluation. The evaluation organisation reports back to RIVM based on its assignment.

### 5.4 Optimisation and innovation

All the parties involved must contribute to optimisation (improvement) and innovation (modernisation) in the current population screening programmes for cancer, doing so within the scope of their own tasks and responsibilities. The parties must feel they have the opportunity to identify and propose possibilities for optimisation and innovation. Optimisations and innovations can affect inter alia the results of the nationwide monitoring, the activities of another party in the chain, a public value or the test properties in the screening programme; that is why they require careful decision-making and implementation.

An innovation is a radical change to screening that goes beyond the underlying Health Council advice or the existing permit under the law

covering population screening. Examples are changes to the test, the target group, the condition being investigated or the screening interval. An innovation will usually have major consequences for the implementation or results of the population screening. The following governmental bodies are involved in decision-making about innovations and in their implementation: The Health Council of the Netherlands, ZonMw, the Ministry of Health, Welfare and Sport and the RIVM-CvB.

An optimisation is any less radical change to the programme. An optimisation remains within the limits of the underlying Health Council advice or the existing permit under the law covering population screening. Optimisations are often improvements in the organisation, the process, the quality, the accessibility and the affordability (the public values) of the population screening programme. Changes to the test can also constitute an optimisation if the following conditions are met:

- the essence of the test (the test principle) does not change
- the disadvantages of the new test are the same as or less than those of the old test
- the benefits of the new test are the same as or greater than those of the old test, and
- there is no dispute about these points

The Health Council of the Netherlands is not required to give its opinion on the introduction of optimisations and, in terms of responsibilities, these can be dealt with through the hierarchical line of the VWS, RIVM-CvB and the screening organisations. Sometimes consultation and agreement between the three parties (VWS, RIVM-CvB and the Health Council) may be required to make the correct distinction between optimisations and innovations. For optimisations and tenders, RIVM-CvB can impose temporary project frameworks on the screening organisations.

Frameworks for population screening programmes for cancer:

- a. When a party identifies a possible optimisation or innovation, it informs the RIVM-CvB.
- b. If necessary, the RIVM-CvB agrees on the potential optimisation or innovation with the working group in question and the programme committee. If necessary, the RIVM-CvB subsequently agrees on this with the Ministry of Health, Welfare and Sport.

The focus is currently on policy relating to scientific research about population screening for cancer. Details of the policy will be finalised in the implementation frameworks of the various population screening programmes for cancer.



## Appendix 1 Definitions

### **Policy framework**

An overview of the legal and policy frameworks that have been established for a population screening programme.

### **Population screening programme**

A screening that is programmatic in character (also termed a 'prevention programme'). Offered by the State authorities as part of the National Population Screening Programme (NPB)

### **Diagnostics**

Medical examination following an indication; response to a request for help.

### **Evaluation**

Determine (on a structural basis or on an ad hoc basis focusing on specific research questions) whether and to what extent the objectives of the population screening programme are being achieved. (See also "Monitoring".)

### **Innovation**

All activities that are geared to modernising a population screening programme. An innovation is any radical change to a screening programme that goes beyond the underlying Health Council advice or the existing permit under the law covering population screening. Innovations can be either technological or non-technological in nature. (See also "Optimisation".)

### **Quality**

Satisfying the specified requirements.

### **Quality assurance**

The entirety of the planned and systematic actions required to provide sufficient assurance that the population screening programme satisfies and will continue to satisfy the specified requirements.

### **Quality improvement**

The entirety of planned and systematic actions aimed at increasing the options for satisfying the specified requirements.

### **National indicators (indicator set)**

Quantifiable aspects of population screening, associated care and the alignment between the two that give an indication (sign) of the quality, accessibility or affordability (i.e. the public values).

### **Nationwide quality requirements**

Requirements (minimum or maximum levels) that apply nationwide for population screening, that are connected to the public values and that must be satisfied by the organisations, implementation parties or the implementation.

### **Minimum dataset**

Specification of the requirements that are set for recording the data and providing the data for a population screening programme. The minimum dataset describes which data should be collected and recorded, in what system and for what purpose.

### **Monitoring**

A systematic activity aimed at safeguarding (and tracking) the screening process and the quality of its implementation, and improving it where necessary. (See also "Evaluation".)

### **Optimisation**

All activities that are geared to improving a population screening programme. This is a less radical change to a screening programme, which thus stays within the underlying Health Council advice or the existing WBO permit. (See also "Innovation".)

### **Public values**

Values (persistent views on the setup and activities of society) that concern the public interest. The public values for population screening are quality, accessibility and affordability.

### **Guideline** (adopted from the National Health Care Institute)

A guideline is a document with recommendations aimed at improving the quality of care(a) based on systematic summaries of scientific research and weighing up the pros and cons of various care options, supplemented by the expertise and experience of care professionals(b) and care users(c).

- a. Aspects that can be distinguished in the quality of care are effectiveness, safety, patient/client-centred care, efficiency, timeliness and equality.
- b. The term 'care professionals' covers physicians, pharmacists, physiotherapists, healthcare psychologists, psychotherapists, dentists, midwives, obstetrician and other professional care providers and care staff.
- c. The term 'care users' is taken to mean patients, clients, families of patients and clients, and family-based carers/informal caregivers.

### **Screening**

The systematic offer of medical examinations among a population who are in principle not affected. The initiative comes from the provider.

### **Tasks**

The term for a set of activities, and the associated authorisations and responsibilities, carried out by one or more individuals or organisations, including the timing and the location within the population screening programme.

### **Implementation framework**

A description of the way in which population screening should be implemented, based on the legal and policy frameworks as described in the Policy Framework. It gives a description of the primary process, the allocation of roles (tasks and responsibilities) to the parties involved and

the quality requirements that must be satisfied by each party and by the implementation.

**Care chain**

A care chain is the cohesive whole of efforts (including the healthcare provided) for implementing the population screening programme and associated care (that is delivered by various parties) in which the focus is on the client.

**Care provider**

Person (professional) or organisation (institution) delivering care.

## Appendix 2 Abbreviations

GDPR (AVG)	General Data Protection Regulation (“Algemene Verordening Gegevensbescherming”)
BMHK	Cervical cancer (“baarmoederhalskanker”)
BC	Breast cancer
BSN	Citizen service number
CBP	Dutch Data Protection Authority (“College bescherming persoonsgegevens”)
CRC	Colorectal cancer
GDPR	General Data Protection Regulation
GR	Health Council of the Netherlands (“Gezondheidsraad”)
HR-HPV	high-risk type of human papillomavirus
iFOBT	immunological Faecal Occult Blood Test
IGZ	Dutch Healthcare Inspectorate
KWZi	Care Institutions (Quality) Act - lapsed
NEN	Dutch standards institute (“Nederlands Normalisatie-instituut”)
NPB	National Population Screening Programme
PNS	Prenatal and neonatal screening
National Institute for Public Health and the Environment (RIVM)	National Institute for Public Health and the Environment
RIVM-CvB	Centre for Population Screening
SO	Screening organisation
VWS	Ministry of Health, Welfare and Sport
Wabb	Personal Public Service Number (General Provisions Act) (“Wet algemene bepalingen Burgerservicenummer”)
WBO	Population Screening Act
Wbp	Personal Data Protection Act
Wet BIG	Individual Healthcare Professions Act
WGBO	Dutch Medical Treatment Contracts Act
Wbsn-z	Act on the Use of the Citizen Service Number in Healthcare
WHO	World Health Organization
Wkkgz	Healthcare Quality, Complaints and Disputes Act
Wkcz	Clients’ Right of Complaint (Care Sector) Act (“Wet klachtrecht cliënten zorgsector”) - lapsed
Wpg	Public Health Act
WTZi	Care Institutions (Accreditation) Act
ZonMw	Netherlands Organisation for Health Research and Development

## Appendix 3 Overview of relevant legislation and regulations

### **Population Screening Act**

The Population Screening Act (WBO) protects the population from the hazards associated with certain kinds of population screening. Population screening is defined here as medical examination of people that is carried out in order to put into practice an offer made to the entire population or a subcategory thereof, aimed at detecting diseases of a certain nature or with certain risk indicators for the benefit (in whole or in part) of the people to be examined.

The law forbids offering population screening programmes without a permit for cancer, severe diseases or abnormalities for which no treatment or prevention is possible, or where the screening uses ionising radiation. Population screening programmes for cancer are therefore subject to permit requirements.

The population screening decree imposes general regulations that are needed for protecting the people to be examined against the risks of population screening programmes for which a permit is required. The details of these regulations may differ between the various categories of population screening.

A permit can be granted subject to restrictions or it may be associated with regulations; these are aimed at protecting the people to be examined against the risks or at ensuring that the population screening programme in question provides worthwhile benefits, and only insofar as is necessary given the nature of the population screening programme for which the permit is granted. Before deciding about an application, the Minister will consult the Health Council of the Netherlands. The Health Council draws up a recommendation – generally a detailed one – that also investigates the pros and cons of the intended population screening programme using the Wilson and Jungner criteria.

All WBO permits relating to population screening programmes have a section or appendix that formulates regulations that apply equally to all authorisation holders. Specific regulations may have been formulated as well.

The Healthcare Inspectorate monitors the compliance with the WBO (and any permit issued under it). In the first instance, it will only have to test compliance with the permit regulations. A penalty is imposed for each infringement if the permit regulations are infringed.

### **Grant scheme for public healthcare**

For the implementation of a population screening programme for cancer, the Minister of Health, Welfare and Sport can grant a subsidy to screening organisations, insofar as:

- the population screening programme for breast cancer focuses on women aged 50 to 75
- the population screening programme for cervical cancer focuses on women aged 30 to 60,

- the population screening programme for bowel cancer focuses on men and women aged 55 to 75, and
- they are not required to make any payments for participating in the screening programme.

The Minister of Health, Welfare and Sport may impose obligations when granting the subsidy:

- with respect to the quality of the population screening programme;
- with respect to recording data for evaluating the process and its effect;
- with respect to referrals for further diagnostic tests;
- with respect to a way of implementing population screening that helps improve the population screening programmes
- that are aimed at realising the purpose of the subsidy; or
- with respect to the way that the subsidised activity is carried out or the resources that are used for it.

Monitoring observance of the grant scheme and subsidy obligations is not a task for the Healthcare Inspectorate but for the party that grants the subsidy (RIVM) and the Audit Department of the Ministry of Health, Welfare and Sport.

### **The Medical Treatment Agreement Act (WGBO) and the Individual Healthcare Professions Act (Wet BIG)**

The essence of the relationship between the patient/or participant in a population screening programme and the healthcare provider is laid down in the Medical Treatment Agreement Act (WGBO). It also ensures the usual informed consent, privacy, the qualitative duty of care of the healthcare provider, keeping patient records and other legal relationships between healthcare provider and patient/participant.

The Individual Healthcare Professions Act (Wet BIG) is primarily intended to ensure the quality of the professionals who are covered by this act. A distinction is made between what are known as the 'registered professions' and professions to which 'protection of title' applies. Legal disciplinary law is applicable to the registered professions. With respect to population screening for cancer, these are gastrointestinal and liver specialists, radiologists, general practitioners and gynaecologists. In principle, working in the field of individual healthcare is 'free' (i.e. not restricted to qualified groups), but this does not apply to what are known as 'reserved procedures'. These may only be carried out by professionals defined in law and only by others under specific conditions, such as instructions given by the authorised professional. It should be borne in mind that the authorisation only applies even then insofar as you are capable and competent of performing the work. The legal authorisation is therefore not the only aspect. Reallocation of tasks and job differentiation in healthcare have now created a nuanced system of authorisations.

The legal system of the Individual Healthcare Professions Act is too general to assure the required quality of those who implement population screening programmes. Additional conditions are imposed in the quality requirements.

### **The Healthcare Quality, Complaints and Disputes Act (Wkkgz)**

After lengthy parliamentary discussions, the Healthcare Quality, Complaints and Disputes Act (Wkkgz) has replaced the Care Institutions (Quality) Act (KWZi) and the Clients' Right of Complaint (Care Sector) Act (Wkcz). The Wkkgz has a broader scope than the KWZi.

In summary, a healthcare provider must ensure the provision of 'proper care' that is at least safe, efficient, effective and client-oriented in accordance with the professional standards, or carried out in accordance with the quality standards determined by the National Health Care Institute.

The main lines of the Wkkgz are (in highly summarised form):

- Systematically monitoring and improving the quality of care and maintaining data for it;
- An incident register in which personal details can be processed, even without permission from the party involved;
- Giving information to the clients to let them make choices;
- Notifying the Healthcare Inspectorate of sentinel events, violence in care settings, and cancellation of agreements with a care provider because of poor performance;
- A simple-to-use mechanism for submitting complaints in which the client must have the option of being assisted by a mediator appointed by the care provider;
- Affiliation of the care provider to an arbitration body recognised by the Minister of Health, Welfare and Sport that can issue binding rulings about compensation to the client of up to € 25,000; and
- Measures taken by the Minister of Health, Welfare and Sport (and temporary measures taken for the sake of speed by the Healthcare Inspectorate) if a care provider fails to comply with the Wkkgz.

All organisations that carry out actions as part of the population screening programme, such as screening organisations and GP practices, are covered by the Wkkgz.

The Healthcare Inspectorate is responsible for monitoring compliance with this act too.

### **The Care Institutions (Accreditation) Act (WTZi)**

The laws in the previous sections focus primarily on the quality of care. The Care Institutions (Accreditation) Act (WTZi) focuses more on the organisation of the care institution because of the public character and the relatively dependent position of the client.

The WTZi is applicable to institutions that offer insured care. This law imposes requirements on the governance structure and transparency of the institution. The law thus builds upon Healthcare Governance, and was the reason why institutions in the field drew up the more detailed Care Sector Governance Code. The screening organisations must comply with the WTZi.

### **The Personal Data Protection Act (Wbp)**

The Personal Data Protection Act (Wbp) formulates the key regulations for recording and using personal details, a term that covers all data

regarding an identified or identifiable natural person. Transparency, restriction to intended aims and lawful processing of personal details are the most important guiding principles. The various population screening programmes process personal data and thus, to a greater or lesser degree, specific personal details. A particularly strict regime applies to special personal details such as those about health. The Wbp includes a mandatory duty to report data leaks that have (or may have) seriously harmful consequences for the protection of personal details. Each clearly distinct processing action involving personal details must be reported by the responsible party to the Wbp register kept by the monitoring body, the Dutch Data Protection Authority (CBP). Since 2016 it has been called the Personal Data Authority.

### **The Personal Public Service Number (General Provisions) Act (Wabb) and the Act on the Use of the Citizen Service Number in Healthcare (Wbsn-z)**

The Personal Public Service Number (General Provisions) Act (Wabb) comprises general provisions relating to the unique 'Citizen Service Number' (BSN) and its use by government bodies. The Act on the Use of the Citizen Service Number in Healthcare (Wbsn-z) formulates the duty to use the Citizen Service Number (BSN), and the associated obligations in healthcare.

#### **Note:**

A legislative amendment (Parliamentary Paper 33509) is under way regarding the processing of data in which 'pull' systems are used. This involves exchange of data in which a later healthcare provider can request data from a patient's records from an earlier healthcare provider in the chain. A nuanced permission system would have to be used for this. However, the Upper House of the Dutch parliament has expressed its objections regarding the feasibility and necessity of this bill. It is currently unclear whether this bill will be accepted.

### **The Nuclear Energy Act**

This act also imposes regulations to provide protection against the hazards associated with the use of radioactivity, such as for the National Programme for Breast Cancer Screening.

This use has a notification obligation or, where permits are issued, an obligation to obtain a permit. Special regulations apply to medical use of and protection against radiation, and these refer explicitly to population screening.

The key decree that covers radiation regulations is the Radiation Protection Decree. This contains the basic regulations for working with radioactive substances and devices that emit ionizing radiation.

Naturally enough, the primary responsibility for the compliance with the nuclear energy act lies with the reporting party or, if a permit has been issued, with the authorisation holder (which in this case will be the screening organisation). The Dutch Healthcare Inspectorate monitors compliance.

### **Use of Bodily Materials (Consultation) Act (WZL, bill currently being prepared)**

In anticipation of general legal regulations on (further) use of bodily material (proposed bill for a Use of Bodily Materials (Consultation) Act), a clear policy has to be determined for population screening programmes regarding storage and use of bodily material taken in the context of population screening for purposes that are covered by the screening (primary diagnostic testing and follow-up diagnostic testing, internal quality control and quality improvement, education and training) and other purposes (further use, including use for scientific research). To determine a policy for storing and using bodily material for the various population screening programmes, a distinction has to be made between the primary goal – screening – and other goals (further use). Such 'further use' for scientific research may ultimately yield major benefits for the improvement of the programmes, but must not burden the existing implementation at the same time. Different rules currently apply for further use of anonymous bodily materials (no opt-out system) than for bodily materials that can be traced to a person (permission must be obtained).

On instructions from the RIVM-CvB, the legal conditions for storing and using bodily materials that have been obtained in the context of population screening have been defined. In 2012/2013 the RIVM-CvB presented advice to the Ministry of Health, Welfare and Sport about handling bodily material in screening programmes.

### **The Public Health Act (Wpg)**

The Public Health Act (Wpg) comprises the framework for public health. With respect to general local/regional public health policy, the municipal executive must promote the creation and continuity of public healthcare and its internal cohesion, and its alignment with curative healthcare and the medical assistance in accidents and emergencies.

For this, their responsibilities include at least helping with the setup, implementation and alignment of prevention programmes, including health promotion programmes.

Furthermore, this act also stipulates that the Minister of Health, Welfare and Sport promotes the quality and effectiveness of public healthcare and is responsible for maintaining and improving the national support structure and for promoting interdepartmental and international cooperation in the field of public healthcare.

The intention is that the screening programmes for which the organisation is currently dispersed will all be based on the Wpg in due course.

### **The RIVM Act**

Taking due note of the RIVM Act, the Minister has ordered the National Institute for Public Health (RIVM) to implement the national management and supervision of programmatic prevention programmes. The population screening programmes for cancer are an example of this.

Nationally based management of the programmatic prevention programmes also means that the RIVM is responsible for paying the

costs of these programmes on behalf of the Ministry of Health, Welfare and Sport.

### **General Data Protection Regulation**

Privacy legislation in Europe is currently being thoroughly revised. The current Directive 95/46/EC is being replaced by a regulation called the General Data Protection Regulation (GDPR). In June, another version of the GDPR was presented by the third player on this European chessboard, namely the Council of the European Union (the leading role being taken by the judicial authorities, hereinafter referred to as the 'Council'). This is considerably more favourable for scientific research.

The tripartite discussions between the three players listed are starting now. The world of scientific research is trying to influence these discussions together with the patient organisations.

### **Public Procurement Act 2012 and European tendering guidelines**

In the Netherlands, the regulations for handling "European tenders" are laid down in the Public Procurement Act of 2012. This act is the national implementation of the current European tendering directives 2014/24/EC (for the "classical government") and 2014/25/EC (for the utility sectors).

The act states the principles and regulations that have to be used in European tendering procedures. Additionally, the act states the guiding principles that apply to national and multiple private tenders.

The Public Procurement Act is applicable to the tenders that are issued for the population screening programmes for cancer.

### **NEN7510 (Information security for the care sector)**

Information security is important for population screening programmes because (special) personal details are exchanged in the care chain of population screening. Information security is about:

1. confidentiality
2. availability
3. integrity

1. Ad 1) Confidentiality means that only people who are authorised are allowed to view the data.
2. Ad 2) Available means that the data is accessible.
3. Ad 3) Integrity means that the data is correct.

Multiple frameworks are available to ensure proper organisation of information security. One generally accepted information security framework is NEN 7510. This standard is applicable to the population screening programmes in accordance with the "comply or explain" principle.

### **Digital government 2017**

In 2010 the authorities jointly determined a government-wide vision on services under the motto 'Services: working together'.

Six targets that their services have to comply with by 2020 have been formulated in this vision:

- Our actions are focused on questions from the general public, companies and institutions.
- We make sure that the general public, companies and institutions can settle things quickly and securely.
- We do not bother the general public, companies and institutions with the differences between our organisations; we operate as a single government.
- We do not ask any unnecessary questions. We will not keep asking for data that has already been entered into the basic registration systems or for information that is available within our own organisation.
- We are transparent and accessible.
- We will set up our services as efficiently as possible with due observance of the needs of the general public, companies and institutions.

The Digital 2017 programme will assist these broader aims for government-wide services. From 2017 onwards, the general public and companies must be able to handle all their government-related matters digitally (Digital Government 2017). VWS, RIVM and the screening organisations will also have to comply with this (as soon as possible) for their population screening programmes. An essential part of this is that the government must make sure that all information that is relevant to the general public is available in digital form. Additionally, the public must be able to send all questions and applications to the government digitally and receive all messages from the government digitally. This also imposes high requirements on the information security for population screening.

## Appendix 4 The Wilson & Jungner criteria<sup>8</sup>

The criteria defined by Wilson and Jungner in 1968:

- The disease to be detected should be an important health problem.
- There should be a generally accepted treatment for the disease.
- Facilities for diagnosis and treatment should be available.
- There should be a recognisable latent or early symptomatic stage of the disease.
- There should be a reliable detection method.
- The detection method should be acceptable to the population.
- The natural course of the disease to be detected should be adequately understood.
- There should be agreement on whom to treat.
- The costs of detection, diagnostic tests and treatment should be acceptably in balance with the costs of medical care as a whole.
- The process of detection should be a continuing process and not a "one-time only" project.

In 2008, the World Health Organization (WHO) drew up a list with additional criteria.

The additional criteria drawn up by the WHO:

- The population screening programme should respond to a recognised need.
- The objective of the population screening programme should be defined at the outset.
- There should be a defined target population for the population screening programme.
- There should be scientific evidence of population screening programme effectiveness.
- The population screening programme should integrate education, training, testing, clinical services and programme management.
- There should be quality assurance for the population screening programme to minimise the potential risks of screening.
- The population screening programme should provide guarantees of informed choice and respect the privacy and autonomy of the individual.
- Access to the population screening programme must be guaranteed for the entire target population.
- Programme evaluation of population screening should be planned from the outset.
- The benefits of the population screening programme should outweigh the possible disadvantages of the screening.

<sup>8</sup> Source: Public Health Papers No. 34 – Principles and practice of screening for disease (J.M.G. Wilson and G. Jungner). World Health Organization, Geneva, 1968

## Appendix 5 Public values<sup>9</sup>

The public value '**quality**':

- *The programmes are effective*  
The programmes are effective in terms of the screening test used (test characteristics), the participation of the target group, and the contribution to health gains and/or offering treatment options.
- *The programmes are demand-oriented*  
The programmes take account of the wishes and needs of the target group.
- *The programmes are safe and uniform at a national level*  
The programmes are implemented responsibly and uniformly at a national level. The benefits of the programme outweigh the possible disadvantages of the screening for the target group. The continuity of the programme is guaranteed.
- *The programmes are innovative*  
The parties involved have knowledge and experience available that are used structurally to ensure continuous improvement of the programmes. Relevant innovations in methodology and screening methods, diagnostics and treatment are noted in time. The possible consequences for the programmes are discussed with the Ministry of Health, Welfare and Sport, ZonMw, the Health Council and other relevant parties.

The public value '**accessibility**':

- *The programmes are accessible*  
The programmes are organised in such a way that there are as few obstacles as possible that prevent the target group from taking part.
- *The programmes guarantee that the required activities are carried out in good time*  
The target group is invited to take part in the programme in time. The throughput times in the programme are acceptable, including the lead times for diagnostics and treatment.
- *Participation in the programme is a free choice*  
Participation in the programmes is voluntary. The information to the general public and the target group is updated, objective and balanced and helps them make a well-informed choice. Balanced information discusses the pros and cons of the programme.

The public value '**affordability**':

- *The costs of the programme are clear*  
The costs of the programmes are clear so that the government can weigh up the use of public resources against deployment for the government's other tasks.
- *The programmes are efficient*

<sup>9</sup> Adopted from uniform text on Public Values (version 1.1). Determined in the RIVM-CvB team meeting dated 21 October 2013.

The programmes are implemented at the lowest costs possible in relation to the required quality and accessibility. The programmes are also cost-effective.

## Appendix 6 Definitions

The stated versions of the documents indicated below have been used for purposes that include creating this policy framework.

- Policy Framework for Population Screening for Cancer 2014
- Policy framework for Prenatal and Neonatal Screening 2016
- Fact sheet for the National Programme for Breast Cancer Screening 2015
- Fact sheet for the Cervical Cancer Population Screening 2015
- Fact sheet for the Bowel Cancer Population Screening 2015
- VWS Subsidies (Framework) Act (1998)
- Instructions from the Ministry of Health, Welfare and Sport 2015 to the RIVM-CvB
- Public Health Papers No. 34 – Principles and practice of screening for disease (J.M.G. Wilson and G. Jungner). World Health Organization, Geneva, 1968
- Grant scheme for public healthcare (2015)
- Implementation of the Breast Cancer Population Screening (version dated 30 December 2014)
- Implementation of the population screening programme for cervical cancer (2014 version)
- Implementation of the population screening programme for bowel cancer (December 2014 version)
- Standardisation of public values (Version 1.1; 21 October 2013)
- Population Screening Act (1992)
- RIVM Act (including the decree PG/JFB-3147964 in the Government Gazette for implementing Article 3, paragraph 1, part a of the RIVM Act.

**RIVM**

Committed to *health and sustainability* -