



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

Policy framework for Prenatal and Neonatal Screening

RIVM Report 2018-0043

H.M. Vermeulen | R. van Velzen | F. Abbink



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

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Colophon

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

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Synopsis

Policy framework for Prenatal and Neonatal Screening

The Policy Framework for Prenatal and Neonatal Screening provides an overview of the legal and policy-related frameworks for five preventive screening programmes available during pregnancy and immediately following childbirth. These frameworks have been defined by the Dutch Ministry for Public Health, Welfare and Sport (VWS). There are three screening tests for the unborn child: for Down's, Edwards' and Patau's syndromes, for a number of infectious diseases, including HIV, and for physical abnormalities. The neonatal screening tests concern the child's hearing and the neonatal heel prick.

The National Institute for Public Health and the Environment (RIVM) has been responsible for national population screening programmes since 2006 and in that role monitors the quality, accessibility and affordability of them. The policy framework is an instrument that enables RIVM to perform its supervisory tasks, while responsibility for the conduct of screening programmes lies with the operational organisations.

The policy framework also sets out the parameters for collaboration between parties involved in the preparation of, decision-making on and conduct of antenatal and neonatal screening, the reason being that adequate alignment of all logistical and substantive processes is key to ensure that the quality of screenings is up to par. In particular, the transition from population screening to further diagnostic tests (medical examinations if indicated) and treatment is a key step for which the parties within the population screening programme and the care chain bear joint responsibility.

In addition, the framework sets out relevant requirements for the elaboration of screening plans. The main focus of these plans is on the way in which screenings are conducted.

The policy framework is checked annually to confirm it is up to date and amended if necessary.

Keywords: population screening, prenatal screening, antenatal screening, neonatal screening, policy framework, policy

Publiekssamenvatting

Beleidskader Pre- en Neonatale Screeningen

Het Beleidskader Pre- en Neonatale Screeningen geeft een overzicht van de wettelijke en beleidsmatige kaders voor vijf screeningen die tijdens de zwangerschap en kort na de geboorte preventief worden aangeboden. Deze kaders zijn door het ministerie van Volksgezondheid, Welzijn en Sport (VWS) vastgesteld. Er zijn drie screeningen voor het ongeboren kind: op het syndroom van down, op enkele infectieziekten zoals hiv, en lichamelijke afwijkingen. De screeningen vlak na de geboorte betreffen het gehoor van het kind en de hielprik.

Het RIVM voert sinds 2006 de regie op de bevolkingsonderzoeken en bewaakt vanuit die rol de kwaliteit, bereikbaarheid en betaalbaarheid ervan. Het beleidskader is een instrument om de regie te voeren. De uitvoering ligt bij de uitvoeringsorganisaties.

Het beleidskader beschrijft eveneens hoe partijen samenwerken die betrokken zijn bij de voorbereiding van, besluitvorming over en uitvoering van de pre- en neonatale screeningen. Voor een goede kwaliteit van de screening is het immers van belang dat alle logistieke en inhoudelijke processen goed op elkaar aansluiten. Vooral de 'overgang' van een uitslag van een bevolkingsonderzoek naar een diagnose en behandeling is een belangrijke stap, waarvoor partijen binnen het bevolkingsonderzoek en de zorg gezamenlijk verantwoordelijk zijn.

Daarnaast worden de kaders weergegeven die relevant zijn voor de nadere uitwerking van de draaiboeken van de screeningen. Deze draaiboeken zijn vooral gericht op de wijze waarop de screeningen worden uitgevoerd.

Het beleidskader zal regelmatig worden getoetst en indien nodig aangepast aan de actualiteit.

Kernwoorden: bevolkingsonderzoek, Pre- en Neonatale Screeningen, beleidskader, beleid

VWS adoption letter

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Enclosure(s)

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 Prenatal and Neonatal Screening provides an overview of the legal and policy frameworks adopted by the Dutch Ministry of Health, Welfare and Sport (VWS) for prenatal screening for infectious diseases and erythrocyte immunisation (PSIE), prenatal screening for Down's, Edwards' and Patau's syndromes, the structural ultrasound scan (SEO), neonatal hearing screening (NGS) and neonatal blood spot screening (NHS). This document also describes the cooperation between the parties who are involved in preparation, decision-making and implementation of the prenatal and neonatal screening programmes. This policy framework also gives the applicable preconditions for further elaborating the frameworks for the implementation of the screening programmes in question (the programme organisation and guidelines). The programme organisation and guidelines focus above all on implementing the screening programmes.

This policy framework was drawn up for the public sector parties and operational organisations and professionals involved in the preparation, direction, coordination and implementation of prenatal and neonatal screening programmes, including parties 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 prenatal and neonatal screening 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 Dutch Ministry of Health, Welfare and Sport (VWS). This document has been formally adopted by the Dutch Ministry of Health, Welfare and Sport.

1.3 Distribution and updating

This policy framework for prenatal and neonatal screening 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. After the policy framework has been amended, the Ministry of Health, Welfare and Sport will once again formally adopt it.

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 (the Healthcare Insurance Act), 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 assurance legislation, including the Healthcare Quality, Complaints and Disputes Act (Wkkgz).

Appendix 4 gives an overview and brief explanation of the legislation and regulations that apply specifically to prenatal and neonatal screening.

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 healthcare as “health-protecting and health-promoting measures for the population or specific groups within the population, which includes the prevention and early detection of (treatable) diseases”. The national government fulfils that responsibility inter alia through prevention programmes (including population screening programmes, which are also termed “screening” in this report). 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. At present, the only prenatal and neonatal screening tests that require a WBO permit are the prenatal screening for Down’s, Edwards’ and Patau’s syndromes and the structural ultrasound scan.

2.3 National Population Screening Programme

The National Population Screening Programme (NPB) consists of the national programme funded by the State, namely the three population screening programmes for cancer and the five prenatal and neonatal screening programmes. A policy framework has been drawn up for three population screening programmes for cancer, comparable to this policy framework for prenatal and neonatal screening (PNS).

The policy frameworks for PNS and for population screening for cancer together constitute an integral whole within the NPB.

The following prenatal and neonatal screening tests fall within the National Population Screening Programme:

Screening during pregnancy

Prenatal Screening for Infectious Diseases and Erythrocyte Immunisation (PSIE)

The aim of the PSIE test (a blood test for pregnant women) is to prevent hepatitis B and HIV carrier status, congenital syphilis and haemolytic disorder in the foetus and/or neonate.

Every pregnant woman is offered a blood test on her first visit to the obstetrician. The laboratory then tests the blood for the presence of three infectious diseases (hepatitis B, syphilis and HIV), for the ABO blood groups, rhesus D and rhesus C, and for blood group antibodies. After the first blood sample, various follow-up actions may be initiated within the screening programme if the results of the blood tests give reason to do so.

Prenatal screening for Down's, Edwards' and Patau's syndromes

The aim of the screening for Down syndrome is to inform people who want to have this information in good time of the presence or absence of the disorder in question so that they can make a well-informed decision about further options.

Prospective parents who wish to do so can arrange for a test during the pregnancy to show the likelihood that their baby has Down's, Edwards' or Patau's syndrome. This is done through what is known as a 'combined test', comprising a blood test between weeks 9 and 14 and an ultrasound scan between weeks 11 and 14 of the pregnancy. In the screening for Down syndrome (trisomy 21), information is also given on the likelihood of trisomy 13 (Patau's syndrome) and trisomy 18 (Edwards' syndrome). This is followed by a counselling talk with the provider of obstetric care if the pregnant woman indicates that she would like to know more about the screening.

Structural Ultrasound Scan

The aim of the structural ultrasound scan (anomaly scan) is to inform people who wish to have this information on time of the presence or absence of the disorder in question so that they can make a well-informed decision about further options.

Prospective parents who wish for this can have their unborn baby tested for the presence of neural tube defects and defects in organs and limbs. This test, known as the '20-week scan', is performed between the 18th and 22nd weeks of pregnancy. Abnormal observations in the structural ultrasound scan can lead to a change in the policy for the birth. This may affect the location, the duration of the pregnancy or the method of delivery. For a number of disorders, treatment is possible immediately following the birth.

Screening after the birth

Neonatal blood spot screening

The aim of the neonatal blood spot screening is to detect in good time a number of rare severe disorders that affect neonates in order to prevent or limit severe damage to the baby's physical and mental development. The disorders cannot be cured, but they can be treated.

A blood spot test is offered for all babies between 72 and 168 hours after the birth. The baby's blood is screened for a number of rare, severe disorders. Most are hereditary. In the event of an abnormal result, the baby will be referred to a university hospital or general hospital, where a definite diagnosis will be made and treatment will be started.

Neonatal blood spot screening for the Caribbean Netherlands

At present, prenatal and neonatal screening is only carried out in the European Netherlands. Since 2010, the islands of Bonaire, Sint Eustatius and Saba – collectively known as the Caribbean Netherlands – have been special municipalities within the Netherlands. This means that the Dutch Minister of Health, Welfare and Sport is responsible for healthcare in the Caribbean part of the Netherlands. As of 1 January 2015, blood spot screening has also been carried out on the islands of Bonaire, Sint Eustatius and Saba. For more on this, see Appendix 4, 'Overview of relevant legislation and regulations'.

Neonatal hearing screening

The aim of neonatal hearing screening is to detect hearing loss as soon as possible so that treatment can start before the baby is six months old. Evidence shows that this has a beneficial effect on language and speech development.

The hearing test should in principle be performed as soon as possible after the first 96 hours, and certainly no later than 168 hours after the birth. In the event of an abnormal result for one or both ears, the hearing test can be repeated twice if required. If the result remains abnormal, this is followed by referral to an audiology centre for further diagnostic tests and treatment as necessary. The hearing test is usually offered in combination with the blood spot test.

The neonatal hearing screening is part of the basic care package in youth healthcare services. The said basic care package in youth healthcare services is based on the Public Health Act and is determined by the Ministry of Health, Welfare and Sport. The neonatal hearing screening test differs in a number of respects from the other prenatal and neonatal screening tests described in this policy framework. For example, the Health Council of the Netherlands does not play a role in the hearing screening, no reference function has been set up and there is no regional coordinating organisation for neonatal hearing screening of the kind described further on in this document.

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 5 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 requested to do so 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.

2.4.2 *Public values*

Population examinations/screening must be carried out in a way that complies with the relevant public values adopted by the government authorities, namely quality, accessibility and affordability. The public values must be brought carefully into equilibrium, creating the optimum situation in terms of the setup and implementation of the screening tests. See Appendix 6 for details of how the public values are applied.

The public values are quantified and assessed using monitors and evaluation studies. For further explanation, see Section 5 ("Quality assurance and quality improvement of prenatal and neonatal screening").

2.4.3 *Cooperation in the care chain*

A population screening programme (systematically offering medical examinations to a population that is in principle not affected, with the provider taking the initiative) is embedded in a care chain rather than being a stand-alone task. 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 examinations if indicated) 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 population screening and the care process it is linked to.

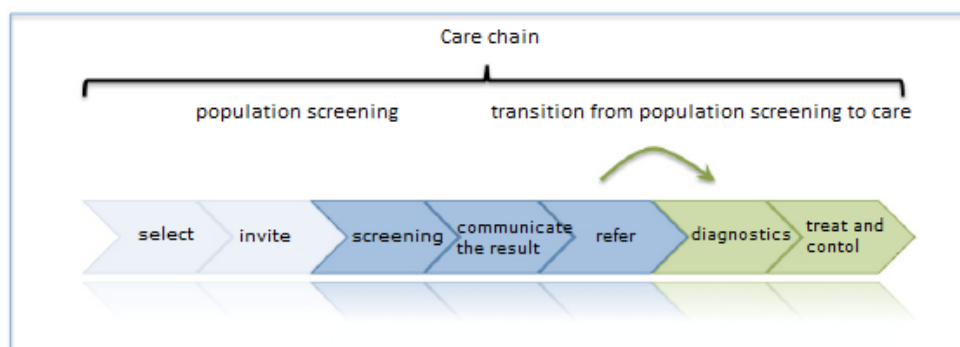


Figure 1: Steps in the population screening programme (steps 1 through to 5) and follow-up care (steps 6 and 7).

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. If necessary, they can be referred to the care process in which further diagnostic tests and any necessary checks and treatments can take place. The participants in prenatal and neonatal screening are not actively selected and invited to participate in the way the screening organisations do in the population screening programmes for cancer. In prenatal and neonatal screening, the pregnant woman is informed early on of the option of having the screening tests. The steps in the care chain are described briefly below for each screening test.

Prenatal screening

Prenatal Screening for Infectious Diseases and Erythrocyte Immunisation (PSIE):

In the first appointment with the provider of obstetric care (the obstetrician, midwife, GP or gynaecologist supervising the pregnancy), the pregnant woman is informed of the option of having a prenatal screening test for infectious diseases and erythrocyte immunisation. A blood sample is taken for the PSIE test and analysed at a laboratory. As soon as the results from the blood test are known, the obstetric care provider informs the pregnant woman about them. If necessary, follow-up actions are taken or the provider of obstetric care passes the pregnant woman on to the healthcare provider. The population screening is completed once the pregnant woman has received the result of the screening and (depending on the result) any follow-up actions relating to the screening have been taken. Some follow-up actions are carried out after the birth.

Screening for Down's, Edwards' and Patau's syndromes and the structural ultrasound scan (SEO):

In the initial contact with the provider of obstetric care, the pregnant woman is asked whether she would like information about the screening for Down's, Edwards' and Patau's syndromes and the structural ultrasound scan. This is only followed by a counselling talk with the provider of obstetric care if the pregnant woman indicates that she would like to know more about one or both screening tests. If the pregnant woman then says that she would like one or both screening tests done, an appointment is made for the screening. The screening

test for Down's, Edwards' and Patau's syndromes consists of a blood test of the mother and a nuchal translucency test via an ultrasound scan. In the SEO test, an ultrasound scan is made. This ultrasound scan is used to examine the development of the neural tube and the baby's organs and to check that the unborn child is growing properly and that there is sufficient amniotic fluid. As soon as the results are known, the pregnant woman is informed about them. Depending on the outcome of the examinations, the pregnant woman may be referred to a centre for prenatal diagnostic tests if she so wishes.

Neonatal screening

Neonatal blood spot screening (NHS):

In the third trimester of the pregnancy, the provider of obstetric care gives the pregnant woman a leaflet with general information about the hearing screening and neonatal blood spot screening. When the baby's birth is registered at the Registry of Births, Deaths and Marriages, the parents are given another copy of this information leaflet. After the birth, the screener makes an appointment with the parents for the screening test or pays them a visit. For the blood spot test, a blood sample is taken and analysed at a screening laboratory. The parents hear nothing if the result is good.¹ In the event of an abnormal result, the GP is informed by the medical advisor from the RIVM-DVP regional office. The GP then arranges a referral to a paediatrician who specialises in the disorder.

Neonatal hearing screening (NGS):

In the third trimester of the pregnancy, the provider of obstetric care gives the pregnant woman a leaflet with general information about the hearing screening and neonatal blood spot screening. When the baby's birth is registered at the Registry of Births, Deaths and Marriages, the parents are given another copy of this information leaflet. After the birth, the screener makes an appointment with the parents for the screening test or pays them a visit for the hearing test. In some regions, the hearing test is carried out at the child health clinic when the baby is a couple of weeks old. If sufficient hearing cannot be demonstrated in one or both ears after three sets of tests, the baby is referred to an audiology centre, where further examinations are carried out, followed by treatment if required.

¹ This aspect is due to change in future so that parents will always receive a report of the result.

3 Involvement of the public authorities in prenatal and neonatal screening tests

3.1 Key players among the authorities

Various governmental bodies are involved in the preparation or amendment and reassessment of prenatal and neonatal screening. The Health Council of the Netherlands and the Netherlands Organisation for Health Research and Development (ZonMw) have a task that is primarily preparatory with regard to new screening tests and far-reaching changes to the existing screening tests. 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.

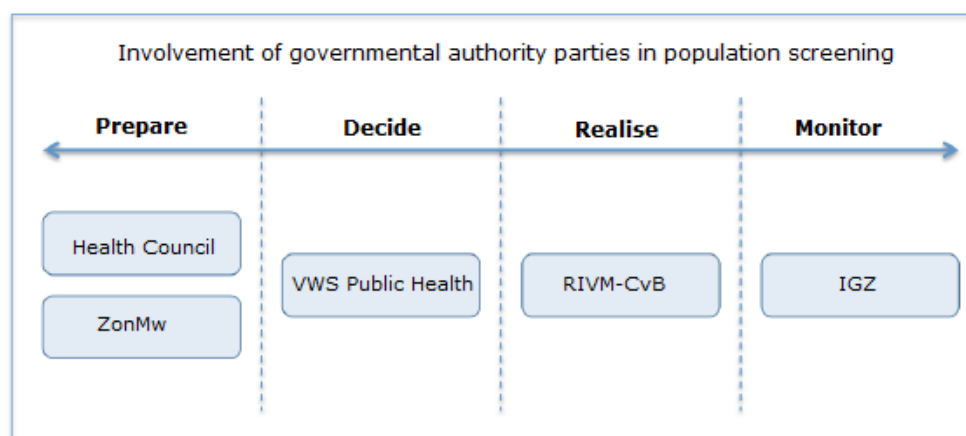


Figure 2: Involvement of the public authorities in the screening tests.

The involvement of the authorities in prenatal and neonatal screening is explained in more detail below.

- 3.1.1 *Dutch Ministry of Health, Welfare and Sport – Public Health Directorate²*
 The Minister of Health, Welfare and Sport bears political responsibility for prenatal and neonatal screening 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 the Ministry of Health, Welfare and Sport in prenatal and neonatal screening:

- a. The Ministry of Health, Welfare and Sport determines the legal and policy frameworks for prenatal and neonatal screening.
- b. The Ministry of Health, Welfare and Sport instructs the RIVM-CvB to direct and manage the implementation of prenatal and neonatal screening nationwide. These instructions define the

² For the screening for Down's, Edwards' and Patau's syndromes and the structural ultrasound scan, this is the Public Health Directorate and the Curative Care Directorate.

context and the preconditions for the management and implementation of the screening programmes. The prenatal and neonatal screening programmes must comply with the legal and policy frameworks and the public values of quality, accessibility and affordability, as well as being aligned with the care delivery. The RIVM-CvB provides financial and substantive accountability reports to VWS periodically.

- c. The Minister of Health, Welfare and Sport provides funding³ for the National Population Screening Programme (see also Appendix 3).
- d. The Ministry of Health, Welfare and Sport gives ZonMw instructions for contracting, funding and facilitating research into prenatal and neonatal screening.
- e. The ministry can ask the Health Council of the Netherlands⁴ to make recommendations about possible new screening tests (and the desirability thereof), and changes, innovations or reassessment of current screening tests.
- f. The Minister of Health, Welfare and Sport takes decisions regarding far-reaching changes in prenatal and neonatal screening.

3.1.2 *Health Council of the Netherlands*⁵

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.

The tasks of the Health Council of the Netherlands in prenatal and neonatal screening (excluding neonatal hearing screening):

- a. The Health Council advises the Minister of VWS both on request and spontaneously about the current state of scientific knowledge, innovations and major changes in prenatal and neonatal screening.
- b. The Health Council advises the Minister of VWS about permit applications⁶ under the Population Screening Act (WBO).

3.1.3 *Netherlands Organisation for Health Research and Development (ZonMw)*

ZonMw is an autonomous administrative authority 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.

³ The nationwide direction and coordination by the RIVM-CvB is financed from the State budget of the Ministry of Health, Welfare and Sport. See Appendix 3 for the specific frameworks for funding the regional coordination and implementation.

⁴ This is not applicable to neonatal hearing screening because the Health Council of the Netherlands does not have a role in neonatal hearing screening.

⁵ The Health Council of the Netherlands does not have a role in neonatal hearing screening.

⁶ At present, the only prenatal and neonatal screening tests to require a WBO permit are the prenatal screening for Down syndrome and the structural ultrasound scan.

The tasks of ZonMw in prenatal and neonatal screening:

- a. 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.

3.1.4

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.

The RIVM-CvB' tasks in prenatal and neonatal screening:

- a. On instructions from the Ministry of Health, Welfare and Sport, the RIVM-CvB directs prenatal and neonatal screening 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 alerts and advises the ministry and other governmental parties about developments and major changes (including innovations) that are important for prenatal and neonatal screening and that require measures and/or policy changes.
- c. Where relevant (see Appendix 3), the RIVM-CvB funds the implementation of prenatal and neonatal screening on behalf of the national government. The operational organisations and professionals are the parties contracted to implement the screening.
- d. The RIVM-CvB sets the parameters for the implementation and assures the quality by setting requirements and monitoring them (e.g. programme organisation and guidelines, 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 monitors and evaluates the prenatal and neonatal screening programmes with the aim of safeguarding their effectiveness, efficiency, reliability, nationwide uniformity and alignment with care delivery.
- 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 (Healthcare Inspectorate) and/or other governmental authority bodies in the event of emergencies relating to prenatal and neonatal screening.

- k. The RIVM-CvB encourages cohesive implementation of the prenatal and neonatal screening programmes 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 Central Council on Prenatal Screening⁷ and the Programme Committees advise the RIVM-CvB throughout. These committees contain 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 *Dutch 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 prenatal and neonatal screening:

- a. The Healthcare Inspectorate investigates emergencies and incidents, assesses the measures taken by the healthcare provider, takes measures itself if necessary, and advises the Minister of VWS about the enforcement of the applicable legislation on prenatal and neonatal screening.

⁷ The Central Council on Prenatal Screening has a decision-making task in addition to its advisory task. For example, the Central Council on Prenatal Screening determines the nationwide quality requirements. In 2016, the Central Council on Prenatal Screening is due to be replaced by a programme committee.

4 Involvement of the various parties in implementing prenatal and neonatal screening tests

4.1 Key players in the implementation

The implementation of the screening is a collaborative venture in which many different parties have tasks as part of the chain, from determining policy through to actually offering the prenatal and neonatal screening tests 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 prenatal and neonatal screening tests: on the left are the parties involved and on the right the main tasks of these parties in the prenatal and neonatal screening programmes.

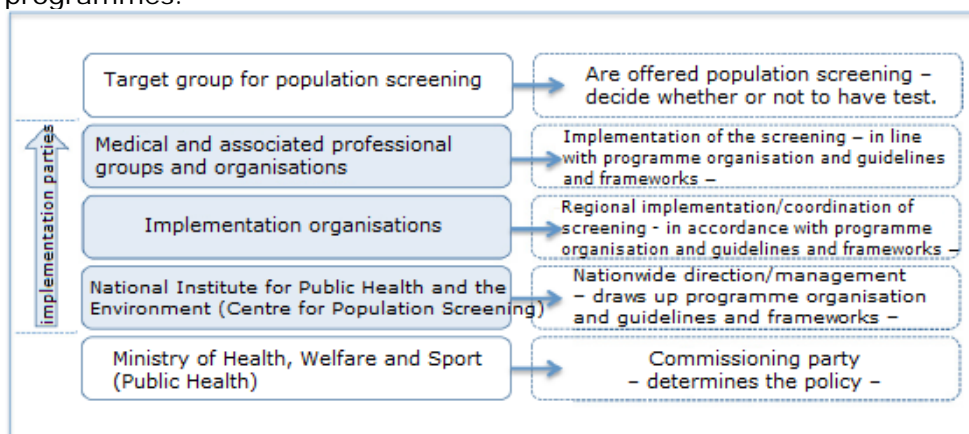


Figure 3: Cooperation between parties involved in the implementation.

The sections below give the frameworks for the parties involved in the regional coordination and implementation of the prenatal and neonatal screening tests. These frameworks form the preconditions and guiding principles for the further design and implementation of the screening programmes in question. Programme organisation and guidelines have been drawn up for each screening programme.

4.1.1 Regional coordination and implementation of the screening

Where necessary, the implementation of the prenatal and neonatal screening is coordinated by a dedicated regional implementation organisation⁸, taking into account the national implementation framework⁹.

⁸ For the PSIE and the newborn blood spot screening this is RIVM-DVP, for the screening for Down's, Edwards' and Patau's syndromes and the structural ultrasound scan this is the regional centres for prenatal screening (the permit holders); there is no regional coordinating organisation for the neonatal hearing screening.

⁹ The implementation frameworks for each screening test are worked out in more detail in the programme organisation and guidelines. There are combined guidelines for the screening for Down's, Edwards' and Patau's syndromes and the structural ultrasound scan.

General tasks/frameworks for the prenatal and neonatal screening tests:

- a. The regional implementation organisation arranges the implementation of prenatal and neonatal screening and commissions the implementation parties.
- b. The regional implementation organisation coordinates the implementation of the screening and makes sure that its implementation complies with the legislation and regulations and the national framework for the implementation as set by RIVM-CvB (the programme organisation and guidelines).
- c. The regional implementation organisation maintains a relevant regional network for the implementation of the screening, consults with parties in the region and encourages cooperation (where relevant for the screening) between these parties involved in the screening and the associated care.
- d. The regional implementation organisation monitors the quality of the implementation by the implementation parties.
- e. The regional implementation organisation provides the RIVM-CvB with data on the national monitoring and evaluation of prenatal and neonatal screening. The organisations are also responsible for the quality of this data.

4.1.2 *Implementation of the screening*

Various professionals and organisations are involved in the implementation of the screening and the associated care (including providers of obstetric care, audiology centres, counsellors, ultrasound scanning centres, local and specialist laboratories, hospitals, etc.). They collaborate in accordance with the national programme organisation and guidelines for the prenatal and neonatal screening programmes.

General tasks/frameworks for the prenatal and neonatal screening tests:

- 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-CvB¹⁰ can declare relevant guidelines (or parts thereof) to be applicable to the screening programmes and set additional requirements where necessary, following consultations with the professional group.
The permits and/or agreements/contracts oblige the parties to keep to the national programme organisation and guidelines and quality requirements.
- d. The implementation parties make data available for the purpose of assessing the quality of the implementation, and for monitoring and evaluating prenatal and neonatal screening. The organisations are also responsible for the quality of this data.

¹⁰ For the screening for Down's, Edwards' and Patau's syndromes and the structural ultrasound scan, this is the Central Council on Prenatal Screening.

5 Quality assurance and quality improvement of prenatal and neonatal screening

The quality assurance, nationwide monitoring and nationwide evaluation are important instruments that ensure that the implementation of the prenatal and neonatal screening programmes satisfies the quality requirements that have been set and can continually be improved. The details of the quality assurance, monitoring and evaluation of the prenatal and neonatal screening are worked out in the programme organisation and guidelines.

5.1 Reference function

A reference function (assessor) can be set up for the assessment and optimisation of the implementation of the screening programmes. A reference function¹¹ has been established for a number of the prenatal and neonatal screening programmes.

General tasks/frameworks for the prenatal and neonatal screening tests:

- a. The assessor focuses on the optimisation and safeguarding of the substantive medical quality and physical, technical quality of the implementation of the prenatal and neonatal screening programmes or parts of these programmes.
- b. The assessor has sufficient relevant expertise and enjoys the broad support of the professional groups involved.
- c. The assessor assesses the performance of the organisations and professionals involved in the implementation of the prenatal and neonatal screening, monitors the quality and helps improve the implementation.

5.2 Nationwide monitor

The nationwide monitor is used to monitor the public values in the prenatal and neonatal screening programmes, identify problems (in the healthcare chain), enable adjustments to be made and give an account to the Ministry of Health, Welfare and Sport, the Inspectorate, other partners and the general public.

General tasks/frameworks for the prenatal and neonatal screening tests:

- a. The monitoring organisation must be an authoritative party that has an independent position with respect to the RIVM-CvB and the organisations/professionals that deliver the prenatal and neonatal screening programmes and associated care.
- 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

¹¹ A reference laboratory is used for the newborn blood spot screening and the screening for Down's, Edwards' and Patau's syndromes. No reference function has been established for the PSIE, the structural ultrasound scan and the hearing screening.

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. RIVM concludes an agreement with the monitoring organisation for the purpose of the 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 evaluations includes both standard elements and more variable elements. Key aspects are the impact evaluation and the cost effectiveness study. Additional questions, which may originate from the findings from the nationwide monitors, are also answered.

General tasks/frameworks for the prenatal and neonatal screening tests:

- a. The evaluation organisation must be an authoritative party that has an independent position with respect to the RIVM-CvB and the organisations/professionals that deliver the prenatal and neonatal screening programmes and associated care.
- 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 concludes an agreement with the evaluation organisation for the purpose of the nationwide 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 prenatal and neonatal screening programmes, doing so within the boundaries 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 any change to a screening programme that goes beyond the underlying Health Council advice or the existing permit under the law covering population screening¹². Examples are changes to the test, the target group, the disorder being investigated or the screening interval. An innovation will usually have major consequences for the implementation or results of the screening.

¹² No role has been defined for the Health Council in innovations in neonatal hearing 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, the RIVM-CvB and the Health Care Inspectorate.

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 risk-return ratio does not change or if the change is unambiguously positive (more reward and/or less risk). The Health Council of the Netherlands is not required to give its opinion for the introduction of an optimisation, and in terms of responsibility, this can be dealt with through the hierarchical line of the Ministry of Health, Welfare and Sport, the RIVM-CvB and the implementation organisations. Sometimes consultation and agreement between the three parties of the Ministry of Health, Welfare and Sport, RIVM-CvB and the Health Council may be required to make the correct distinction between innovations and optimisations.

General tasks/frameworks for the prenatal and neonatal screening tests:

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

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').

Diagnostics

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

Programme organisation and guidelines

A description of the way in which a screening programme 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.

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. Innovations can be both technological and 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 towards improving a population screening programme within the existing frameworks. (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 programmes 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 of the advantages and disadvantages of various care options, supplemented with 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, obstetricians, nurses and other professional care providers and care staff.
- c. The term 'care users' covers patients, clients, the relatives of patients and clients, and 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

See the programme organisation and guidelines

Care chain

A care chain is the cohesive whole of efforts (in the field of care delivery) for the purpose of the implementation of the population screening programme and associated care, produced by various parties, in which the client is the focus.

Care provider

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

Appendix 2 Abbreviations

AVG	General Data Protection Regulation (“Algemene Verordening Gegevensbescherming”)
AWBZ	Dutch Exceptional Medical Expenses Act (“Algemene Wet Bijzondere Ziektekosten”)
BSN	Citizen service number (“Burger Servicenummer”)
CBP	Data Protection Authority (“College bescherming persoonsgegevens”)
GDPR	General Data Protection Regulation
IGZ	Healthcare Inspectorate (“Inspectie voor de Gezondheidszorg”)
JGZ	Youth healthcare services (“Jeugdgezondheidszorg”)
KWZi	Care Institutions (Quality) Act - lapsed
NBD	Neural tube defects
NEN	Dutch standards institute (“Nederlands Normalisatie-instituut”)
NGS	Neonatal hearing screening (“Neonatale Gehoorscreening”)
NHS	Neonatal blood spot screening (“Neonatale Hielprikscreening”)
NICU	Neonatal Intensive Care Unit
NPB	National Population Screening Programme (“Nationaal Programma Bevolkingsonderzoek”)
PSIE	Prenatal Screening for Infectious Diseases and Erythrocyte Immunisation
RIVM	National Institute for Public Health and the Environment
RIVM-CvB	Centre for Population Screening
RIVM-DVP	Department for Vaccine Supply and Prevention Programmes (“Dienst Vaccinvoorziening en Preventieprogramma’s”)
SEO	Structural Ultrasound Scan (“Structureel Echoscopisch Onderzoek”)
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
Dutch Medical Treatment Act	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
Wlz	Long-Term Care Act (“Wet langdurige zorg”)
Wpg	Public Health Act
WTZi	Care Institutions (Accreditation) Act
ZonMw	Netherlands Organisation for Health Research and Development
Zvw	Healthcare Insurance Act

Appendix 3 Financing

Funding for PSIE:

- The Ministry of Health, Welfare and Sport makes funds available via the National Budget for the nationwide direction, regional coordination and implementation of the PSIE.

Funding for the neonatal blood spot screening:

- The Ministry of Health, Welfare and Sport makes funds available via the National Budget for the nationwide direction, regional coordination and implementation of the neonatal blood spot screening.

Funding for Down's, Edwards' and Patau's syndromes screening and the structural ultrasound scan:

- The Ministry of Health, Welfare and Sport makes funds available via the National Budget for the nationwide direction of the prenatal screening for Down's, Edwards' and Patau's syndromes and the structural ultrasound scan. In the screening programme for Down's, Edwards' and Patau's syndromes, the costs of counselling are reimbursed through the basic health insurance, while the pregnant woman bears the costs of the combined test. The funding for the structural ultrasound scan screening programme takes place entirely via the basic health insurance. The Regional Centres receive compensation for their role in the prenatal screening through a surcharge on the rate for the structural ultrasound scan.

Funding for the neonatal hearing screening:

- The Ministry of Health, Welfare and Sport makes funds available via the National Budget for the nationwide direction and coordination of the neonatal hearing screening¹³. The neonatal hearing screening programme is part of the youth healthcare services basic package and the funding for the implementation of the hearing screening takes place via the Municipalities Fund.

¹³ The neonatal hearing screening that is offered to babies in the Neonatal Intensive Care Units (NICUs) is not part of this screening programme.

Appendix 4 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.

Because neonatal blood spot screening currently only addresses treatable disorders, it is not a population screening programme that is subject to a permit requirement. The same applies for the PSIE and NGS.

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.

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 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 WGBO also covers how children are represented by their parents or other legal representatives.

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. These include the professions of doctor, obstetrician and nurse. 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 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. The Wkkgz also applies to RIVM, insofar as it offers 'care' itself (as defined within the act). That is only the case for the 'heel prick' (neonatal blood spot screening).

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 by or 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 VWS that can issue binding rulings about compensation to the client of up to € 25,000.
- Measures taken by the Minister of VWS (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 screening, such as obstetric practices and youth healthcare organisations, 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 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.

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 (2015) unclear whether this bill will be accepted.

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. Youth healthcare services are just one of the elements that are underpinned by the Public Health Act. Control of infectious diseases is also handled via the Public Health Act. 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, 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. For the PSIE and the NHS, this will come into effect as of 1 January 2018.

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 antenatal and neonatal screening programmes are examples of this.

Nationally based management of the programmatic prevention programmes also means that RIVM is responsible for paying the costs of these programmes on behalf of the Ministry of Health, Welfare and Sport.

The Healthcare Insurance Act (Zvw)

The Healthcare Insurance Act (Zvw) is the successor to the former private insurance schemes and the Compulsory Health Insurance Act. It came into effective on 1 January 2006 and it is part of the new healthcare system. Under the Healthcare Insurance Act, everyone who lives in the Netherlands and/or pays wage taxes is required to take out basic health insurance.

Any subsequent care (diagnostics or treatment) resulting from the screening is paid by the basic health insurance.

The costs of the screening examinations are also paid from the basic health insurance for Down's, Edwards' and Patau's syndromes screening and the structural ultrasound scan. In the screening programme for Down's, Edwards' and Patau's syndromes, the costs of counselling are reimbursed through the basic health insurance, while the pregnant woman bears the costs of the combined test. The funding for the structural ultrasound scan screening programme takes place entirely via the basic health insurance.

Health insurance in the Dutch Caribbean and the BES Healthcare Insurance Decree

BES Healthcare Insurance is a general health insurance scheme for the islands of Bonaire, Sint Eustatius and Saba (BES). A uniform health insurance scheme for all legitimate residents serves the interests of equality before the law and avoids some people remaining uninsured. This insurance covers both medical and long-term care. The health insurance is based on the BES Healthcare Insurance Decree and the BES Healthcare Insurance (Claims) Scheme.

As in the European part of the Netherlands, the Minister of Health, Welfare and Sport has been tasked with examinations for rare and severe disorders (the neonatal blood spot screening). The nationwide administration and supervision of the examinations, the regional coordination (including the requisite data processing for the implementation plus the monitoring and evaluation of the programme) are tasks done by RIVM.

Pursuant to the temporary Article 4a of the Public Health Act, the neonatal blood spot screening does not apply to the public bodies Bonaire, Sint Eustatius and Saba. A claim to that has been included since 1 January 2015 in Article 16, paragraph 1, sub g of the BES Healthcare Insurance Decree and it is now being carried out on the islands.

The claim on the grounds of the BES Healthcare Insurance Decree may lapse as of 1 January 2018 because Article 12a of the proposed bill for the Public Health Act will also be applicable to those public bodies and the neonatal blood spot screening will become part of what is offered under that new article.

Article 12a of the bill proposing the new Public Health Act reads as follows:

1. Through RIVM, our minister handles the direction and the coordination of the implementation plus the records, monitoring and evaluation of the arrangements for population screening indicated by our minister, which includes neonatal blood spot screening. A non-standard package can be included for the public bodies of Bonaire, Sint Eustatius and Saba.
2. When implementing neonatal blood spot screening, deviations relating to data from children up to the age of six months are possible from Article 15b of the Personal Data Processing in Healthcare (Additional Provisions) Act.
3. By order of our Minister, rules may be set on the implementation of population screening, as defined in the first paragraph.

The Long-Term Care Act (Wlz)

The Long-Term Care Act (Wlz) was introduced as of 1 January 2015, replacing the Exceptional Medical Expenses Act (AWBZ). The Wlz is for all people who have a lifelong reliance on care. Children and adolescents aged up to 18 with multiple disabilities are entitled under this act to personal care, nursing, residential care, supervision and treatment.

The AWBZ budget (for implementation of the PSIE and the NHS) has been transferred as of 2015 because of the Wlz to the VWS budget. The shift has no consequences for the implementation in practice. This is a temporary situation; from 1 January 2018, it will be embedded in the legal framework via the Public Health Act.

The 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 antenatal and neonatal screening programmes.

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 and (3) integrity.

Ad 1) Confidentiality means that only people who are authorised are allowed to view the data.

Ad 2) Available means that the data is accessible.

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

From 2017 onwards, the general public and companies must be able to handle all their government-related matters digitally (Digital Government 2017). VWS and RIVM 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 5 The Wilson & Jungner criteria¹⁴

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 screening programme should respond to a recognised need.
- The objective of the screening programme should be defined at the outset.
- There should be a defined target population for the screening programme.
- There should be scientific evidence of screening programme effectiveness.
- The 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 screening programme should provide guarantees of informed choice and respect the privacy and autonomy of the individual.
- Access to the screening programme must be guaranteed for the entire target population.
- Programme evaluation should be planned from the outset.
- The benefits of the population screening programme should outweigh the possible disadvantages of the screening.

¹⁴ 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 6 Public values¹⁵

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

¹⁵ Adopted from uniform text on Public Values (version 1.1). Determined in the RIVM-CvB team meeting dated 21 October 2013.

Appendix 7 Definitions

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

- Programme organisation and guidelines for newborn hearing screening (Version 3.0, May 2013)
- Programme organisation and guidelines for newborn blood spot screening (Version 10.0, 1 July 2014)
- Programme organisation and guidelines for prenatal screening for Down syndrome and structural ultrasound scans (version 5.0, January 2014)
- Programme organisation and guidelines for prenatal screening for infectious diseases and erythrocyte immunisation (version 4.0; 1 January 2014)
- Fact sheet for newborn hearing screening (version dated May 2014)
- Fact sheet for newborn blood spot screening (version dated May 2014)
- Fact sheet for prenatal screening for Down syndrome and structural ultrasound scans (version dated May 2014)
- Fact sheet for Prenatal Screening for Infectious Diseases and Erythrocyte Immunisation (version dated May 2014)
- 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
- Standardisation of public values (Version 1.1, 21 October 2013)
- Population Screening Act (1992)
- The RIVM Act (including the decree PG/JFB-3147964 in the Government Gazette for implementing Article 3, paragraph 1, part a of the RIVM Act.

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