***ZINNIGE ZORG* ROOM FOR IMPROVEMENT REPORT**

Appropriate post-treatment surveillance of women treated for breast cancer

Neoplasms ICD-10: C00-D48

Date 25/07/2016
Status draft

Zorginstituut Nederland* and *Zinnige Zorg

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Systematic screening
Within the framework of the *Zinnige Zorg Programme, Zorginstituut Nederland* systematically assesses the Dutch minimal and mandatory package of health care that all Dutch health care insurers must. There are four phases to this systematic assessment: screening, in-depth assessment, implementation and monitoring. In 2015 we published a screening report: Systematic analysis of neoplasms. One of the topics mentioned in response to this screening and which is eligible for in-depth study is *Appropriate post-treatment surveillance of women treated for breast cancer*. The aim of the in-depth phase is to map the potential for improving after-care (the period following primary treatment). We engaged external parties to carry out research into possibilities for designing post-treatment surveillance, which is part of after-care. We describe current care practice based on eight elements of good and appropriate care. Where lacunas exist, there is room for improvement.

Room for Improvement Report
We conclude that room exists for improving post-treatment surveillance for women treated for curable forms of breast cancer. A more appropriate design of post-treatment surveillance is necessary for a more appropriate interpretation of after-care in a broader sense. It is important that post-treatment surveillance is in line with the actual individual risk of a locoregional recurrence. This creates room for other topics such as coping with the consequences patients can expect after treatment has ended and they return to their everyday lives. Research shows that designing after-care more appropriately is possible by supplying individualised post-treatment surveillance based on:

1. risk stratification and
2. providing good information and shared decision-making

Risk stratification
Recommendations in both international and Dutch guidelines on post-treatment surveillance are uniform and based on consensus. This is unlike the treatment of breast cancer, which is individualised and based on characteristics of the tumour and the patient. Our research shows that the prevailing guidelines are not in line with the actual risk of locoregional recurrences. For most women the actual risk of a recurrence is low and differentiated over time. Room for improvement exists in post-treatment surveillance: some patients require more intensive surveillance (longer than the current 5-year surveillance recommended in the guidelines). The majority of patients need no intensive monitoring or less (less than five years or out-of-hospital monitoring). A nomogram, like that developed by the Dutch Integral Cancer Centre (hereafter: IKNL) in collaboration with the University of Twente, can help in this process.

Providing good information and shared decision-making
After treatment, many women feel uncertain about whether the cancer will return and about the long-term consequences of treatment.
Research shows that in addition to providing good information and shared decision-making on risk-stratification, other after-care topics are also important elements in providing post-treatment surveillance in its broadest sense. Room for improvement exists here: designing post-treatment surveillance properly, so it is part of after-care, based on providing good information and shared decision-making. This applies in particular to the following preferential topics: hormonal therapy, breast reconstruction and, more generally, the objective and clinical value of post-treatment surveillance. Research also shows that optimal timing is needed when providing information, as is harmonisation and coordination of the care professionals

involved. Both care providers and patients feel this is essential for patients to retain a good quality of life and/or regain control of their lives.

Realising a more appropriate design of post-treatment surveillance will require a number of activities so that risk-stratification, the proper provision of information and shared decision-making become part of the accepted care arsenal of care professionals. In view of the low, differentiated risk of recurrence, managing patients' realistic expectations is essential in relation to the objective and usefulness of post-treatment surveillance (frequency and duration). An implementation discussion will take place, together with the parties involved, to elaborate on further activities.

1 Introduction

1.1 Systematic screening

Zorginstituut Nederland (hereafter: the *Zorginstituut*) systematically assesses the insured package within the framework of the *Zinnige Zorg Programme*. There are four phases to this systematic assessment: screening, in-depth assessment, implementation and monitoring. In 2015 we published a screening report: Systematic analysis of neoplasms.[1] One of the topics mentioned in response to this screening and which is eligible for in-depth study is 'Appropriate post-treatment surveillance of women treated for breast cancer'. The objective of the in-depth phase is to map the potential for improving the period after primary cancer treatment, also referred to as the after-care period, and thus shed light on possible points for improvement.

After-care has various objectives: detecting recurrences, monitoring and treating the physical and psychosocial consequences of the disease and treatment, and evaluating medical actions. This report is specifically about post-treatment surveillance. Post-treatment surveillance is part of after-care and includes repeated contact between the patient and her doctor, e.g. in the form of surveillance schedules. How post-treatment surveillance is carried out depends on the individual patient's situation, which relates to the form of cancer treated.[2]

After-care
After-care is an essential part of care for individual patients, during and after the treatment of cancer. It is comprised of three elements:

1. Detecting new manifestations of treated breast cancer or new malignancies associated with it (also known as post-treatment surveillance);
2. Detecting, informing, guiding, dealing with physical or psychosocial (early and late) consequences of the disease and/or treatment, and
3. Evaluating one's own medical actions.

Post-treatment surveillance
Post-treatment surveillance encompasses the protocolled and programmed approach to detecting recurrences and early and late effects of cancer (treatment). Post-treatment surveillance can be a part of after-care. Its content depends on the individual patient's situation. The doctor in charge discusses the nature and form of after-care with the patient.

Start of post-treatment surveillance period
This signals the period after primary treatment, which is comprised of surgical treatment and additional treatments, i.e. radiotherapy and/or (neo-) adjuvant systemic treatment, but excludes hormone therapy. Depending on the additional treatment, post-treatment surveillance starts about 4 to 12 months after surgical treatment.

[1] Systematic Analysis of Neoplasms (ICD: C00-D48), *Zorginstituut Nederland*, Diemen, 16 April 2015. Series number 2015039237

[2] The definition of after-care we use is that of the World Health Council as amended by the KWF: "After-care includes all individual care of patients after their initial (primary) treatment for cancer. It includes providing information, guidance, discussing complaints and symptoms, assessing immediate or late effects of the disease, treatment of recurrences or other manifestations of the disease and treatment and attention to social consequences. Within the programme, post-treatment surveillance can be seen as a part of after-care. Interpretation depends on the individual situation. The attending physician discusses the nature and form of after-care with the patient".

The aim of the in-depth analysis is to shed light, based on in-depth research, into post-treatment surveillance for women after receiving treatment for curable forms of breast cancer. We will establish the potential for improvement and how this can be achieved in joint collaboration with the parties. In appendix 2: accountability provides detailed information about the method of the *Zinnige Zorg* programme, the parties involved and the process that led to this Room for Improvement Report.

The *Zorginstituut* is responsible for the contents of this Room for Improvement analysis.

1.2 Defining the parameters of the in-depth analysis

Due to increased incidence and the improved chance of survival, a growing number of women eventually follow the post-treatment surveillance pathway after curative treatment for breast cancer. The question is how to design this post-treatment surveillance, in the best way possible, in view of the different objectives.

Research
During a consultative meeting to demarcate the in-depth questions, the parties involved in the care field[3] proposed potential points for improving post-treatment surveillance for women after they have received curative treatment for breast cancer. We translated these potential points for improvement into a number of research questions and subsequently commissioned two parties to carry out external research (see Appendix 3). To summarise, research took place into:

(i) The most appropriate design for post-treatment surveillance based on actual locoregional risk of recurrence and
(ii) Possibilities for providing good information and shared decision-making. This offers a basis for designing the post-treatment surveillance pathway in view of the other objectives of after-care.

Shared decision-making is an important pillar of good care and increasing patients' self-management. It is an effective way of reaching decision-making with a patient that is appropriate in her particular case. Providing good information is a precondition to proper decision-making and pre-dates the decision-making process.

Another proposal made during the round of consultations was to study how detecting psychosocial care needs takes place in practice.
The Breast Cancer Monitor 2013 of the Dutch Breast Cancer Association shows that about one-third of patients were not asked about psychosocial complaints or informed about the possibility of support. [4] Several parties have developed various activities relating to this topic. To avoid unnecessary repetition of research, this research question was therefore excluded from the in-depth research.

Patient population
We focus specifically on the group of women who were treated for a curative disease, i.e. disease stages I to III (7th TNM classification). This study does not discuss treatment and/or post-treatment surveillance for women with genetic forms of breast cancer. Breast cancer in men is also beyond the scope of this study.

[3] The parties involved are: Dutch Breast Cancer Association, NPCF, Living with Cancer, NHG, NHvH, NVVR, NVRO, NIV, NVMO, NVZ, STZ, NFU, FMS, ZN.
[4] B-force 2013, https://bforce.nl/sites/default/files/Bforce_Inzicht_psysoczorg.pdf, Dutch Breast Cancer Association.

1.3 Elements of good and appropriate care

In view of the external research results, which show that post-treatment surveillance can be individualised, we describe current care practice based on the elements of good and appropriate care. The *Zorginstituut* has identified eight approaches as elements of good and appropriate care. We discuss these based on both quality criteria and package criteria (see summary).

Kwaliteitscriterea	
Kenbaarheid van zorg	Beschikbaarheid van kwaliteitsstandaarden (zoals richtlijnen), informatiestandaarden, patiëntinformatie/keuzehulpen en meetinstrumenten (PREMs/PROMs).
Toepassing in de praktijk	Implementatiegraad van kwaliteitsstandaarden, patiënten versies/keuzehulpen en meetinstrumenten: analyses praktijkdata, literatuur. • Worden aanbevelingen in de praktijk geïmplementeerd? • Hoe is de uitvoering van de zorg?
Uitkomsten van zorg	Is er kwaliteitsinformatie over uitkomsten van zorg beschikbaar en vindbaar?
Pakketcriterea	
Effectiviteit	Is de zorg effectief, wat heeft de patiënt aan de behandeling? • Wetenschappelijke onderbouwing van richtlijnen. • Er kunnen signalen zijn die aanleiding geven om (opnieuw) te onderzoeken of de sorg bewezen effectief is en voldoet aan het criterium *Stand van de Wetenschap en Praktijk* middels een formele beoordeling volgens de GRADE systematiek?
Kosteneffectiviteit	Is de zorg kosteneffectief? • Hebben richtlijnen hier iets over geschreven? • Er kunnen signalen zijn die aanleiding geven om (opnieuw) te onderzoeken of de zorg kosteneffectief is.
Noodzakelijkheid	Is het noodzakelijk om de behandeling te verzekeren?
Uitvoerbaarheid	Is voldaan aan de randvoorwaarden en de houdbaarheid van het deel uitmaken van een interventie in het basispakket?
Overall	
Samenhang in de kwaliteitscirkels	Hier kijken we wat de samenhang van de kwaliteitscirkel is en wie zich hiermee bezig houdt.

We describe the eight elements of good and appropriate care based on external research that we commissioned, analyses of guidelines, analyses of practical data and analyses of quality data.

See appendix 2 for a detailed explanation of the system used and the various elements.

1.4 Structure of this report

In **section 2** we discuss the way that breast cancer presents, paying attention to epidemiology, volume and cost developments and what patients experience during the post-treatment surveillance pathway. In **section 3** we discuss the external research results and the elements of good and appropriate care. All input ultimately resulted in a number of recommendations for improving the quality of care for women in the post-treatment surveillance pathway after having received curative treatment for breast cancer. This is described in **section 4**. Lastly, in **section 5**, we discuss the follow-up phase: implementation.

2 What is breast cancer?

In this section we sketch the context of the research questions based on a description of the disease, the epidemiology and what a patient experiences during the care pathway after having completed primary treatment.

- Unlike treatment for breast cancer, which is individualised based on tumour characteristics and patient characteristics, post-treatment surveillance is uniform for just about the entire population of breast cancer patients.
- A locoregional recurrence can still be cured. It is important that the frequency and duration of post-treatment surveillance is in line with the actual individual risk of a recurrence so that monitoring does not lead to unnecessary anxiety and uncertainty.
- Thus, after-care has other objectives in addition to simply checking for recurrences. These objectives of after-care help determine what form the post-treatment surveillance pathway takes.

2.1 Disease and treatment, epidemiology and cost development

The clinical picture

In the Netherlands, annually breast cancer is diagnosed in ca. 14,000 women (and 100 men). One in eight women will be diagnosed with breast cancer during her life and the incidence is still rising.[5] Similarly to other solid tumours, breast cancer mainly affects older women, though it can also affect younger ones. The prognosis for breast cancer is improving. This is partly because, as a result of population screening, the disease is being discovered at an early stage in which cure is still possible and partly due to improved treatment possibilities that are frequently standardised in multidisciplinary treatments.

Customised treatment

A disease that is limited to a breast or the auxiliary lymph nodes is in principal still curable (stages I to III). Women with a curable form of breast cancer are treated with a combination of various treatment modalities: surgery, radiotherapy and/or systemic duration of treatment.[6] In order to determine local and supplementary treatments, the risks are estimated based on a number of factors such as age, size of the primary tumour, number of metastases in the lymph nodes, histological grade of the tumour, expression of hormone receptors and overexpression of the HER2/neu gene.

The size of the tumour and the status of the lymph nodes have a strong predictive value in relation to the chance of the tumour recurring in the breast or elsewhere in the body. Certain tumour characteristics are also important for therapy selection. Numerous other factors have a potential prognostic and predictive value, but are still not widely used in clinical practice. Instruments that support physicians in making decisions, such as the Nottingham Prognostic Index and Adjuvant Online, make use of prognostic factors to individualise treatment and bring it in line with the patient's requirements. MammaPrint identifies clusters of genes that are involved in

[5] www.cijfersoverkanker.nl, July 2016

[6] Chemotherapy, hormone treatment, monoclonal antibody therapy or a combination of these.

the genesis of breast cancer, and its use may improve the individualisation of treatment even further.

Epidemiology, volume and cost developments

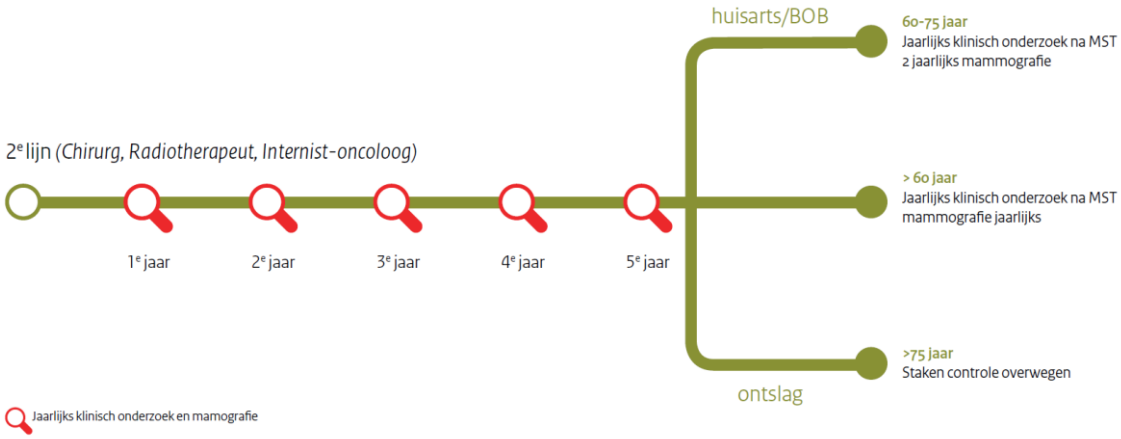
Improved treatments are being converted into national survival statistics. The majority of breast cancer patients are treated for stages I and II (60-84% have stages I-II, 7th TNM classification) and are post-menopausal (87% >50 years, 58% >60 years).[7] The five-year survival of women in the early stages of the disease is 87-98% and the ten-year survival is 78%-94%. For women with stage III breast cancer, these statistics are, respectively, 65%-85% and 46%-76%.[8] In 2013 the total number of women diagnosed with breast cancer was 104,213, the total costs of after-care was approximately €700 million. Expectations are that due to improved survival, more women will be given post-treatment surveillance and after-care and by 2030 the costs could increase to €1,208,000.[1]

2.2 What do these patients experience?

The care pathway after completing primary treatment

Primary treatment is followed by a period of after-care in which the hospital physician carries out general checks. One of the most important objectives of post-treatment surveillance of breast cancer is to detect locoregional recurrences. This is done by means of routine physical examination of the breasts and armpits (palpation) and by means of routine mammograms.

In general, a schedule of annual checks continues for five years. A patient older than 60 years who has undergone breast amputation can return to the national breast cancer population screening after five years of check-ups. A patient older than 60 years who underwent a breast-conserving operation can be referred back to her GP for annual clinical examination and a mammogram every other year in the hospital. For women older than 75 years, one might consider ending check-ups after five years. Women younger than 60 years remain under hospital surveillance for an annual mammogram and clinical examination by a medical specialist.[9] This could be a surgeon-oncologist, a radiotherapist-oncologist or a medical oncologist.



[7] Nederend J, Duijm LE, Voogd A et al, Trends in incidence and detection of advanced Breast Cancer at Biennial Screening Mammography in the Netherlands: a population-based study. Breast Cancer Res 2012

[8] Integraal Kankercentrum Nederland, http://www.cijfersoverkanker.nl/selecties/overleving_borst, July 2016

[9] National guidelines of the Dutch Integral Cancer Centre, Mammacarcinoom, 2012

The tumour may recur after completing primary treatment. Following the example of the Health Council of the Netherlands in 2017[10], the Dutch Breast Cancer Guidelines recommended only post-treatment surveillance for the detection of asymptomatic locoregional recurrences or a second primary tumour in the other (contralateral) breast. A locoregional recurrence is when the tumour recurs locally in the breast in the original spot and/or in the regional lymph nodes (in the armpit, sternum or clavicle). A survival advantage can be expected of treatment of a locoregional recurrence. The objective of this treatment is essentially still curative. [11,12,13,14] A recurrence elsewhere in the body (distance metastasis) can no longer be cured. Multidisciplinary recommendations on after-care, both international and Dutch, are uniform, based on consensus and not based on the actual risk of a local recurrence. This is unlike the treatment of breast cancer, which is individualised and based on characteristics of the tumour and the patient.

Breast cancer and its treatment can have massive physical and psychosocial consequences in the period immediately following treatment and in the long term. Diagnosis and a timely referral in the event of symptoms or problems of a psychosocial or physical nature are important for maintaining quality of life. Some women receive supplementary hormone treatment. For this group, in addition to detection of the locoregional recurrence, the objectives continue to include monitoring treatment and possible adverse events for several years.

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[10] Health Council of the Netherlands. After-care in oncology. Distinguishing between goals, substantiating content. The Hague, 2007

[11] Rojas MP, et al. Follow-up strategies for women treated for early breast cancer (Cochrane Review). In: The Cochrane Library, 2005

[12] Hayes DF. Clinical practice. Follow-up of patients with early breast cancer. N Engl J Med. 2007 Jun 14;356(24):2505-13.

[13] Rosselli Del Turco M, Palli D, Cariddi A, Ciatto S, Pacini P, Distante V. Intensive diagnostic follow-up after treatment of primary breast cancer. A randomized trial. National Research Council Project on Breast Cancer follow-up. Jama 1994;271(20):1593-7.

[14] GIVIO. Impact of follow-up testing on survival and health-related quality of life in breast cancer patients. A multicenter randomized controlled trial. The GIVIO Investigators. Jama 1994;271(20):1587-92.

3 Research results and elements of good and appropriate care

In the previous section we saw how, unlike when treating cancer, post-treatment surveillance is not individualised based on the patient's risk profile. The following is a brief description of the results of the research into possibilities for more appropriate post-treatment surveillance. Afterwards we describe current medical practice based on the eight elements of good and appropriate care. Where lacunas exist, there is room for improvement.

- Research shows that individualising post-treatment surveillance is possible. However, lacunas exist between what – according to research – is possible, and current medical practice.

3.1 Research results on the risk of a locoregional recurrence

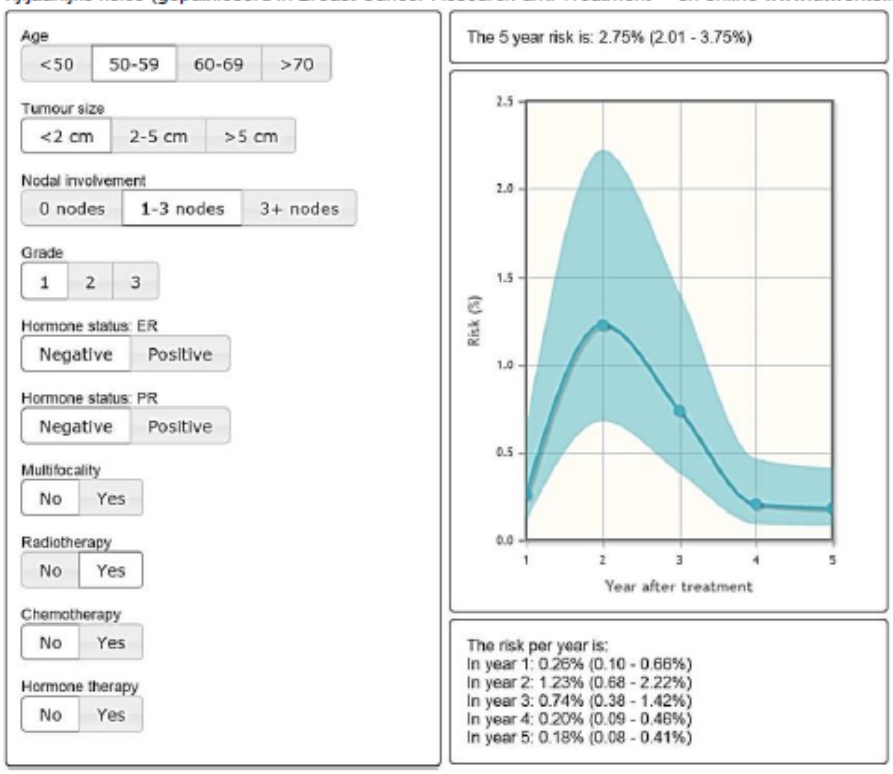
To gain insight into possible ways of designing more appropriate post-treatment surveillance, we studied the risk of a locoregional recurrence and how it relates to the recommendations in the guidelines on post-treatment surveillance. For this research question, patients with curable forms of breast cancer were selected from the Dutch Breast Cancer Registry (hereafter: the NKR) from the (incidence) years 2003-2006. (N=37,230).[15]

What does the study show?
The risk of a locoregional recurrence was determined based on a nomogram. Variables included in this nomogram are: size of tumour, lymphatic status, level of tumour-differentiation, multifocality, hormone status and type of treatment.[16] The current nomogram did not take the molecular profile into account, nor contralateral tumours. In the Netherlands, the risk of a locoregional recurrence for breast cancer patients after receiving essentially curative treatment was described as low by the research group; 3.8% of the women had a recurrence after five years. After 10 years 6% had a locoregional recurrence. The risk of a recurrence varies in time, with the highest risk ca. 2.5 years after treatment, after which a decline is seen in the risk. Furthermore, sub-groups can be distinguished with a significantly different risk of a recurrence. The largest group of patients who underwent curative treatment have a low risk of a recurrence in comparison with the average. A few sub-groups continued to have a higher average risk even after five years follow-up, whereby a role is played by a younger age, a larger tumour and metastases in the lymph nodes.

[15] Internal validation took place by means of bootstrapping. External validation took place based on NKR data from (incidence) years 2007 and 2008. Source: report Appropriate post-treatment surveillance for women treated for breast cancer-detection of a locoregional recurrence', IKNL in collaboration with the University of Twente and Performation, June 2016. report commissioned by *Zorginstituut Nederland*.

[16] Witteveen A. Vliegen I.M. Sonke G.S. et al, Personalisation of breast cancer follow-up: a time dependent prognostic nomogram for the estimation of annual risk of locoregional recurrence in early breast cancer patients. Breast Cancer Research and Treatment, 152 (3), 627-636. http://doi.org/10/1007/s10549-015-3490-4

vijfjaarlijks risico (gepubliceerd in *Breast Cancer Research and Treatment* [25] en online www.utwente.nl/influence)



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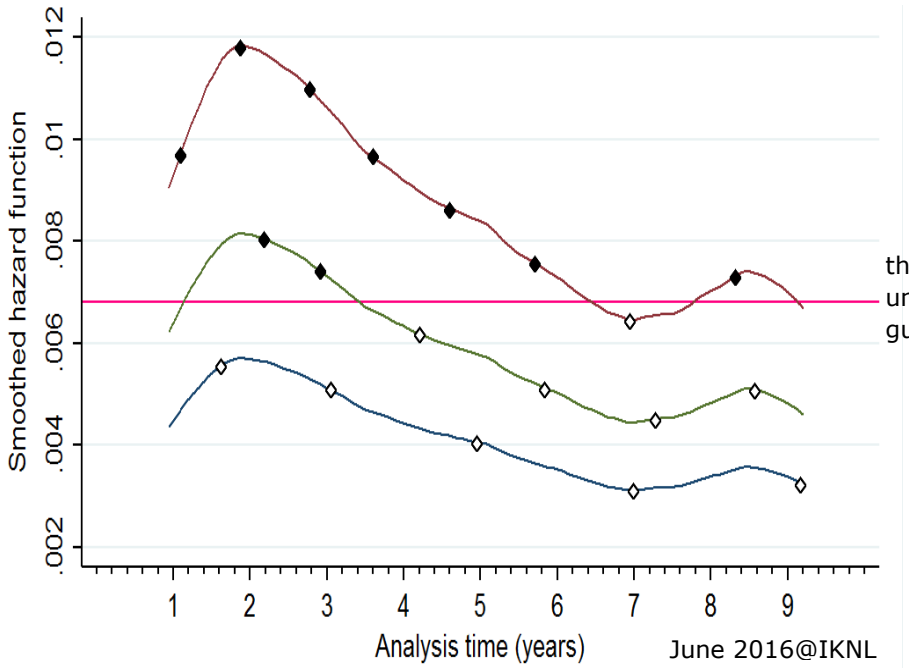
The follow-up question is how does this picture relate to current guideline recommendations. In other words, what are the consequences of the current guidelines for detecting a locoregional recurrence in practice?

What is possible?

A lower limit for the risk of a recurrence can be determined using the current guidelines. The focus when determining the lower limit is fixed at the moment when the post-treatment surveillance schedule ends (five years). After all, the current guideline recommendation (Guidelines on Breast Cancer, 2012) advises five years of post-treatment surveillance, after which patients are discharged from surveillance, depending on their age, and return to population screening or to their GP. This risk can be fixed as a threshold value in order to analyse how the actual risk of a recurrence relates to this threshold value of the various sub-groups. The following figure gives an example, using three risk groups, of the picture that results from the actual risk of a recurrence and how this relates to the 5-year threshold value.



The upper line in the figure is a high-risk treatment group that has an increased risk relative to the threshold value (brown line) eight or nine years after primary treatment. Under the current guidelines, i.e., five years of post-treatment surveillance, this means that a longer surveillance period is indicated for this group. Vice versa, in the example of the group with the lowest risk, no hospital surveillance is indicated (though they should be monitored by their GP or via population screening). This is because the risk for this group remained under the threshold value (dark blue line) during the entire post-treatment surveillance period. There is also a group for which the peak in particular exceeds the threshold value between 2.5 to 3 years. This group could be eligible for hospital surveillance for less than five years. A nomogram, as developed by the IKNL in collaboration with the University of Twente, can serve as an aid. [17]

3.2 Research results on providing good information and shared decision-making

To shed light on possibilities for providing good information and shared decision-making for this target group, we carried out research into what is known in the scientific literature. At the same time, interviews were carried out by focus groups with separate expert panels comprised of patients and medical specialists, complemented with a B-force questionnaire of the Dutch Breast Cancer Association.[18]

[17] Witteveen A. Vliegen I.M. Sonke G.S. et al, Personalisation of breast cancer follow-up: a time dependent prognostic nomogram for the estimation of annual risk of locoregional recurrence in early breast cancer patients. Breast Cancer Research and Treatment, 152 (3), 627-636. http://doi.org/10/1007/s10549-015-3490-4

[18] Report on Providing good information and shared decision-making for women treated for breast cancer. IKNL in collaboration with the University of Twente, June 2016. report commissioned by *Zorginstituut Nederland*.

What does the study show?
No literature was found specifically on women after primary treatment. To nevertheless obtain insight into possibilities for providing good information and shared decision-making in the after-care period, we searched the scientific literature for topics relevant in relation to the general objectives of after-care and post-treatment surveillance: early detection of a locoregional recurrence, monitoring (adverse) effects of treatment and monitoring hormone therapy. Using these topics, preference-sensitive aspects were identified if the literature specifically indicated them for the group of women after curative treatment. Clearly this does not mean that no other preference-sensitive topics exist in after-care. These could not yet be identified when the research was carried out.

> Preferred or preference-sensitive decisions are when there is more than one treatment option or where dilemmas exist about the advantages and disadvantages of the intervention.[19]

Topics identified from the literature as topics with possible preference-sensitive aspects in the period following curative treatment are the detection of a locoregional recurrence, specifically determining the frequency and duration of post-treatment surveillance. In addition, preference-sensitive topics include decisions surrounding starting/stopping and/or adjusting hormone therapy and opting for breast reconstruction (timing and type).
Breast cancer patients' information needs, as described in the remaining literature, covers a variety of topics, such as, e.g., physical and psychological functioning, sexuality and work/re-integration and physical side effects of treatment, such as cardiovascular problems and, in the long term, osteoporosis.

A systematic review[20] of 39 largely observational studies of different types of tumour shows strong signals of a positive effect of joint decision-making on cognitive-affective outcomes, e.g. understanding and satisfaction with the decision. The positive outcomes of joint decision-making on cognitive-affective outcomes seem to be independent of the field of application. Thus, in all probability the positive outcomes of joint decision-making can be extrapolated to after-care for women with breast cancer.

The scientific field of research, specifically for women in the post-treatment surveillance period, is in its infancy. Therefore, additional interviews took place, e.g. via focus groups with separate expert panels comprised of patients and medical specialists. Also, a B-force questionnaire of the Dutch Breast Cancer Association was deployed. These show that the disease and its treatment have a massive impact on the life of women with breast cancer. The need for information covers a broad domain. After treatment, many women feel uncertain about whether the cancer will return and about the long-term consequences of treatment. This creates a dilemma between on the one hand the need of reassurance and on the other hand wanting to be free of the role of a patient. Both patients and care professionals feel that providing good information and shared decision-making are essential for patients in

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van der Weijden T, Dreesens DHH, van de Bovenkamp H, Shared decision-making and guidelines, ISBN 978-90-368-0266-6, Bohn Stafleu van Loghum 2014, DOI 10.1007/978-90-368-0267-3_16

[20] Shay LA, Lafata JE. Where is the evidence? A systematic review of shared decision-making and patient outcomes. Medical decision-making: an international journal of the Society for Medical Decision Making. 2015; 35: 114-31.

maintaining and/or resuming control of their life. An important precondition is proper harmonisation between the care professionals involved.

What is possible?
Insights from the above-mentioned study suggest possibilities for harmonising post-treatment surveillance with patients' need of information and with preference-sensitive topics. Broad support exists, among both patients and care providers. In particular, post-treatment surveillance can be designed so information is provided at moments when preference-sensitive choices arise in relation to the topics: hormone treatment, breast reconstruction and the objective and clinical usefulness of carrying out post-treatment surveillance. An essential aspect is to optimise harmonisation and coordinate the number – and frequency – of care professionals involved.

3.3 Current care practice based on the eight elements of good and appropriate care

The research results show that individualised post-treatment surveillance is possible. Below we describe current medical practice based on the eight elements of good and appropriate care. The basis for the schedule of this systematic analysis is as mentioned in section 1.3. An extensive explanation per criterion is provided in appendix 2.

Room for improvement exists where there are lacunas between the research results and this systematic analysis. This is described in section 4.

1: Knowledge about good care:
Knowledge about good care is about the availability of quality standards, information standards, patient information/decision aids and instruments of measurement (PREMs/PROMs). Quality standards are dynamic products that are continually being developed and if necessary adjusted.

What does the analysis show?

Quality Standards
Differences exist between international multidisciplinary guideline recommendations and Dutch ones, in relation to the frequency and the duration of routine hospital post-treatment surveillance. Up until 2011 the Dutch multidisciplinary guidelines advised a surveillance frequency of once per three years, or per six months respectively during the first and second surveillance years, followed by annual surveillance for a total of five years, depending on the woman's age. In 2012 the Dutch guidelines were changed to annual monitoring during five control years (see section 2 for a description of the surveillance schedule). The recommendations of the most recent international guidelines of the ASCO dating from 2015 (American Society of Clinical Oncology) and of the ESMO dating from 2015 (European Society of Medical Oncology) recommend even more frequent surveillance per year.[21] [21] [22] On the contrary, the recommendation of the NICE guidelines, dating from 2009, advises annual surveillance during five years and reverting – from the age of 50 years – to

[21] The recommendation in the ASCO guidelines on post-treatment surveillance can be found on the following link: ASCO Care and Treatment Recommendations for Patients > Follow-Up Care for Breast Cancer 2015
[22] Primary Breast Cancer: ESMO Clinical Practice Guidelines, Ann Oncol (2015) 26 (suppl. 5): v8-v30.

the national screening programme (a mammogram once every three years). Ceasing post-treatment surveillance can be considered for women older than 70 years.[22] Most recommendations in the international guidelines and the Dutch guidelines are based on consensus and the differences reflect a lack of good evidence of the most optimum form of post-treatment surveillance schedules.

Recommendations in Dutch multidisciplinary guidelines on post-treatment surveillance for medical specialists and GPs are compatible.[23,24] They also recommend, among other things, shared decision-making, though without providing any concrete pointers. The English guidelines do concretely recommend discussing the objective of post-treatment surveillance with the patient and discussing her preferences, specifically regarding surveillance she wants to undergo. This is because scientific literature shows no advantages or disadvantages of surveillance by a medical specialist in a hospital or by another care professional.[25]

Choice information and information standards

Various sources are available in the field of patient information and decision aids. The objective of the Dutch Breast Cancer Association (BVN) is to provide good patient information, contact with fellow sufferers and promote patients' interests. This includes information about living with breast cancer after treatment, e.g. information on the consequences or adverse effects of treatment. For instance, the BVN took the initiative in creating B-Aware [*B-Bewust*, Be aware of breast cancer]. Other sources of patient information are the websites of Kanker.nl, Kiesbeter.nl, Thuisarts.nl, ZorgkaartNederland.nl and Volksgezondheidenzorg.info.

Instruments of measurement: patients' experience and indicators

Instruments of measurement can be used to increase the transparency of the quality of care.

The Miletus Foundation has developed and validated a PROM for breast cancer, which formed the basis for a pilot study that started in 2016. The NBCA set up the PROM taskforce. The CQ-index Mammacare – experience of care for breast cancer (benign and malignant) (Nivel, 2007) – was developed to measure patients' experience. A general oncology-PREM has been developed based on a CQI that can be augmented with a section specifically for breast cancer (mammacare module). The set of indicators for breast cancer was jointly submitted by 17 parties for the *Zorginstituut*'s Transparency Calendar. This includes the set of indicators approved by the *Zorginstituut* for 2015.

[23] National guidelines of the Dutch Integral Cancer Centre, Mammacarcinoom, 2012

[24] NHG standard Diagnosing breast cancer, GP Act 2008:51(12):598-609

What could improve?

- Managing patient expectations on the objective and clinical usefulness of carrying out routine hospital surveillance.
- Introducing and implementing the nomogram
- Optimising the availability and timing of information provision .
- Optimising information material and decision aids for shared decision-making on topics that the study identified as value-sensitive.
- Changing the Dutch multidisciplinary guidelines on Breast Cancer, based on the above-mentioned points.

2: Application in practice

Application in practice is about the level of implementation of quality standards, patients' versions/decision aids and instruments of measurement: analyses of data on actual practice, the literature.

What does the analysis show?

Regarding the use of medical diagnostic tests, it seems that 10% of the women who received curative treatment never had a mammogram. Less than three mammograms were made for the women, in total about 35%, who remained in the post-treatment surveillance pathway. To find out what this says about the current guideline recommendation, we determined which patients were involved. Hopefully, this will supply some background information. It seems that fewer mammograms were made of patients older than 75 years than those younger than 75 years. The guideline recommendation for women older than 75 years is that ending post-treatment surveillance can be considered.[26,27] Possible other reasons for not making a mammogram could be a mastectomy or the development of metastases which makes a mammogram less appropriate. Conscious avoidance of surveillance is another possible reason for no mammogram having been made. These groups could not be identified based on the available data.
As a result, we were unable to examine the true reasons for deploying other diagnostic tests than mammograms. At the moment this research was done, the relevant data sources were not well harmonised.[24]

Research with data from patient files shows that more routine surveillance takes place than the annual routine surveillance recommended in the current guidelines. This frequency increases when treatment involves several specialists. Almost entirely ignored was the recommendation in the oncology post-treatment surveillance report of the Health Council of the Netherlands, dating from 2007, to supply each patient with a written after-care plan, including arrangements on harmonisation between the care professionals concerned. This does not differ from the picture in 2011 when several routine checks were advised under the guidelines then in use. [28] Another aspect that may contribute to more frequent routine checks is the lack of knowledge, that of both patients and doctors, about the limited value of routine checks in detecting distance metastases.

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[26] KPMG-Plexus. Diagnostic tests in women treated for breast cancer. Amstelveen June 2016 Utrecht June 2016, commissioned by *Zorginstituut Nederland*.

[27] IKNL in collaboration with the University of Twente and Performation. Appropriate post-treatment surveillance for women treated for breast cancer – detecting locoregional recurrence. Utrecht June 2016, commissioned by *Zorginstituut Nederland*

[28] SME Geurts, F de Vegt, S Siesling et al., Pattern of follow-up care and early relapse detection in breast cancer patients. Breast Cancer Res Treat. 2012;136(3):859-68

Interviews carried out by focus groups with individual panels of experts comprised of patients and medical specialists and the B-force questionnaire of the Dutch Breast Cancer Association revealed that, in practice, barely any shared decision-making at all is taking place on preference-sensitive topics. This applies in particular to shared decision-making on designing post-treatment surveillance (i.e. its frequency and duration). In relation to the proper provision of information, it seems that though information is present, it is not always customised to suit the information requirements of patients. In general, information on after-care and post-treatment surveillance is already being given during treatment or when treatment ends. This is thought to be premature, as the information provided may not contribute to a better understanding of the objective of after-care and the post-treatment surveillance involved. Furthermore, too little account is taken of the changing needs of patients during the course of after-care. Currently no decision aids are available for the after-care period, though initiatives do exist for realising possible instruments in relation to this.[29]

Is the care given, as discussed in the analysis of the data on current practice, good and appropriate? Earlier, when describing the guidelines, mention was made of the fact that both national and international guidelines recommend post-treatment surveillance based on consensus. There are differences in the recommendations; they reflect the lack of consistency in scientific literature on the best way to organise post-treatment surveillance. Without a norm based on properly documented guideline recommendations, we are therefore unable to draw firm conclusions regarding to the picture presented by post-treatment surveillance in current practice. We can establish, based on data from daily practice, that the current guidelines are not line with the daily practice of post-treatment surveillance and vice versa.

What could improve?

- The availability of a nomogram, the provision of information and shared decision-making.
- Harmonising the frequency and content of post-treatment surveillance between care providers, e.g. in the form of an after-care plan. This could involve, e.g., the possibility of having post-treatment surveillance carried out by a single discipline.
- The recommendations mentioned in this report demand (extra) training of the professional group concerned, specifically in the field of skills relating to shared decision-making. This includes (extra) training or expectation management for doctors about the objective of post-treatment surveillance and the limited value it has in detecting distance metastases.

3: Care outcomes

When looking at care outcomes, we look at whether quality information on outcomes is available and findable.

What does the analysis show?

[29] IKNL in collaboration with the University of Twente. Providing good information and shared decision-making for women treated for breast cancer. Utrecht June 2016, commissioned by *Zorginstituut Nederland*

The positive cognitive effects of providing good information and of shared decision-making mentioned in the literature have not been systematically measured in practice.

What could improve?

- The (continued) development of care outcomes (PROMS/PREMS) and their availability for measuring care for women in post-treatment surveillance after they have received curative treatment for breast cancer.

4: Effectiveness of good care

In relation to the effectiveness of care, we look at whether care is effective, how does a patient benefit from treatment?

What does the analysis show?

International and national guideline recommendations differ on the frequency and duration of post-treatment surveillance. These differences reflect the lack of consistency in the scientific literature on the optimum method of organising post-treatment surveillance and the clinical value of medical diagnostic tests. [30]

Despite the lack of a well-founded norm from guidelines on the clinical value of post-treatment surveillance and medical diagnostic tests, we did not carry out a methodological assessment of the literature. Additional elements must be involved, alongside test characteristics, in order to assess the clinical value of post-treatment surveillance and the tests involved. Such factors as the actual risk of a recurrence in the Dutch population and information on current practices in post-treatment surveillance must be assessed integrally. Data and information relating to these various elements were not yet available at the time of this in-depth analysis.

A medical test is said to have clinical value if it involves an expected health gains in terms of survival or improved quality of life. When assessing the effectiveness of medical tests, the *Zorginstituut* feels it is important to involve the entire care pathway, i.e., test plus treatment.[31,32]

A recent high-quality systematic literature summary of nine studies (the majority of which were observational in nature) provided no new insights in comparison with the early literature on the clinical value of post-treatment surveillance and medical diagnostic tests. In particular, no firm position is provided on the optimum frequency and duration of carrying out surveillance mammograms. The literature does suggests the need for routine physical examination by a medical specialist and routine mammograms do seem to have health gains in terms of survival (clinical value) while routine physical examination does not. Direct comparisons with other diagnostic tests are lacking. Apart from studies of test characteristics, no studies were found on the clinical value of doing a breast MRI for the detection of a locoregional recurrence.[33]

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[30] ME-TA report. Evidence-based substantiation of recommendations for follow-up in oncological guidelines – part 1, contribution to Screening report within the framework of the *Zinnige Zorg* programme, OND1356491, Brussels 014

[31] *Zorginstituut Nederland* report. Package Management in Practice, part 3', 2013

[32] Report commissioned by *Zorginstituut Nederland*, carried out by the Dutch GRADE Network, 'GRADE-method for diagnostic tests and test strategies, 2008

[33] Robertson C, Arcot Ragupathy, Boachie C, Fraser C, The clinical effectiveness and cost-effectiveness of different

What could improve?

- Assessing the clinical value of carrying out routine hospital surveillance in conjunction with other elements of health care (e.g. the actual risk of a recurrence).
- (Continued) development, or continued updating of the nomogram, in part based on the risk of a second (ipsilateral or contralateral) primary tumour and in view of continued developments in the care of women with breast cancer.

5: Cost-effectiveness

This is where we assess whether the care is cost-effective.

A separate study of the cost-effectiveness is not relevant within the framework of the research questions. See our report, Cost-effectiveness in practice. [34]

6: Necessity of good care

This is where we examine whether this treatment has to be insured. This involves an examination of the burden of disease and the need to insured care.

A separate study of necessity is not relevant within the framework of the research questions. See our low burden of disease feasibility report.[35]

7: Feasibility of good care

When examining feasibility, we look at the sustainability of including the intervention in the basic package both now and in the future.

As post-treatment surveillance is a part of standard care for women treated for breast cancer, the organisation of this care is described as being embedded in daily practice. Diagnostic tests to detect locoregional recurrence are part of the arsenal of instruments care providers have at their disposal.
The sustainability of this is not at risk.

8: Consistency in quality circles

This is where we examine the consistency of quality chains and which parties are involved.

What does the analysis show?
Various parties in health care are paying a lot of attention to improving the quality of care for women in the post-treatment surveillance pathway after receiving curative treatment for breast cancer. The *Zorginstituut* can contribute to this by providing knowledge, data and research, and through its combined tasks in the field of package management and quality improvement. By choosing this topic, the *Zorginstituut* envisages possibilities for synergy with current initiatives, such as the Quality and Appropriateness Agenda (hereafter: the K&D agenda), of the partners in the outline agreement (hereafter: the HLA partners).

The quality circles demonstrate a high level of consistency. This criterion is not currently in need of improvement.

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surveillance mammography regimens after the treatment for primary breast cancer: systematic reviews, registry database analysis and economic evaluation.

[34] *Zorginstituut Nederland* 26 June 2015, series number 2015076142

[35] *Zorginstituut Nederland*, 05 March 2012, series number 2011070799

4 Room for Improvement Report

Room for improvement does exist in post-treatment surveillance for women who have received curative treatment for breast cancer. This is apparent from the external research results, which show that post-treatment surveillance can be individualised, and from the description of current care practice based on the elements of good and appropriate care. Below we describe in which fields action is needed.

4.1 In which fields is action needed?

A number of activities are needed to realise a more individualised form of post-treatment surveillance.

Risk stratification
Post-treatment surveillance can be further individualised by implementing the nomogram and by continuing its development, i.e. updating it, as the basis for altering the national guidelines on post-treatment surveillance. This will lead to risk stratification of the acknowledged care arsenal at the disposal of care professionals. In view of the external research results, some patients will need more intensive surveillance (longer than the current guideline recommendation of 5 years surveillance). The majority of patients need no intensive monitoring or less (less than five years or out-of-hospital monitoring).

Providing good information and shared decision-making
Individualised post-treatment surveillance, based on providing good information and shared decision-making, will only be possible if both patients and care providers know which topics form the basic contents of surveillance. Knowledge about these topics can be increased by optimising information material and by timing the provision of information. This applies in particular to topics identified by the research as value-sensitive, such as hormone therapy and breast reconstruction. In view of the low, differentiated risk of recurrence, managing the realistic expectations of patients is essential in relation to the objective and the need of post-treatment surveillance.

The following schedule summarises, per field, which activities are needed.

<u>Knowledge</u>	• Managing patient expectations on the objective and clinical usefulness of carrying out routine hospital surveillance. • Introducing and implementing the nomogram • Optimising the availability and timing of information provision . • Optimising information material and decision aids for shared decision-making on topics that the study identified as value-sensitive.

	• Changing the Dutch multidisciplinary guidelines on Breast Cancer, based on the above-mentioned points.
Application in practice	• The availability of a nomogram, the provision of information and shared decision-making. • Harmonising the frequency and content of post-treatment surveillance between care providers, e.g. in the form of an after-care plan. This could involve, e.g., the possibility of having post-treatment surveillance carried out by a single discipline. • The recommendations mentioned in this report demand (extra) training of the professional group concerned, specifically in the field of skills relating to shared decision-making. This includes (extra) training or expectation management for doctors about the objective of post-treatment surveillance and the limited value it has in detecting distance metastases.
Care outcomes	• The (continued) development of care outcomes (PROMS/PREMS) and their availability for measuring care for women in post-treatment surveillance after they have received curative treatment for breast
Effectiveness of good care	• Assessing the clinical value of carrying out routine hospital surveillance should be assessed in conjunction with other elements of care (including the actual risk of a recurrence. • (Continued) development, or continued updating of the nomogram, in part based on the risk of a second (ipsilateral or contralateral) primary tumour and in view of continued developments in the care of women with breast cancer.

4.2 What will patients notice of all this?

Designing appropriate post-treatment surveillance is necessary.
A more realistic design of post-treatment surveillance, based on the actual risk of a recurrence, will create room for other care issues that may arise during the post-treatment surveillance period. This could involve the consequences a patient can expect after treatment has ended and how she can pick up the threads of her former life.

Individualised post-treatment surveillance will ensure that post-treatment surveillance takes place where an indication exists and patients without an indication will not be unnecessarily burdened with hospital visits and undergoing physical and diagnostic examinations. The realistic provision of information about the actual risk of a recurrence and about the objective, value and necessity of routine hospital surveillance will allow patients room for other important after-care topics. Post-treatment surveillance should be based on moments at which choices or decisions are needed on topics with value-sensitive aspects: customised and at the right moment.

4.3 Cost Consequences

The main focus of the Room for Improvement analysis is to improve care and health gains for patients. Naturally, implementing these improvement actions will also have consequences for the costs of care. These can be found in the Budget Impact analysis (BIA). Current data do not permit an exact calculation of the costs effects of implementing the improvement activities. For this we had to make assumptions. The BIA is described below.

Estimated budget impact
To calculate the impact of risk stratification in post-treatment surveillance of breast cancer, we compared the current situation with a future situation in which risk stratification is used.

The current situation is based on 9,525 patients whose post-treatment surveillance period started in 2008. The number of check-ups involving a mammogram received by these patients during post-treatment surveillance period 2008-2013 was 35,797 (KPMG Plexus, 2016).

We assume that the new post-treatment surveillance situation will involve an annual mammogram. Unexpected mortality was not taken into account, so that the actual number of post-treatment surveillances will be lower. We define the threshold value for post-treatment surveillance as the risk of a recurrence 5 years after primary treatment ended, as this is the moment at which secondary care ends post-treatment surveillance in the current situation. Three groups can be identified with this threshold value:

- The first group has a lower risk than the threshold value during the entire post-treatment surveillance period. This group makes up about 50% of the total number of patients (IKNL in collaboration with the University of Twente, 2016). *In the situation using risk stratification, this group will receive no post-treatment surveillance in secondary care.*
- The second group has a lower risk than the threshold value in the first 5 years with, on average, a 3-year post-treatment surveillance period. About 15% of the patients are in this group (IKNL in collaboration with the University of Twente, 2016). *In the new situation, this second group will have about 4,286*

*(9,525 * 3 * 15%) check-ups (involving a mammogram).*

- The third group has a higher risk than the threshold value after the first five years, with an average of 7.2 years after starting the post-treatment surveillance period. About 35% of the patients are in this risk group (IKNL in collaboration with the University of Twente, 2016). *In the new situation, this third group will have about 24,003 (9,525 * 7,2 * 35%) check-ups (involving a mammogram).*

Compared with the current situation, the number of post-treatment check-ups in the new situation with risk stratification is reduced by about 7,508 check-ups *(35,797 minus 4,286 minus 24,003)*.

To calculate the impact, we calculated the reimbursement of post-treatment surveillance in secondary care. Post-treatment surveillance involves at least a mammogram. We assumed the following care activities: 085091, 086902 and 086941. According to Opendisdata.nl, care activity 086902[36] was claimed most in 2015. According to the Care product viewer, this care activity is converted to care product 020107008[37], research or breast cancer treatment during a visit to a day clinic or a day-time appointment. This care product involves not only a mammogram, but also visits to a day clinic, telephone consultations and other diagnostic tests. In 2016, based on open *dis*-data, the average reimbursement for this care product was € 520.

Risk stratification of post-treatment surveillance after primary treatment for breast cancer results in estimated possible savings of at least € 3.9 million per year (€ 520 * 7,508).

Assumptions
The risk-groups mentioned in the study carried out in 2016 by the IKNL in collaboration with the University of Twente can easily be identified. If this were not the case, using risk stratification would not be possible.

Limitations
Mortalities during the control period were not taken into account. They were taken into account in calculating the current situation as fewer mammograms were registered for these women, which is one explanation of why the number of check-ups per person is lower than the prescribed 5. Not taking mortalities into account may result in the actual impact being underestimated.

Furthermore, no account was taken of the exclusion of women upon reaching the age of 75 years. This resulted in overestimating the number of check-ups in the situation in which risk stratification took place. This led to an underestimation of the impact of risk stratification.

It was assumed that hormone therapy is supervised separately from post-treatment surveillance by means of mammograms. Any overlap between these two activities is limited.

The primary objective of adjuvant hormone therapy is to prevent distance metastases. This has no effect on how post-treatment surveillance is organised, as the primary objective of post-treatment surveillance is to detect a locoregional recurrence. Combining the supervision of hormone therapy with post-treatment

[36] Mammogram, whether or not with contrast in the milk ducts.
[37] NZa: Opendisdata.nl: Care product 020107008, 5 October 2016.

surveillance may lead to marginally overestimating the effect of risk stratification.

5 Implementation

5.1 Implementation

About three months after publishing the Room for Improvement Report, the *Zorginstituut* will organise a meeting to discuss implementation and the role that each party can play. This will include offering parties the possibility of implementation research or advice to help facilitate implementation of the said Room for Improvement report.

Implementing these improvement activities is the task of the parties in health care based on their respective accountabilities within the health care system. In response to consultation on this Room for Improvement report, the various parties made suggestions about who can play a role in the implementation process.

BVN sees a role for the patients' organisation (e.g. via B-Aware) in drawing up a list of topics to be discussed during post-treatment surveillance.
The NVvH, the NIV, the NVMO and the NFU propose involving the NABON in any follow-up steps resulting from this Room for Improvement Report.
Where necessary, (further) collaboration will be sought with other parties.

The *Zorginstituut* will monitor progress of the improvement measures and report on it to the Minister of VWS. One year after its publication, an interim progress report will be drawn up, and the second, final progress report will be drawn up two years after publication.

Zorginstituut Nederland will organise joint follow-up meetings in order to promote collaboration, discuss progress and resolve any signs of stagnation.

Appendix 1: List of abbreviations and concepts

Concept	Explanation
7th TNM classification	7th TNM Classification of Malign Tumours (Tumour Node Metastasis) is the system for classifying stages of cancer
Asymptomatic	without disease symptoms
B-Aware	Project encouraging shared decision-making in cancer cases
Treatment methods	The treatment of breast cancer generally comprises a number of treatments: surgery, radiotherapy and/or chemotherapy or hormone treatment.
Population screening	The two-yearly screening of women between 50 and 75 years of age for breast cancer.
B-force	B-force is an online panel of (former) breast cancer patients and everyone (once) connected with the disease, set up by the Dutch Breast Cancer Association
BVN	Dutch Breast Cancer Association
Contralateral breast	Breast on the other side of the body.
CQ-index Breast care	The objective of CQI Breast care is to measure experienced quality of care surrounding the study and/or treatment of a benign or malignant breast disorder from the perspective of the patient.
DICA	Dutch Institute for Clinical Auditing
FMS	The Federation of Medical Specialists
HLA partners	Partners in the Outline Agreement
ICD-10	Tenth edition of the International Statistical Classification of Diseases and Related Health Problems
IKNL	Netherlands Integral Cancer Centre
Incidence	Number of *new* cases of a disorder per year, per thousand or hundred thousand of the population.
K&D agenda	Quality and appropriateness agenda
KWF	Queen Wilhelmina Fund for combating Cancer
Mamma carcinoma	Breast cancer
Metastases	Metastases are when a malignant tumour (the so-called primary tumour) have spread to elsewhere in the body.
Monoclonal antibody therapy	Monoclonal antibodies are proteins (defence mechanisms or antibodies) developed in a laboratory. Protein receptors are made so that they can recognise and become attached to the outside of cancer cells. They ensure that the cell (core) no longer receives the signal to divide or promote cell death in cancer cells. This can take place in different ways. For instance, by switching off a receptor that is permanently activated. Or by blocking the connection between growth factor and the receptor.
Multifocality	The presence of two or more individual carcinomas in the same breast.
NBCA	NABON Breast Cancer Audit
Neo-adjuvant systemic treatment	Neo-adjuvant refers to something given prior to surgery, with the objective of shrinking the tumour.
NFU	Federation of University Medical Centres in the Netherlands (NFU)
NHG	Dutch College of General Practitioners

NIV	Dutch Association of Internal Medicine
NIVEL	Dutch Institute for Research into Health Care
NPCF	Dutch Patients' Federation (nowadays the PFN)
NVMO	Dutch Association for Medical Oncology
NVRO	Netherlands Association for Radiotherapy and Oncology
NVvH	Dutch College of Surgeons
NVvR	Dutch Radiology Association
NVZ	Dutch Hospitals Association
NZa	Dutch Health Care Authority
Palpation	To feel internally or externally using the hand or hands, as part of medical research
PREM	Patient Reported Experience Measure
Prevalence	Number of cases per thousand or per hundred thousand of the population at a specific moment
PROM	Patient Reported Outcome Measure
Recurrence	New manifestation of treated cancer or new malignancies associated with the latter
Risk of a recurrence	The risk of developing a new tumour.
STZ	Collaborating Top-Clinical Hospitals
ZN	Association of Dutch Healthcare Insurers

Appendix 2: Accountability

In this 'Accountability' appendix we explain the main outline of how the *Zinnige Zorg* programme works, with attention to the quality elements and package criteria and the use of claims data in analyses, we provide a summary of the parties involved, describe how we have worked together with the parties and turn our attention to describing the process.

1. Working method of the *Zinnige Zorg* Programme

The *Zorginstituut* designed a systematic working method for the *Zinnige Zorg* Programme for examining the use that is made of care in the insured package. The key is to identify and combat ineffective and/or unnecessary care, thus improving quality of care for patients, increasing health gains and avoiding unnecessary costs. We do this based on a circle of improvement as illustrated in figure 1 below. This circle is comprised of four sequential phases:
1. Screening phase
2. In-Depth Analysis Phase
3. Implementation phase
4. Evaluation phase

Figure 1: *Zinnige Zorg*'s circle of improvement

Screening phase
The objective of the screening phase is to select a number of topics for in-depth analysis with a potential for improving quality of care and avoiding unnecessary costs by using care more appropriately. These topics are recorded in a 'Systematic Analysis' report and sent, together with the underlying analysis, to the Minister of VWS.

Figure 2 on the next page shows how the various sources are consulted in order to arrive at a good analysis and a good choice of in-depth topics. Sources include guidelines, scientific literature, claims data and other data, and the parties in health care. This involves not only collecting and analysing all the detailed information, but

also searching for signals from daily practice in order to obtain a succinct picture of the care provided in the current situation. This is done from the perspective (the 'spectacles') of the *Zorginstituut*, using the "elements of good care" (see explanation below).

Figure 2: From sources to in-depth topics

The choice of in-depth topics is based partly on the analysis made using the elements of good care, the size of the topic (number of patients, burden of disease, budget impact), possible improvements and what the parties in health care feel is important.

<u>In-Depth Analysis Phase</u>
The screening phase is followed by the in-depth phase. The objective of this phase is to make the method for achieving potential improvements in the selected topics as concrete as possible.

For each topic, detailed analyses are carried out and the missing data are completed using extra data-analyses, practice-oriented research and/or a literature study.

In this phase too, the *Zorginstituut* works very closely with the parties involved. The final results are recorded in a so-called Room for Improvement Report. This states which improvements in care and in health are considered possible, regarding both content and extent, and provides an estimate of the total sum in avoidable costs (Budget impact). The *Zorginstituut* also sends the Room for Improvement Report to the Minister of VWS.

<u>Implementation phase</u>
The implementation phase is primarily a task for the parties in health care: patients, care professionals, institutions, health insurers and the government. It takes place based on agreements made in the in-depth phase. In the implementation phase the *Zorginstituut* can play a supportive and facilitative role, for instance, by organising meetings, providing data and feedback, and by carrying out additional research. Periodically, the *Zorginstituut* reports progress made to the Minister of VWS.

Evaluation phase
During the monitoring phase, the *Zorginstituut* examines, together with the parties involved, whether results have been achieved. Based on this, we decide whether new actions are necessary. During this phase, we also examine whether all necessary information is structurally available.

Elements of good care

Care is analysed both in the screening phase and in the in-depth phase. To this end, the *Zorginstituut* uses "Criteria of good care" which are based on the quality and package management tasks of the *Zorginstituut*. The following analysis schedule is used, both for Screening reports and for Room for Improvement reports:

1. Knowledge about good care
A description of what we know about the availability of national and international quality standards (such as guidelines), measuring instruments (questionnaires and indicators) and information standards.[38] Are there outcome indicators which are relevant to patients, such as measures of quality of life, PROMs[39] and PREMs[40]. We examine whether the quality standards, instruments of measurement and information standards have been included in the *Zorginstituut*'s register, thus showing that they fulfil the procedural criteria of the Assessment Framework[41].
In addition to procedural matters, we also look at the content of standards and guidelines: what recommendations are made that are relevant to our topic and what scientific evidence is there for the recommendations? We also look for concordance between guidelines in primary and secondary care.

2. Application in practice
An analysis, usually of national claims data, of the level of implementation of quality standards, patients' versions/decision aids and measuring instruments. Are recommendations being implemented in practice? This is where we examine what care is implemented in practice (including concurrence between primary and secondary care) and what the experts think about this.

3. Care outcomes
Is information available about quality of care and care outcomes, and can it be found by care providers, patients and citizens? On which websites (public database and public information) can they be found?

4. Effectiveness
Is the care effective, do patients benefit from the treatment? If we deem the scientific evidence for the guidelines, as assessed under Knowledge, to be of sufficient quality, we take the guideline recommendations as our point of departure. A formal assessment, based on the criteria approved by the *Zorginstituut,* including

[38] *Zorginstituut Nederland*. Assessment Framework for quality standards, information standards & measuring instruments 2015. Diemen, 2015. (Version 2.0)
[39] PROMs: Patient-Reported Outcome Measures: outcome measures of care, reported by patients without the mediation of a care provider. Source: *Zorginstituut Nederland*. Conceptual framework for appropriate care and variations in practice. Diemen, 2015. Report no. 1504.
[40] PREMs: Patient-Reported Outcome Measures: outcome measures of care, reported by patients without the mediation of a care provider. Source: *Zorginstituut Nederland*. Conceptual framework for appropriate care and variations in practice. Diemen, 2015. Report no. 1504.
[41] *Zorginstituut Nederland*. Assessment Framework for quality standards, information standards & measuring instruments 2015. Diemen, 2015. (Version 2.0)

the GRADE system,[42] only takes place if this is prompted by the bottlenecks and if the guideline recommendations are based in insufficient scientific evidence.

The most important aspect of an assessment of effectiveness is the so-called PICO: Patient – Intervention – Comparator - Outcome. For which group of patients is the care intended and is that the group for which research is available? Which treatment or care is being offered and has this care been studied? With which control treatment (regular care, standard therapy) was that care compared and what is the added value of the recommended care? And which outcomes relevant to patients were examined in order to determine whether the care was effective?

5. Cost-effectiveness[43]
Cost-effectiveness clarifies the relationship between the efficacy of treatment (how does treatment benefit a patient?) and the costs that must be incurred to achieve this effect. We check whether the guidelines say anything about cost-effectiveness and we look at other (scientific) literature. If necessary, we carry out cost-effectiveness research ourselves.

6. Necessity[44]
This is where we examine whether care should be included in the basic health insurance or whether it involves costs which people should be able to pay without the need of insurance. The assessment of 'necessity' involves two different aspects: the severity of the disease (burden of disease) and the societal necessity of actually insuring the treatment concerned. While the emphasis with burden of disease is on medical necessity, with 'necessity to insure', the emphasis is on the question of whether insurance is actually necessary.

7. Feasibility[45]
Care that is not feasible cannot be supplied. The principle of feasibility indicates whether the preconditions have been fulfilled and how sustainable it is to include an intervention in the basic package. Relevant to this are, e.g., basis of support, how care is organised, indications and administration, funding, jurisdiction and ethics. This also involves, for instance, whether funding exists for an intervention that may be included in the basic package.

8. Consistency in quality circles
This is where we look at whether quality circles are used that focus on improving care, who uses them, and the interdependence that exists between quality circles.

Care improves when quality improvements are followed up by embedding in quality cycles. E.g.: quality standards and instruments of measurement are realised> implemented> the effects are measured> any quality standards and instruments of measurements are altered. Or: innovations are developed> implemented> assessed.

Use of claims data in the analyses

The *Zinnige Zorg* programme makes regular use of quantitative data. It is particularly important that these data are used meticulously for the quality of the

[42] *Zorginstituut Nederland*. Assessment of established medical science and medical practice. Final updated version. Diemen, 2015.
[43] *Zorginstituut Nederland*. Cost-effectiveness in practice. Diemen, 2015.
[44] *Zorginstituut Nederland*. Package Management in Practice, part 3. Diemen, 2013. (pages 33 etc./43 etc.)
[45] *Zorginstituut Nederland*. Package Management in Practice, part 3. Diemen, 2013. (pages 33 etc./43 etc.)

analysis, acceptance of the findings and the protection of privacy. The *Zorginstituut* explicitly recognises the importance of this and takes all necessary measures for processing the available data meticulously. The following is an explanation of key elements of how we process quantitative data.

Zorginstituut Nederland carries out research, based on questions relating to care content, into how care from the basic package is used in practice. To do this we collect information from many sources: from discussions with interested parties to scientific publications, from RIVM statistics to claims data.

These are partly quantitative data and relate mainly to claims data. When using data, the *Zorginstituut* has various measures for ensuring that security and privacy are guaranteed optimally. For example, the *Zorginstituut* uses pseudonymised personal data over several years and from various sources, which can be combined to answer a specific problem. This is what makes it possible to determine, for instance, whether a patient received medicinal treatment from a GP before undergoing surgery. Or to see which type of long-term care patients receive after an intervention. Combining data sources also makes it possible to carry out refined case-mix corrections.

We use claims data from the Declaration Information System (DIS) and from health insurers (via Vektis) in order to obtain an impression of care practice. Claim data reflect registration practices and not necessarily the care actually provided. Nevertheless, these data do form an important source of information, sometimes the only one, and can provide valuable signals relating to care quality. A detailed examination of the possibility of using other sources of data is a topic of research, in collaboration with VWS and other parties in health care.

2. Parties involved

This systematic analysis was approved in agreement with
care professionals, patients, institutions, health care insurers and the government.

Dutch Breast Cancer Association (BVN)
Dutch College of Surgeons (NVvH)
Netherlands Association for Medical Oncology (NVMO)
Dutch Radiology Association (NVvR)
Netherlands Association for Radiotherapy and Oncology (NVMO)
Netherlands Association for Internists (NIV)
Dutch College of General Practitioners (NHG)
Dutch Nurses & Care Givers (V&VN) Oncology
Living with cancer
Dutch Patients' Federation
Dutch Federation of University Medical Centres (NFU)
Association of Dutch Healthcare Insurers (ZN)
Federation of Medical Specialists (FMS)
Collaborating Top-Clinical Hospitals (STZ)
Dutch Association of Hospitals (NVZ)

Designing the Room for Improvement Report on post-treatment surveillance of women treated for breast cancer

Start of the in-depth phase
During a consultative meeting, in order to demarcate the in-depth questions, the parties involved in the care field[46] proposed potential points for improving the post-treatment surveillance of women after they have received curative treatment for breast cancer. We translated these points for improvement into a number of research questions and subsequently commissioned two parties to carry out external research (see Appendix 3). The external research and the systematic analysis of the eight elements of good and appropriate care took place between December 2015 and June 2016

Draft Room for Improvement Report
The findings from the analyses and the meeting resulted in a draft Room for Improvement Report, containing improvement measures formulated for improving after-care for women treated for breast cancer. We have provided an indication of the consequences for health care costs if the improvements are implemented. This is known as a Budget Impact Analysis (BIA).

[46] The parties involved are: Dutch Breast Cancer Association, NPCF, Living with Cancer, NHG, NVvH, NVVR, NVRO, NIV, NVMO, NVZ, STZ, NFU, FMS, ZN

Consultation
The draft Room for Improvement Report was send to the parties for consultation purposes, in August 2016. We asked the parties for written responses. Appendix 7 contains a summary of all responses of the parties consulted, and an explanation of how the *Zorginstituut* processed these responses.

Room for Improvement Report
The findings from the analyses and the written responses of the parties to the draft Room for Improvement report resulted in this final Room for Improvement Report.

Appendix 3: Third-party studies commissioned by *Zorginstituut Nederland*

Disclaimer
The study reports mentioned here are the underlying study reports used by the *Zorginstituut* in realising this report.
Responsibility for the data and conclusions in the underlying study reports rests entirely on the research institutions that drew up the reports. The *Zorginstituut* did not always adopt those data and conclusions in its own reports.
The following summary of sources used by the *Zorginstituut* is by no means complete.

Below is a summary of the underlying study reports on which this Room for Improvement Report is based. These reports can be accessed via the 'secured section' of *Zorginstituut Nederland*'s website. The most important findings are summarised in the previous sections.
See:
https://www.zorginstituutnederland.nl/pakket/lopende+dossiers/programma+zinnige+zorg/nieuwvormingen---nacontrole-borstkanker.html

KPMG-Plexus. *Diagnostic tests in women treated for breast cancer.* Amstelveen June 2016 Utrecht June 2016

IKNL in collaboration with the University of Twente and Performation. *Appropriate post-treatment surveillance for women treated for breast cancer – detecting locoregional recurrence.* Utrecht June 2016

IKNL in collaboration with the University of Twente. *Providing good information and shared decision-making for women treated for breast cancer.* Utrecht June 2016

Research task	**Implementing party/contribution to the research problem**
Study into possibilities for designing post-treatment surveillance based on the actual risk of a locoregional recurrence	IKNL in collaboration with the University of Twente and Performation Contribution to research into possibilities for individualised post-treatment surveillance
Research on the use of medical tests in the post-treatment surveillance of women treated for breast cancer	KPMG Plexus Contribution towards analysing elements of good and appropriate care
Research into possibilities for the proper provision of information and shared decision-making for women treated for breast cancer	IKNL in collaboration with the University of Twente. Contribution to research into possibilities for individualised post-treatment surveillance Also a contribution towards analysing elements of good and appropriate care

Appendix 4: Summary of parties' reactions

	Parties' comments *ZIN's responses*
BVN	**BVN feels that the report makes good reading and agrees with the conclusion that more attention should be paid to providing good information and shared decision-making.**
	BVN agrees that more room should be created for individualised post-treatment surveillance/after-care, and that information and care requirements should help determine the content of post-treatment surveillance. According to BVN, essential aspects of this are the realistic management of expectations and providing patients with information about the objective and value of routine post-treatment surveillance. BVN sees a role in this for their organisation.
	We share this opinion which is completely along the lines of our Room for Improvement Report. After the Room for Improvement Report has been approved, we will organise an implementation meeting in which together with the parties we will harmonise the improvement measures, according to the respective responsibilities of the parties in health care.
	BVN wonders why the report focussed mainly on post-treatment surveillance and not on after-care. BVN feels this was a missed opportunity.
	This topic was demarcated in an early stage of the proceedings. All parties involved were able to air their views and agreed with the choice of post-treatment surveillance topics for in-depth research. *It is important that post-treatment surveillance is in line with individuals' risk of a recurrence and that this is accompanied by the efficient provision of information and shared decision-making. This will create space for other important topics relating to after-care. ZIN feels that the outcomes of the study 'Providing good information and shared decision-making' provides pointers for a concrete interpretation of other after-care objectives via the process of providing good information and shared decision-making.*
	BVN has doubts about using the nomogram, they wonder whether this is the right instrument for recurrence risk stratification. BVN advises discussion of this matter with the medical professional group. BVN also asks that attention is given to the use of diagnostic tests such as the Mammogram.
	The main objective of the current nomogram is to estimate the risk of a recurrence that is yet to be cured. The model includes a number of factors, including, e.g., the various treatment modalities (see section 3.1). In addition, in our report we advised continued developed of the nomogram. The scope of this Room for Improvement topic is post-treatment surveillance. Diagnostic tests and instruments for risk stratification with a view to choosing therapy are therefore beyond the scope. After the Room for Improvement Report has been approved we will organise an implementation meeting in which we will, together with the parties, elaborate upon the improvement measures in agreement with one another.
	BVN is concerned that no mammogram was made for some of the women and that 10% of the women received no check-up mammogram at all.
	When the study was taking place, the relevant data sources were not properly aligned with one another to be able to gain insight into their backgrounds (see section 3.3 under Application in practice). However, without a standard based on well-founded guideline recommendations, we cannot attach firm conclusions to

	the picture presented of post-treatment surveillance. ZIN does feel that this picture is a reason for (extra) training for the professional groups involved, as recommended in this report. This includes (extra) training of care professionals about the objective of routine post-treatment surveillance.
	BVN wonders what topics will be named in the guidelines, which will be amended, how they will be elaborated upon and which parties will be involved.
	We will ensure that the parties involved will accept their responsibility in relation to this. We will organise an implementation meeting after the Room for Improvement report has been approved. The Zinnige Zorg programme works according to an improvement circle, which also involves implementation and monitoring. See appendix 2 of the report.
	BVN made a few suggestions for elaborating on implementation (e.g. transmural agreements on post-treatment surveillance, an after-care plan and option grids).
	Where applicable, these have all been incorporated in the Room for Improvement report. We will organise an implementation meeting after the Room for Improvement report has been approved.
	BVN also recommended a number of changes in the text.
	Where applicable, these have all been incorporated in the Room for Improvement report.
	BVN would like to see in the Room for Improvement report a list of topics that need to be discussed during the after-care pathway. B-Aware could play a role here.
	We appreciate the importance of good agreements between all the parties on the contents of post-treatment surveillance. However, a list of topics is beyond the scope of this Room for Improvement Report. In our opinion, this is a topic that the parties involved must take up during the implementation phase.
	BVN argues in favour of a single point of contact during post-treatment surveillance.
	We agree wholeheartedly. This could involve, e.g., the possibility of having post-treatment surveillance carried out by a single discipline. We have incorporated this in sections 3.3 and 4.1.
	BVN emphasises the importance of having feedback on the results of after-care and making this information available.
	We are in full agreement; this is in line with the Room for Improvement Report.
	BVN wonders what is the source of our claim that one-third of the patients were not asked about psychosocial symptoms.
	This claim comes from the title of your study of B-force and the data on which it was based. This is mentioned in footnote 4, section 1.2 (B-force 2013, Dutch Breast Cancer Association.)
	According to the BVN, not doing a follow-up study into psychosocial symptoms is a missed opportunity.
	We concur with your opinion that paying attention to psychosocial symptoms is an important aspect of post-treatment surveillance. Several parties have already developed various activities relating to this topic. To avoid unnecessary repetition of research, this research question was therefore excluded from the in-depth research.
NIV and NVMO	**The NIV and the NVMO are certainly in favour of an individualised follow-up schedule, whereby high-risk groups will probably attend check-ups more frequently and low-risk groups less frequently and possibly even be referred back earlier to population screening. Individualised follow-up is in line with increasingly "personalised" treatments.**

	The NIV and the NVMO make suggestions for further elaboration of the Room for Improvement Report.
	ZIN is pleased that the NIV/NVMO concur with the report on the matter of individualised (risk-stratified) post-treatment surveillance. *We will plan a meeting with the parties in which we elaborate on the improvement measures and harmonised them with one another.*
	It is not clear to the NIV and the NVMO from the report whether patients who receive anti-hormone therapy will perhaps never belong to the low-risk groups (after all, there was a reason for adjuvant hormone therapy). On the other hand, anti-hormone therapy will also reduce the risk of a local recurrence.
	The primary objective of adjuvant hormone therapy is to prevent distance metastases. This has no effect on the organisation of post-treatment surveillance for the detection of a locoregional recurrence.
	The NIV and the NVMO comment that during post-treatment surveillance attention must also explicitly be given to the adverse effects of adjuvant hormone therapy.
	We agree wholeheartedly with this. It is important that post-treatment surveillance is customised to suit the actual individual risk of a recurrence and that space is created for other important matters such as coping with the consequences a patient can expect when treatment has ended. ZIN feels that the outcomes of the study 'Providing good information and shared decision-making' provides pointers for a concrete interpretation of other after-care objectives via the process of providing good information and shared decision-making.
	Noticeable is that 10% of the women treated received no mammogram check-up at all and that 35% received < 3 mammograms. Possible explanations for this is that these are post-mastectomy patients, or it was the patient's own choice or they were older and/or multi-morbid patients.
	Using the available data, we were unable to link the groups you cite to the picture presented in these analyses.
	Noticeable is that almost no other diagnostics were used, except for bone density measurements.
	This is in accordance with the guidelines: no indication exists for routine check-ups for distance metastases.
	The NIV and the NVMO warmly recommend research in the field of providing information and shared decision-making making. Questions can be put to patients via hospitals.
	We are very happy to see the interest of the NIV and the NVMO in this topic. We will plan a meeting to harmonise further elaboration with the parties.
NVRO	**The agrees with improved risk stratification and feels moreover that support by a monogram based on recent outcome data will be very valuable. The NVRO states that other literature also found a very low risk of a locoregional recurrence, thanks to improvement treatment possibilities.**
	ZIN is pleased that the NVRO's opinion is in line with the Room for Improvement Report. It is true that the risk of a locoregional recurrence is low, but there is some degree of spread and differentiation over the course of time. This can be seen from the nomogram.
	The NVRO does comment that, apart from the risk of a locoregional recurrence, the risk of an ipsilateral or a contralateral new tumour should also be included.
	This is in line with our proposal for continued development of the nomogram as

	described in section 4.1. Although we recommend further development, this is not a reason for reticence in using the nomogram. We feel supported in this by the very low risk of a recurrence as you yourself cited. We describe the factors included in the nomogram in section 3.1.
	The NVRO refers to the limited value of routine check-ups in the form of a physical examination, as we know from the literature that 40-55% of recurrences are found through a check-up mammogram or, in 40-50% of cases by the patient herself.
	ZIN is aware of these data on the limited value of a physical examination for detecting a locoregional recurrence. On the whole, ZIN agrees with the NVRO. However, the various relevant factors must be assessed integrally in order to assess the clinical value of post-treatment surveillance. What we have in mind is the actual risk of a recurrence and the information on current post-treatment surveillance in practice, thus including the data from the literature cited by the NVRO.
	The NVRO rightly mentioned that post-treatment surveillance should also take into account – certainly in view of the low risk of a recurrence – the monitoring of late effects (physical or psychosocial) and the importance of valid PROMS.
	We agree with the NVRO that monitoring late effects is very important for assessing medical actions. However, this requires scientific research and this is still on-going. The decision was therefore made not to include the assessment of medical actions as part of post-treatment surveillance. ZIN therefore feels it is very important to develop the PROMS further. We have included this as an improvement activity.
	The NVRO is not clear what will constitute the 'concrete pointers' for providing information and shared decision-making that are supposed to be included in the guidelines.
	The guidelines should include as concrete pointers the optimisation of information material and decision aids for shared decision-making on topics that the study identified as value-sensitive.
	Attention is requested for the importance of patients remaining under surveillance so that scientific research is still possible, to be able to continue assessing the results of treatment. It is claimed that patients who participate in scientific research increasingly fail to attend surveillance due to costs (personal contribution).
	Scientific research that is carried out should have a separate source of funding, and not be funded via the basic insured package.
	In relation to the consequences of this Room for Improvement Report, the NVRO is not entirely clear about what the elements 'cost-effectiveness' and 'necessity of good care' mean for patients.
	Post-treatment surveillance after breast cancer is insured care, meaning that patients are entitled to this care via the health insurance. Each insured client has their excess deductible in relation to this health insurance. The Minister introduced personal excess to make people more conscious of the care they consume. And in particular to keep care expenditure in the Netherlands manageable. In other words, the care is insured, but there is a threshold. Political discussion is currently taking place about the sustainability of the personal excess. Your input is a contribution to this political debate.
	The NVRO asks for further elaboration of a number of topics relating to implementation, such as the use of diagnostics, the coordination between care professionals and the use of an after-care plan.
	Expectations are that more individualised post-treatment surveillance will result

	in more individualised deployment of diagnostics. We did not include this as a separate improvement activity. Optimising harmonisation between care professionals will also contribute to making more individualised use of diagnostics. We incorporated this in section 4.1. We will organise an implementation meeting after the Room for Improvement report has been approved.
NVvR	**The NVvR endorses the Room for Improvement Report and argues in favour of further elaboration of the guidelines based on scientific research**
	We share this opinion which is completely along the lines of our Room for Improvement Report. This is apparent from our recommendation that the nomogram undergoes further development (see section 4.1). After the Room for Improvement Report has been approved, we will organise an implementation meeting in which together with the parties we will harmonise the improvement measures, according to the respective responsibilities of the parties in health care.
	The NVvR also recommended a number of changes in the text.
	Where applicable, these have all been incorporated in the Room for Improvement report.
NVvH	**The NVvH endorses the conclusions as formulated. It proposes involving the NABON in any further steps.**
	ZIN is pleased to hear that the NVvH supports the improvement measures named in the report. We will plan a meeting to harmonise further elaboration with the parties.
	The NVvH does point out that designing individualised post-treatment surveillance based on shared decision-making is at odds with the policy of risk stratification.
	We acknowledge the possibility that post-treatment surveillance based on risk stratification and shared decision-making may be contradictory. However, from the perspective of patients it is important that they receive realistic information on the possibilities of post-treatment surveillance and other objectives of after-care by means of shared decision-making and the proper provision of information. This is essential if patients are to retain quality of life and management over their own life.
NFU	**The NFU is in complete agreement that studies/check-ups for detecting recurrences should be used less. The NFU suggests involving the NABON in any subsequent steps.**
	ZIN is pleased that the NFU supports the improvement measures named in the report. We will plan a meeting to harmonise further elaboration with the parties.
	Additional research into the effectiveness of risk stratification is needed.
	This is in line with our proposal for continued development of the nomogram.
	The NFU points out that in many hospitals harmonisation between care professionals can be optimised by limiting the number of care providers per post-treatment surveillance. This is what the 2012 guidelines say, but hospitals are struggling with it.
	We agree wholeheartedly. This could involve, e.g., the possibility of having post-treatment surveillance carried out by a single discipline. We incorporated this in section 3.3.
	The NFU feels that the discussion should not be so much about reducing the frequency of post-treatment surveillance, but rather about its content, insofar as it focusses on detecting locoregional recurrences.
	It is important that post-treatment surveillance is customised to suit the actual individual risk of a recurrence and that space is created for other important topics such as coping with the consequences a patient can expect when

	treatment has ended.