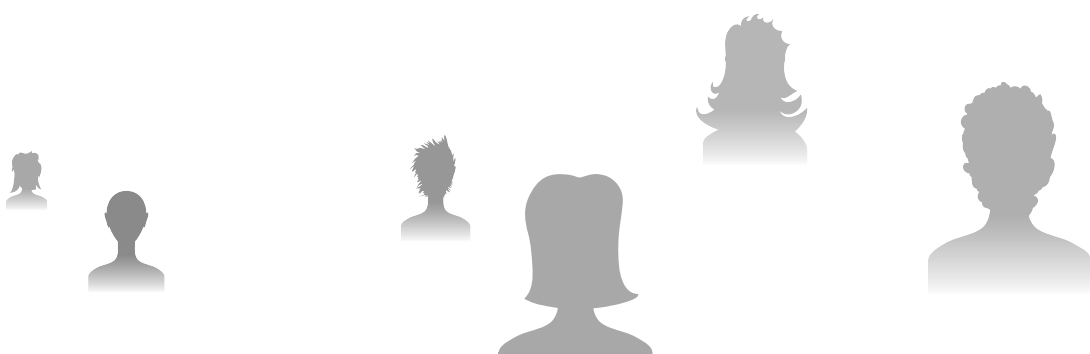
# chapter 7

## General discussion



Follow-up after breast cancer treatment has been studied for over two decades, but no consensus on frequency, duration or form has been reached. At the same time, there is an increasing prevalence of breast cancer, due to the increased prevalence of risk factors, the aging population, and a decreasing mortality rate as a result of better screening and treatment options.

Current follow-up after treatment consists of frequent hospital visits and annual mammography.[1] As the group of breast cancer survivors is expanding, these follow-up visits have an increasing impact on national health care costs and capacity. In this era of increasing costs and limited healthcare budgets, these frequent hospital visits should no longer be standard care in the absence of evidence supporting their value. Follow-up care should be tailored to the patient, following the trend of more personalised treatments based on patient, tumour and treatment characteristics.

Reduction of frequency or duration of follow-up, however, is controversial. More insight into patient and professional related factors that influence follow-up practice will enable policymakers to address these factors in order to implement the most effective tailored follow-up. The most important considerations are discussed below.

# 7.1 AIMS OF FOLLOW-UP

## Detection of a salvageable locoregional recurrence

One of the main aims of breast cancer follow-up has historically been detecting salvageable recurrences.[2,3] This is only aimed at detecting locoregional recurrence (LRR), as in even in the case of early detection of distant metastases, cure can unfortunately no longer be offered. This has been confirmed in several studies, showing that a more intensive follow-up strategy including additional investigations to detect distant metastases did not result in a survival benefit.[4-6] As a result, early detection of asymptomatic distant metastases will only result in a decreased quality of life in patients due to the awareness of having an incurable disease, whereas treatment will only start when symptoms occur.

However, since not only mortality, but also LRR rates have decreased over the last decades, follow-up visits for detecting LRR may no longer be appropriate. In addition, there is no evidence that frequent routine hospital visits improve survival or quality of life.

For safe introduction of more tailor-made follow-up strategies, it is essential to have a good estimate of the LRR risk in breast cancer. As demonstrated in Chapter 2, the up-to-date LRR risk for the large group of postmenopausal women with hormone sensitive tumours is very low, so the chance of detecting these recurrences during routine hospital follow-up visits is small. Most LRRs will be detected on mammograms or by the patient herself.[7-10] As it has been demonstrated that physical examination by professionals contributes very little to the discovery of local recurrences,[1] the detection of LRR can no longer be the justification for routine hospital follow-up visits in this population. Whether this conclusion can also be drawn for other subgroups of patients, needs to be evaluated based on current LRR risks. Online nomograms are available (http://research.nki.nl/ibr/ibr/index.html and https://www.tuftsmedicalcenter.org/ibtr/), but overestimate the LRR risks, especially for the high risk patients. Reason for the overestimation are the fact that the models were based on data of patients treated before the introduction of more effective systemic therapy, different definitions of ipsilateral breast cancer recurrence (IBTR) and the small group size of high risk patients (only 20% of the cohort).[11,12] The available tools should be updated with data from recent trials to more accurately estimate

current LRR risk. In addition, LRR risk may vary not only based on risk factors, but also over time after treatment, as was shown in a large Dutch cohort with almost 18.000 patients.[13] Ideally a dynamic prediction tool should be developed for LRR, in which patient related factors over time are taken into account, as described for overall survival by Fontein et al..[14] Implementation of these prediction tools may provide more insight for professionals and patients in actual LRR risks and identify the group of patients with high risk of LRR which might need closer monitoring. At the same time these tools could convince them of the safety of reduced follow-up frequency for the large group of low risk patients, hence increasing adherence to tailored schedules with reduced frequency. Without such tools, health care professionals may tend to overestimate the risk of LRR due to availability bias;[15] a cognitive bias that causes people to overestimate the probability of events associated with memorable or vivid occurrences, such as the memory of that one local recurrence they found during a follow-up visit, or that one local recurrence that was detected in a patient just after they had ended follow-up.

## Detection and treatment of early and late side effects

Another important aim of follow-up is the monitoring of side effects, both physical and psychosocial. As detecting LRR may no longer be the justification for clinical follow-up, the frequency of visits can be tailored to the presence of treatment side effects. Luckily, most patients have few side effects, so usually no standardised contacts for this purpose are needed.

If physical side effects occur, they are most prevalent in the first year after treatment in case of surgery and chemotherapy, justifying follow-up to monitor patients in this year. A selected group of patients will experience side effects of their ongoing endocrine treatment or have late side effects of radiation or chemotherapy in the following years. All patients should be informed about the possible late side effects of these treatments, so they can recognise them when they occur and contact a professional when needed. In addition, an online nomogram is available, which estimates the risk of radiation induced fibrosis (http://research.nki.nl/ibr/fibrosis/index.html).[16] This nomogram is based on data of patients irradiated nearly 20 years ago with old radiation techniques and needs to be updated to be used to individualise follow-up schedules.

A special group is formed by the patients on ongoing endocrine treatment for 5-7 years after treatment. In practice, medical oncologists indicate the need to see those patients themselves twice a year during the length of the treatment to monitor side effects. This is in line with the results in Chapter 4 where the medical oncologist tended to more frequent follow-up for a large group of patients. However, after initial screening with a bone density (DEXA) scan, the side effects of endocrine treatment can in most patients also be monitored by a specialised nurse. Possibly general practitioners (GP's) could also have an important role in monitoring side effects, as they are used to monitoring side effects of all kinds of drugs. Furthermore, with their holistic approach, they are probably best suited to consider these side effects in light of a patient's nature and comorbidities. GPs in the Netherlands have been questioned and are willing to take a more active role in cancer follow-up, provided that they are trained well and their capacity is increased to meet the health care needs of the growing number of cancer survivors.[17] For severe complaints which the GP cannot treat, referral to the medical oncologist should then be facilitated. As described in Chapter 4, the vast majority (>90%) of the hospital based professionals however indicated not to prefer alternative forms such as telephone follow-up or follow-up by the GP, despite the available evidence that this is a safe and cost-effective strategy.[18-21] An educational group program with telephone follow-up by a nurse practitioner could be a good alternative to frequent visits the first year after treatment.[19] Unfamiliarity of professionals with these concepts may be the cause of their reluctance, as previous studies show a statistically significant preference for the existing service. Possible explanations for this result include the endowment effect, which means that people ascribe more value to things merely because they own them, a status quo bias and loss aversion.[22] Financial incentives from the Dutch reimbursement system may also be of influence on the preference of professionals for longer hospital follow-up by in the Netherlands, especially in those patients that receive endocrine treatment.[23]

Besides physical side effects, the impact of having breast cancer and its treatment can also have a major effect on patients' psychological wellbeing. Given this knowledge, professionals see psychosocial support as an important part of the follow-up visits, as was described in Chapter 4. Surprisingly, the psychosocial support given so far has not been perceived as very valuable by the patients, neither before nor after the introduction of nurse practitioners (Chapter 3). Previous studies also report a lack of opportunities to meet informational and psychosocial needs during hospital consultations.[24] One might therefore question whether GPs are not better

equipped for this important aspect as well. They have often known the patient for a long time, are familiar with the support systems that exist in this particular patients' surrounding and may be better informed about the personality of the patient. In addition to the GP's support, educational group programmes, online information/courses, telephone follow-up by a nurse practitioner in the first year after treatment and low threshold consultation of a case manager in case of questions or symptoms are good alternatives to provide optimal and cost-effective support for cancer survivors.[19,25]

Detailed written and online information on the risk and management of possible treatment side effects for each patient, dependent on their treatment, and signs of recurrence should be provided in an individual written aftercare plan.

## Monitoring treatment outcome for training and research purposes

The loss in outcome monitoring is often mentioned as a disadvantage of reduced follow-up. For training purposes of the different professionals involved in breast cancer treatment (surgeons, medical oncologists and radiation oncologists), observation of late side effects of their treatment (for example fibrosis, cardiotoxicity and fatigue) is required. However, there is no need for all specialists to keep patients in the follow-up themselves for this purpose only. Residents could join the nurse practitioner/specialised nurse for a few months to evaluate the late toxicity of their treatment. Alternatively, a special outpatient clinic can be opened in training hospitals to invite patients once after 5 and 10 years on a voluntary basis to monitor late side effects, similar to the clinics established for patients after treatment of Hodgkin lymphoma. The difference, however, is that for Hodgkin lymphoma side effects may be more extensive due to young age at treatment and larger radiation fields. Furthermore, in Hodgkin patients active interventions are offered, whereas this may not be the case for breast cancer patients. However, from clinical experience it seems likely that patients are still willing to participate in such a programme, despite the fact that there is no automatic gain for them personally.

The need for outcome registration can also be met in alternative ways; the most important outcome measures (survival and recurrence) can be studied through the National Cancer Registry and the information collected by the Dutch Institute of Clini-

cal Auditing. The registration of treatment side effects for research purposes does not justify prolonged frequent follow-up visits. These could be evaluated in alternative ways, such as periodic questionnaires sent to patients in combination with special late effect outpatient clinics where patients can be invited based on the outcomes of these questionnaires. Patients already included in clinical trials must adhere to follow-up schedules as specified in the protocols, but the need for frequent follow-up schedules in new trials should also be critically reviewed, dependent on the specific endpoints.

## 7.2 PERSPECTIVES OF FOLLOW-UP

### Patients

Patients seem to have a preference for the organisation of care as explained to them at the start of their treatment (such as with or without nurse practitioner as shown in Chapter 3). This may also be explained by the endowment effect, a status quo bias and loss aversion.[22] The preference for additional investigations and lifelong follow-up that was found in Chapter 3 might also originate from (false) expectations created by the information on follow-up by their treating physicians at the time of treatment. Moreover, due to the high prevalence of breast cancer in the population, the majority of new breast cancer patients have a relative or friend who has been treated for breast cancer in the past and who had long term follow-up with additional investigations, which was common practice at the time. Patients' initial preference for a treatment is very robust and is hard to change, despite later information on evidence for other treatments, or in this case follow-up options.[26] As our tailored follow-up trial and other trials on decreased intensity of follow-up show no decrease in patient satisfaction or increase in patient initiated interval visits, patients do seem to accept less intensive follow-up schedules, as long as they are initially well informed on the purpose, the risks and limitations.

To guarantee a low-threshold opportunity to contact their physician, the possibility of extra visits if perceived necessary should be discussed with the patient. However, it should be stressed that the initiative for these on demand visits should be with

the patient. This will stimulate their awareness of being responsible and in charge of their own health, whereas more frequent routinely planned visits will underline their role as a patient, and can even have an adverse effect by causing anxiety.[27-29]

## Professionals

The preferences and perceived purpose of follow-up among different health care professionals provided in Chapter 4 identifies (false) expectations among caregivers. More specific education of the professionals involved could increase awareness of the limited value of extra visits and additional tests and could underline the safety and cost-effectiveness of telephone follow-up and follow-up by the general practitioner.[18-21] Furthermore, all different specialists indicated that they should be involved in follow-up themselves, despite the recommendation of the guideline that one coordinator should be appointed and the evidence that the more specialists are involved, the more unnecessary visits are performed.[1,30] This conservative attitude was also found in the trial on implementation of tailored follow-up described in Chapter 6, in which the vast majority of interval visits was initiated by the professional. Unfortunately no information on age or years of experience of professionals was obtained in either of the studies, which would be interesting to specify the necessary education.

The preference of professionals for frequent follow-up might be a reflection of a paternalistic approach in which physicians assume that patients are reassured by frequent visits.[23] However, a recent study into patients' perceptions of routine follow-up, shows that frequent follow-up visits might even increase anxiety, as sixty-three percent of patients reported increased levels of anxiety in the days or weeks preceding their routine appointment.[27] On the other hand, seeing healthy patients in an outpatient clinic years after their treatment might increase job satisfaction, motivation and psychological wellbeing of professionals.[31] Paradoxically, this could mean that decreasing hospital follow-up may reduce work load, but have an adverse impact on the risk of burn-out. This effect may be reduced by inviting patients to a special outpatient clinic 5 and 10 years after treatment to evaluate outcome, allowing physicians to not only monitor treatment side effects, but also see the beneficial effects of their treatment.

To enhance coordination and adherence of all professionals to tailored follow-up schedules, in each hospital, tailored (LRR risk or side effect based) follow-up protocols for different risk groups and different treatments should be developed. At the end of treatment the applicable follow-up plan should be determined and explicitly communicated with the patient by a case manager (such as the nurse practitioner). This schedule should be entered in their chart, visible for all professionals involved, and provided to the patient and their GP on paper and online as part of their personal aftercare plan. In general, a single professional (case manager) should perform the follow-up, preferably a specialised nurse or nurse practitioner as patients are more satisfied with the communication by the nurse practitioner (as was shown in Chapter 3) and patients highly value the continuity of care by one caregiver.[32] Alternatively, in the future general practitioners could also assume the role of case manager, provided they have been given sufficient information to do so. Other professionals can be asked to be involved only when needed in case of specific side effects.

## Costs

No marked differences in clinical outcome (time to detection of LRR, overall survival or quality of life) have been reported between different follow-up schedules.[5,10,33] In light of this equal effectiveness, preferably the least costly program should be identified and implemented, as this follow-up concerns a large group of patients. So far, as described in Chapter 5, defining the least costly program has been difficult, due to different ways of defining and calculating costs between studies and countries. Only the randomized trial by Kimman et al.[19] used the incremental cost-effectiveness ratio (ICER) per quality adjusted life year (QALY) gained. The use of QALY's provides the opportunity to put the costs of different follow-up strategies in perspective in relation to other health care costs and should be encouraged in future research.

The incremental costs per QALY of more frequent follow-up are expected to exceed the various (controversial) thresholds that have been proposed (20.000-80.000 euro), because the difference in quality of life and survival are minimal between different follow-up schedules. An example of the impact of minimal benefit on the ICER was shown by Kimman et al, who found a ICER of € 235.750/QALY for hospital follow-up with educational group programme (EGP) versus telephone follow-up with EGP. The

impact of implementation of tailored follow-up on health care cost in the Netherlands in general is hard to predict based on the study in Chapter 6, as the factors influencing frequency of visits and their incidence have to be evaluated (current LRR risk, risk of treatment side effects). As LRR risk has been decreasing over the years, the low risk group might form a vast majority of patients, and hence a large cost reduction. Future research should be aimed at calculating the possible impact.

As there are many parameters that can vary in different follow-up strategies (duration, frequency, type of diagnostic tests, type of caregiver), it is not possible to evaluate all different options in randomised clinical trials (RCTs). Performing more adequate modelling studies with standardised outcome measures such as the ICER and QALY, could be a good alternative to provide more insight in the cost-effectiveness of different strategies in the absence of international RCTs.

## 7.3 FURTHER CLINICAL CONSIDERATIONS

### Guideline implementation

In 2012 the Dutch guideline on follow-up has significantly changed and now advises a minimum of one annual hospital visit and mammogram for the first 5 years follow-up for patients <60 years. For patients 60-75 years it recommends an annual mammogram and a clinical visit, which could also be performed by the GP. For patients over 75 years of age, it can be considered to end active follow-up.

This is a safe policy in light of the low LRR rate and the evidence that most recurrences are found on mammograms, or by the patient herself. However, the added value of the standard clinical visits is unclear and there is no evidence supporting the differentiation based on age, so this should rather be based on risk of recurrence. Furthermore, new guidelines do not automatically translate into clinical practice, especially as this new guideline requires better collaboration among different professionals, changes in patients' behaviour and changes in the organisation of care.[34] As we found in our tailored follow-up trial (Chapter 6) that many interval visits were initiated by professionals, a challenge in implementing this guideline is to break the

routine and preference for frequent follow-up visits which have been the standard of care of many professionals for years. The insight into barriers and facilitators in patients and professionals provided in this thesis can help design the most effective implementation strategy.[35] Based on the results of the implementation of tailored follow-up described in Chapter 6, it can be concluded that the acceptance of fewer follow-up visits by patients and professionals is feasible, but needs close monitoring.

## Written aftercare/survivorship plan

Although the use of a written aftercare plan/survivorship plan was already recommended in 2007, this was found to be a standard policy in only 21% of practices in 2009 (Chapter 4). Although this percentage will have increased over the last years, it is still not standard practice in many hospitals. Such a plan should contain dates of follow-up visits, information about caregivers, and information on the aspects highly appreciated by patients such as information about prognosis, life style, additional investigations, fatigue, pain, genetic factors, prevention and arm function/lymphoedema (Chapter 3). Detailed information on the risk and management of possible treatment side effects for each patient, dependent on their treatment, should be provided. This could for example encompass advice from a physiotherapist in case of impaired shoulder function and treatment options for oedema, information on symptoms of chemotherapy-induced menopause for younger patients, on group training to regain physical fitness, on reintegration at work, contact addresses of psychologists and relevant websites. Such information can empower patients to take control over their own life again, as it allows patients to monitor themselves on relevant complaints and gives them the confidence that they can reach the relevant health professionals when needed. The plan could be provided on paper, but in this era of internet and upcoming e-health, this plan should preferably (also) be available as an interactive online document, owned by the patient, which can be adapted by patients and their care givers when needed. Ideally, a mobile phone application to access this document would make the information more easily accessible. The presence of such a plan for all patients should be an indicator in the Dutch NABON Breast Cancer Audit, as it reflects quality of care.

## 7.4 CONCLUSIONS AND RECOMMENDATIONS

- Patients accept less intensive follow-up schedules, as long as they are initially well informed on the purpose, the risks and limitations of follow-up.
- Implementation of minimised tailored follow-up is feasible, but needs close monitoring as professionals tend to more frequent follow-up.
- Specific education for professionals on the limited effect of clinical visits on psychosocial support and the limited value of early detection of metastases is needed to decrease the number of professional initiated interval visits.
- Implementation of updated online prediction tools may provide more insight in actual LRR risks and convince patients and professionals of the safety of reduced follow-up frequency, hence increasing adherence to tailored schedules.
- Tailoring should not only be done based on LRR risk, but individually, based on the presence of treatment related side effects, either physical or psychosocial.
- If patients do not experience side effects, annual planned mammography and telephone contact coordinated by a single professional, preferably a specialised nurse or possibly in the future a well-trained GP, suffice in case of easily accessible on demand visits.
- In the first year after treatment an optional educational group program combined with telephone follow-up by a nurse practitioner could be implemented.
- Written information on follow-up, risk and signs of recurrence, possible treatment side effects and their treatment options, including contact information, should be provided to all patients on paper, online or in a mobile phone application. The presence of these aftercare plans should in the Netherlands be evaluated in the NABON Breast Cancer Audit.
- To enhance coordination and adherence of all professionals to tailored follow-up schedules, a (LRR risk or side effect based) tailored follow-up schedule should be determined at the end of treatment, based on local protocols. This schedule should be entered in the patient's chart, visible for all professionals involved, and provided to the patient and their GP on paper and online as part of their personal aftercare plan.

- Residents could join the nurse practitioner/specialised nurse to see the late toxicity of their treatment. Alternatively, a special outpatient clinic to monitor late side effects can be opened in training hospitals.
- Patients already included in clinical trials must adhere to follow-up schedules as specified in the protocols, but the need for frequent follow-up schedules in new trials should also be critically reviewed, dependent on the specific endpoints.
- Performing more adequate modelling studies with standardised outcome measures such as the incremental cost-effectiveness ratio (ICER) and quality adjusted life year (QALY), could be a good alternative to provide more insight in the cost-effectiveness of different strategies in the absence of international RCTs.

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