Recommendations for follow-up of women with early breast cancer

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A CLINICAL PRACTICE GUIDELINE

This document supplements guideline recommendation 25 (page 10) and information about follow-up care (pages 97-102) contained in National Breast and Ovarian Cancer Centre's (NBOCC's) *Clinical Practice Guideline for the Management of Early Breast Cancer*, 2nd edition 2001.

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Purpose

This guideline includes statements and recommendations based on available, high level evidence about follow-up care of women with *early breast cancer*. The guideline aims to provide health professionals with information to assist in making management recommendations for improved patient outcomes. NBOCC* also develops information specifically for consumers about early breast cancer, diagnosis and management options.

Endorsed by:

Breast Cancer Network Australia

The Royal Australian and New Zealand College of Radiologist
The Faculty of Radiation Oncc

The Royal Australian College of General Practitioners

The Royal Australasian College of Physicians

The Royal Australasian College of Surgeons

* In February 2008, National Breast Cancer Centre (NBCC), incorporating the Ovarian Cancer Program, changed its name to National Breast and Ovarian Cancer Centre (NBOCC). In July 2011, NBOCC amalgamated with Cancer Australia to form a single national agency, Cancer Australia, to provide leadership in cancer control and improve outcomes for Australians affected by cancer.

Background

Early breast cancer is defined as tumours of not more than five centimetres diameter, with either impalpable or palpable but not fixed *lymph nodes* and with no evidence of distant metastases.[1]

The clinical care of women with early breast cancer may involve surgery, *radiotherapy*, *systemic therapy* and supportive care.[1] Following completion of active treatment, follow-up is required.

The purpose of follow-up care includes:

- the early detection of local, regional or distant recurrence
- screening for a new primary breast cancer
- detection and management of treatment-related side effects
- detection and management of psychosocial distress, anxiety or depression
- review and updating of family history
- observation of outcomes of therapy
- review of treatment, including new therapies which may be potentially relevant to the patient.

Clinical practice recommendations

Many factors influence the individual woman's requirements for follow-up care. Recommendations to individuals should be based on the absolute benefits and potential risks of follow-up care, and the individual's needs. These factors should be discussed with the woman.

RECOMMENDATIONS	LEVEL OF EVIDENCE[3]	REFERENCE
In women who have completed active treatment for early breast cancer:		
Method of detection of *recurrence*, new primary or *contralateral breast* cancer		
A history should be taken at each follow-up visit for symptoms of locoregional or systemic relapse, long-term treatment-related side effects or psychosocial distress	IV	Montgomery[4] de Bock[5]
At each follow-up visit clinical examination should be performed. This includes the breast(s) or chest wall, regional *lymph nodes* and the arm on the treated side. Where appropriate, the examination may also include other organs such as the liver and lungs	IV	Montgomery[4] de Bock[5]
Mammography should be performed annually to detect ipsilateral recurrence† or new primary, or contralateral breast cancer*	IV	†Montgomery[10] *Kollias[11] *Robinson[12] *Kaas[13]
Ultrasound may be used in addition to mammography when indicated on clinical or radiological grounds		
The routine use of PET or MRI is not recommended as part of follow-up. However, the use of MRI may be considered in specific high risk groups		
Women should be advised that between visits they should be aware of the normal look and feel of their breasts, and if changes are detected, to make	IV	Montgomery[4] de Bock[5]

RECOMMENDATIONS	LEVEL OF EVIDENCE[3]	REFERENCE
immediate contact with their GP or the health professional identified as responsible for their follow-up care		
Interval and duration of follow-up		
A standard follow-up schedule is recommended (see NBOCC** recommended follow-up schedule)	I	Rojas[30]
Patient history and clinical examination should occur every 3-6 months for the first 2 years, every 6-12 months for the next 3 years and annually after 5 years	IV	Montgomery[4]
Mammography (and ultrasound if indicated) should be conducted annually following breast cancer diagnosis	IV	Montgomery[4]
There is no evidence to indicate the optimal duration of follow-up. This should be discussed between the patient and the health professionals involved in the woman's care		
Intensity of follow-up		
Intensive follow-up, such as chest *X-ray*, bone scan, CT, PET or MRI scan, tests including full blood count, biochemistry or tumour markers, are not part of standard follow-up and are recommended only if clinically indicated	I	Rojas[30]
Follow-up care provider		
The selection of the provider of follow-up care should be a decision made by the multidisciplinary team and the woman, and be based on the purpose of follow-up and the individual woman's needs. This decision should be reviewed over time		
The multidisciplinary team, including the GP and the woman should be informed of the health professional(s) designated to provide follow-up care, and the schedule for follow-up		NBCC[19] **
A patient-held follow-up schedule should be provided to assist with coordination of the patient care plan		NICE[31]
Psychosocial care and quality of life		
The provider of follow-up care should assess psychosocial distress, the impact of the disease and its treatment, and provide appropriate support and referral		NBCC[20] **
Other follow-up considerations		
Other disease, treatment and patient factors may influence the requirements for follow-up and should be considered. These include: • long-term hormonal therapy • age and hormonal status • genetic factors • accessibility of services • clinical trial participation or data collection and audit		

RECOMMENDATIONS	LEVEL OF EVIDENCE[3]	REFERENCE
• long-term effects of systemic therapy • side effects of active treatment such as secondary lymphoedema • patient preference • co-morbidities and their management • management of interval presentation for investigation of symptoms • bone health • sexuality and body image • fertility • advice about lifestyle factors which may reduce risk of recurrence		
When sufficient evidence does not exist to guide definitive recommendations for follow-up, patients should, if possible, be offered entry into clinical trials		

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NBOCC** Recommended follow-up schedule

Where women are being treated in *clinical trials*, the follow-up schedule may differ from standard recommendations.

Method	Years 1 and 2	Years 3-5	After 5 Years
History and clinical examination	Every 3 – 6 months	Every 6 – 12 months	Every 12 months
Mammography (and *ultrasound* if indicated)	Every 12 months*	Every 12 months	Every 12 months
Chest *X-ray*, bone scan, CT, PET or MRI scans†, full blood count, biochemistry and tumour markers	Only if clinically indicated on suspicion of recurrence		

* First *mammogram* 12 months post diagnosis

† Use of MRI may be considered in specific high-risk groups

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Notes:

Not every clinician involved in the treatment of a woman will be closely involved in her follow-up. Symptoms should be assessed as they arise. The interval of follow-up care will depend on patient, tumour and treatment factors.

Statements of evidence

STATEMENTS	LEVEL OF EVIDENCE[3]	REFERENCE
In women who have completed active treatment for early breast cancer:		

STATEMENTS	LEVEL OF EVIDENCE[3]	REFERENCE
Method of detection of *recurrence*, new primary or contralateral breast cancer		
Breast cancer recurrence or new primary or contralateral breast cancers may be self-detected or detected by breast imaging or clinical examination		Montgomery[4] de Bock[5]
Some recurrences are detected at routine appointments while others are detected when patients present with symptoms between appointments	IV	Donnelly[6] Hiramanek[7] de Bock[5]
Clinical breast examination and mammography can identify asymptomatic recurrences	IV	Perrone[8] te Boekhorst[9] Donnelly[6]
Ipsilateral breast cancer recurrences detected by mammography have better overall survival compared with those detected by clinical breast examination alone	IV	Montgomery[10]
Contralateral breast cancers detected by mammography have better prognostic characteristics† (tumour size, lower *grade* and *lymph* node status) and overall survival* compared with those detected by clinical breast examination alone	IV	†Kollias[11] *Robinson[12] Kaas[13]
No primary studies were identified which addressed the use of *ultrasound*, PET or MRI in routine follow-up care		
Interval and duration of follow-up		
No primary studies were identified which addressed how long follow-up care should continue after diagnosis or treatment		
Increased frequency of follow-up does not improve disease free survival or overall survival	IV II	Kaas[13] Kokko[14]
Treatment-related side effects may occur long after completion of active treatment		
Follow-up care provider		
The profession of the health professional who is responsible for follow-up care does not influence survival outcomes† or psychosocial or quality of life outcomes*	II	†*Grunfeld[15] †*Koinberg[16] *Brown[17] *Koinberg[18]
The health professional who is responsible for follow-up care may include a *medical oncologist*, *radiation oncologist*, surgeon, *breast care nurse* and general practitioner (GP)		NBCC[1 **]
For multidisciplinary follow-up to be effective, good communication and effective referral options between team members is required		NBCC[19 **]
Not every clinician involved in the treatment of a woman will be closely involved in her follow-up		NBCC[1 **]
Psychosocial care and quality of life		

STATEMENTS	LEVEL OF EVIDENCE[3]	REFERENCE
Psychosocial issues, anxiety and depression are common following diagnosis and treatment for breast cancer and individual needs may change over time. Appropriate referral may alleviate depression and anxiety	I	NBCC[20 **]
Follow-up care includes managing the expectations of women and empowering them to request or seek what they need	I	NBCC[21 **]
Some women may find regular checkups psychologically reassuring^ and/or associate them with increased anxiety‡	IV	NBCC[21 **] McCaughan[22] ^Kelly[23] Beaver[24] ^Gaudine[25] Allen[26] ‡Jiwa[27] ‡Renton[28] ‡Pennery[29]
Intensity of follow-up		
Intensive follow-up, such as chest *X-ray*, bone scan, computed tomography (CT), PET or MRI scans, and/or blood tests including full blood count, biochemistry or tumour markers, does not confer any survival benefit or increase in quality of life compared to a standard follow-up schdedule	I	Rojas[30]

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Summary of evidence

The NBOCC* statements and recommendations for follow-up care in women with *early breast cancer* are based on an NBOCC* systematic review[2] of available evidence from randomised controlled trials and other study designs. Many papers have been published; however, a limited number of studies were identified that were considered high quality evidence, such as randomised controlled trials. Studies that included women who had completed active treatment (surgery, *radiotherapy* and/or chemotherapy) for early breast cancer which made any comparisons between different kinds of follow-up care were identified. These included methods of detection of *recurrence*, provider of follow-up care, standard versus intensive follow-up, different frequency or duration of follow-up care and economics of follow-up.

Papers were excluded if they were not investigating follow-up care, defined as routine follow-up for the purpose of detecting recurrence and/or new *primary cancer*, monitoring side effects of treatment and providing psychosocial care. Standard follow-up procedures include personal history, physical examination and mammography. Additional tests may be performed where clinically indicated. Studies investigating diagnostic follow-up procedures (e.g. use of *magnetic resonance imaging* (MRI) or *positron emission tomography* (PET) after clinical suspicion of recurrence) were not included.

Primary studies included in the systematic review were:

- five randomised controlled trials that addressed provider of follow-up care or standard follow-up compared to intensive follow-up

- eight comparative (cohort or case control) studies that examined different methods or providers of follow-up care
- twenty-one observational studies that looked at method of detection of recurrence or patterns of care
- five prognostic studies that examined tumour markers
- twenty-one qualitative studies (surveys, questionnaires, focus groups and interviews) that provided additional information on perceptions of follow-up care and patient needs and preferences.

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Summary of trial or study results

Recurrence

Local recurrence

With current treatment protocols the local *recurrence* rate is 1% – 2% per annum after breast conserving treatment (and radiotherapy)[1], and 1% after *mastectomy*. The usual treatments for local recurrence – surgery and *radiotherapy* – are more effective if used in the earliest phases. Treatment is aimed at maximising the chance of long-term local control, as the effect of uncontrolled local recurrence on the woman's quality of life can be substantial.[8]

Local recurrences are more commonly diagnosed during routine follow-up at a time when the patient is asymptomatic. The percentage of patients with a recurrence being asymptomatic at time of detection varied between 9%[6] and 52%.[8]

Distant recurrence

Common presentations in the symptomatic groups include bone pain, shortness of breath, palpable lesions or enlarged *lymph nodes*.[9] Most patients who are symptomatic present at interval visits; however, some patients wait to attend routine follow-up visits to discuss symptoms.[6,7,32]

Contralateral breast cancer

New contralateral primaries are usually diagnosed as part of the regular mammographic screening while patients are asymptomatic.[10,33,34] The outcomes are based on tumour characteristics and are independent of the original cancer.

Method of detection

The specific methods of detection studied include self detection, clinical examination, mammography and *ultrasound*. The reported rates that each of these methods contribute to detection varies. Many studies report that for symptomatic *recurrences* or new cancers, over 50% are detected by the patient.[2] Over half of asymptomatic recurrences were detected by clinical examination.[6,8,9]

Two studies found 12% of asymptomatic recurrences were detected by mammography.[7,9] Eighty-three percent of *contralateral breast* cancers detected by mammography alone had good or excellent prognostic characteristics.[11] Two studies indicated that patients with contralateral breast cancer detected by mammography had increased

overall survival compared to self detection.[12,13] Two studies found patients with *local recurrence* detected by mammography showed an increased overall survival compared to physical examination.[10,35]

No primary studies were identified which addressed the use of PET or MRI in routine follow-up care.

One study reported between 8%–13% of recurrences were detected by ultrasound;[34] however, no primary studies were identified which supported the routine use of ultrasound in follow-up care. The clinical or radiological grounds on which ultrasound may be used in addition to mammography include younger women, women with dense breasts, and those whose initial breast cancer was unable to be detected by mammography.

Overall, tumour markers have a low sensitivity but a high specificity for detection of recurrence of breast cancer.[36-40] American Society of Clinical Oncology (ASCO) guidelines on tumour markers (2007) state that CEA is not recommended for routine surveillance of breast cancer patients after primary therapy.[41]

Interval and duration of follow-up

Disease-free survival and overall survival did not differ between 3-monthly and 6-monthly intervals, for either standard or intensive follow-up.[14] Annual or biennial mammographic interval did not influence five-year disease-free survival.[13] However, having a *mammogram* within the last 2 years, for women over 65 years with breast cancer, lowered breast cancer specific mortality and all-cause mortality.[42] Studies have shown that attending more than one routine surveillance mammography after breast cancer treatment is associated with lower mortality.[43,44] A potential confounding factor in these studies is that women who attend regular visits may be more likely to seek medical attention for signs or symptoms of *recurrence*, leading to earlier detection and better prognosis.[43] Based on the purpose of follow-up, there are many factors that may influence decisions around the interval and duration of follow-up care. These may include the psychosocial needs of the women and monitoring side effects of treatment.

No primary studies were identified which addressed how long follow-up care should continue after diagnosis or treatment. A survey by de Bock et al (2004)[45] found that 66% of patients would like to attend lifelong follow-up. A large survey of specialists found the preferred median follow-up duration to be 5 years.[46] However, a small survey found that up to 59% of physicians thought follow-up should continue for 10 years or longer from initial diagnosis.[47]

Intensity of follow-up

A Cochrane meta-analysis,[30] two randomised controlled trials[14,48] and a prospective non-randomised cohort study[49] investigated intensive follow-up versus standard follow-up schedules. Standard follow-up is defined as personal history, clinical exam and mammography, with additional tests as clinically indicated. Intensive follow-up includes the routine addition of some or all of: chest *X-ray*, liver *ultrasound* or echography, blood tests, bone scan and tumour markers. No difference in detection of recurrence,[14,48,49] overall survival,[30,49,50] or disease free survival,[30,49,50] was found in any of the studies.

STUDY CHARACTERISTICS	COMPARISON GROUPS	OUTCOMES
Brown, 2002[17] N=61 Multicentre RCT Patients assessed for 1 year	Standard clinic versus patient initiated follow-up	Quality of Life: EORTC QLQ-C30 – Clinic group had higher (worse) results in arm and breast symptoms HAD – no statistical difference Satisfaction – Patient initiated group reported convenience as an

STUDY CHARACTERISTICS	COMPARISON GROUPS	OUTCOMES
		advantage; Clinic group reported reassurance as an advantage
Grunfeld, 2006[15] N=968 Multicentre RCT Median follow-up 3.5 years	Cancer centre versus family physician	Overall Survival – no statistical difference Detection of *Recurrence* – no statistical difference Quality of Life: HAD, SF-36 MCS, SF-36 PCS – no statistical difference
Koinberg, 2004[16] N=264 Multicentre RCT Patients followed for 5 years	Nurse-led versus specialist-led	Overall Survival – no statistical difference Detection of Recurrence – no statistical difference Quality of Life: HAD, SaaC – no statistical difference
Koinberg, 2006[18] N=96 Non-randomised longitudinal study Patients assessed for 1 year	Specialist follow-up versus multidisciplinary education program led by a specialist nurse	Quality of Life: FACT-G – Multidisciplinary group reported worse physical wellbeing at one year SCA – no statistical difference SOC – no statistical difference to one year, worse SOC for specialist group after one year
Etim, 2006[51] N=3828 Retrospective cohort (non-randomised) Follow-up for 3 years	a. Generalist only b. Breast cancer specialist only c. Shared care (generalist & specialist) d. Other cancer specialists exclusively	Shared care had a higher rate of mammography Generalist only less likely to have mammography than breast cancer specialist only or shared care

Notes: EORTC QLQ C30 = European Organisation for Research and Treatment in Cancer Quality of Life Questionnaire; HAD = Hospital Anxiety and Depression; SF-36 MCS = Short Form 36 Mental Component Summary; SF-36 PCS = Short Form 36 Physical Component Summary; SaaC = Satisfaction and Accessibility Scales; FACT-G = Functional Assessment of Cancer Therapy – General; SCA = Self Care Aspects Scale; SOC = Sense of Coherence Questionnaire

Provider of follow-up

Five studies investigated provider of follow-up, three randomised controlled trials,[15,16,17] one cohort study[51] and one non-randomised trial.[18] The two randomised controlled trials reporting on overall survival and detection of *recurrence* compared cancer centre versus family physician and nurse-led versus specialist-led care. Both found no difference in the number of deaths between groups and no significant difference between groups in the detection of recurrence.[15,16]

The five studies reporting on outcomes for different follow-up care providers are included in Table 1.

Patient preferences for provider of follow-up care vary between studies. While the majority of women may be willing to be followed-up by a family physician,[14] some women may find this unacceptable. Preferences for a specialist follow-up provider range between 38%[29] and 86%;[45] while preferences for primary care follow-up ranged between 7%[44] and 39%.[28]

Many primary care providers expressed uncertainty about how follow-up care should be provided[52] and specialists have echoed this concern as they feel unsure of the general practitioners' level of experience and training in oncology.[46] In a large survey of specialists, *breast surgeons* took 60% of the lead in follow-up; however, they were supportive of GP follow-up as a method of reducing clinical workload.[46] Concerns raised by specialists in this survey regarding experience and training of GPs in breast cancer follow-up[46] were supported by a questionnaire of primary care providers, which found only 49% were comfortable having responsibility for breast cancer surveillance.[52]

The selection of the provider of follow-up care should be a decision made by the multidisciplinary team and the woman in the lead-up to completion of active treatment. Evidence indicates that a team approach to cancer care can improve quality of life for the patient.[53] The multidisciplinary team may comprise the core disciplines and includes a surgeon, medical and *radiation oncologist*, *radiologist*, supportive care provider, specialist *breast care nurse*, general practitioner,[19] and breast physician. A care coordinator may also be required. The selection of the provider for follow-up care should be based on the purpose of follow-up and the individual woman's needs. This decision and the agreed schedule should be documented and communicated to all members of the follow-up team and the woman. Regardless of who provides follow-up care, the NBOCC* recommendations should be followed (see Recommendations and Appendix A).

Psychosocial care and quality of life

Quality of life was assessed in the context of psychosocial care. Studies relating to patient or physician perceptions and preferences of follow-up care used qualitative research methods. Some large surveys and questionnaires were conducted with patients or physicians; smaller studies (6 to 30 participants) used focus groups or interviews to identify themes or opinions. The details of follow-up care were often not provided in these studies.

Completion of active treatment may be a time of increased psychological vulnerability. A key theme for patients undergoing follow-up was the fear of *recurrence* and the need for reassurance that they were still disease-free.[22-26] For some patients attending follow-up visits was a cause of anxiety;[22,24,26-29] however, this was often reduced after attending the follow-up visit.[28] Another theme which emerged in multiple papers was the need for continuity of care.[23,28,54]

Some papers suggested that women's psychosocial needs were not being met, often due to time constraints, with clinics being very busy.[22,26,29] In one study, 83% of breast cancer patients expressed a desire for counselling from either their family physician or specialists.[55]

Treatment side effects

While many of the studies acknowledge that follow-up can identify treatment-related side effects, there are no specific requirements for follow-up procedures other than discussing symptoms and problems with the patient.

A significant potential side effect after surgery and/or *radiotherapy* is secondary *lymphoedema*, affecting approximately 20% of breast cancer survivors.[56] Early awareness of the signs and symptoms of secondary lymphoedema and appropriate referral can significantly reduce the development and severity of the condition.[57]

Many side effects are due to *chemotherapy*, endocrine or biological therapy. Some of the side effects will cease once treatment is finished. Newer drug therapies, such as *aromatase inhibitors* and trastuzumab, have individual

side-effect profiles.[58,59] NBOCC* recommends that patients receiving these drugs should be reviewed regularly and monitored for side effects by health professionals familiar with the drugs.[58,59]

Other follow-up considerations

The provision of follow-up care should include prevention, management or treatment of other aspects of health. There is evidence that maintaining a healthy body weight and exercise can improve survival and quality of life after breast cancer.[60] Women should be encouraged in their maintenance of general health and wellbeing as this may influence the *recurrence* of breast cancer.[61,62]

The follow-up schedule should be tailored to individual situations and consider other medical requirements. There is a recent guideline recommending that a written plan be available to all members of the team.[31]

Additional factors that should be considered when planning follow-up care are listed in the recommendations.

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Strengths and weaknesses of the evidence

Five randomised controlled trials were identified: three on provider of follow-up care and two on standard compared to intensive follow-up. However, much information on follow-up was from comparative and observational studies (level IV), and some additional information was identified through qualitative research such as surveys, focus groups and interviews.

Limited high-quality quantitative information was available on follow-up care after breast cancer:

- many international guidelines were identified; however, most were not specific and all acknowledged a paucity of definitive evidence
- eight systematic reviews were identified, with limited definitive information on follow-up procedures
- no trials were identified to suggest the optimal frequency or duration of follow-up.

Unanswered questions

Important unanswered questions about the follow-up of women following treatment for *early breast cancer* are outlined below. High quality evidence from randomised controlled trials is needed for all aspects of follow-up care. Some of these questions may be addressed in ongoing trials:

- optimal duration and frequency of follow-up
- the use of PET or MRI or *ultrasound* as part of routine follow-up
- the optimal model of follow-up care within a multidisciplinary team setting
- subgroups of women who may have specific follow-up care needs
- economic implications of different models of follow-up care
- shared care models of follow-up

- given newer treatments, impact on survival of early detection of asymptomatic metastatic disease.

Ongoing and additional trials or studies

Two ongoing randomised trials investigating follow-up care have been indentified. Areas covered in these trials include:

- outcomes of nurse-led versus standard follow-up, with or without an educational group program on quality of life (MaCare trial)[63,64]
- outcomes on quality of life of a patient-centred strategy to facilitate transition of breast cancer survivors' routine follow-up from specialist to primary care (Follow-up II OCOG).[65]

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This guideline was developed by a multidisciplinary working group convened by NBOCC*.

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External review

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Full details of trial results are provided in the document *Follow-up of patients with early breast cancer: a systematic review* which can be accessed via the NBOCC* website: www.nbocc.org.au

Development process

Priority topic areas for NBOCC* guideline development are determined in consultation with key stakeholders including experts in relevant disciplines and consumer representatives. A specific multidisciplinary Working Group, including consumers, is established for each topic identified and is involved in all aspects of guideline development. A systematic evidence review is undertaken for each guideline. All members are asked to declare any conflicts of interest and these declarations are recorded. The content of the guideline is not influenced by any external funding body. The guideline is reviewed externally by key stakeholders and the wider community and endorsement is sought from relevant professional colleges and groups in Australia.

* In July 2011, National Breast and Ovarian Cancer Centre (NBOCC) amalgamated with Cancer Australia to form a single national agency, Cancer Australia, to provide leadership in cancer control and improve outcomes for Australians affected by cancer.

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Additional resources for follow-up care

Health professionals working in Australia may find the following resources useful:

- National Breast and Ovarian Cancer Centre*. *Psychosocial care referral checklist*. NBOCC*, Surry Hills, NSW, 2008.
- Life after breast cancer – for women who have completed active treatment for early breast cancer: www.nbocc.org.au/lifeafter.