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DEVELOPMENT AND IMPLEMENTATION OF AN EVALUATION FRAMEWORK FOR A BREAST RECONSTRUCTION DECISION SUPPORT TOOL FOR WOMEN CONSIDERING BREAST RECONSTRUCTION FOLLOWING MASTECTOMY

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A thesis submitted in fulfilment of the requirements for the degree of

Doctor of Philosophy

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Sydney Nursing School

Statement of Authorship/Originality

I, Olivia Gallagher, certify that the work presented in this thesis, titled '*Development and Implementation of an Evaluation Framework for a Breast Reconstruction Decision Support Tool for Women Considering Breast Reconstruction Following Mastectomy'* has not previously been submitted for a degree; nor has it been submitted as part of the requirements for a degree, except as fully acknowledged within the text.

I, Olivia Gallagher, also certify that this thesis has been written by me, and that any assistance I have received while undertaking this research and in the preparation of the thesis itself is acknowledged.

In addition, I certify that all information sources and literature used in this thesis are acknowledged and referenced.

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DATE: 20 August 2014

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I dedicate this thesis to my daughter Lauren; a most wonderful interlude to my doctoral studies

The Reconstruction Marathon

Breasts,
Skilfully created, slowly inflated,
Now firm with cleavage between,
Breast reconstruction; a marathon event!
In need of support twenty-four, seven,
They wear a crop top, while I 'phone a friend'.
Meanwhile, I exercise, breathe deeply, keep flexible, keep fit.
'Gotta keep that body moving or the stiffness will stay!'
'Don't forget the physio, five times a day!'
'Massage thrice daily! Let's smooth out those lumps!''
I'm totally obsessed with my curvaceous new bumps.
But maturing.....like wine.....takes time;
Meanwhile, I exercise, breathe deeply, keep flexible, keep fit!
Then I woke up this morning, something had changed; there was a difference!
Not a muscle tightened, moaned or groaned; or put up resistance.
The marathon had ended! I am triumphant; I have won!
'Breasts you are ready, your debut day has come.'
So I'm going shopping, to find a dress worthy to display,
my new bosom buddies, that have been in hiding 'til today.
Then I will exercise, breathe deeply, keep flexible, keep fit,
'cos they're worth it!

by Pauline Wright (Research Participant)
23 April 2007 (final draft 13 August 2007)

Abstract

The overall survival rate for women diagnosed with breast cancer has improved significantly, leading to an increased awareness among clinicians and researchers of the longer-term consequences that women experience as a result of breast cancer. The primary treatment for breast cancer has remained surgical; with an estimated 45 per cent of Australian women diagnosed with breast cancer undergoing mastectomy (Australian Institute of Health and Welfare (AIHW) & Cancer Australia, 2012). Recent research has highlighted an increase in mastectomy rates internationally; including contralateral mastectomy of the non-diseased breast and bilateral prophylactic mastectomy in the absence of a breast cancer diagnosis (with or without BRCA mutation) (Dragun et al., 2013; Elmore, Ganschow & Geller, 2010; Jones et al., 2009; Tuttle, Abbott, Arrington & Rueth, 2010; Yao, Stewart, Winchester & Winchester, 2010; Yi et al., 2010). The impact of breast cancer and its treatments on a woman's body image, relationships, and sense of self has been widely studied (Gilbert, Ussher & Perz, 2010; Lasry et al., 1987; Lewis & Bloom, 1978–79; Manderson & Stirling, 2007; Manganiello, Hoga, Reberte, Miranda & Rocha, 2011). Breast reconstruction is one option for women who undergo mastectomy: it has been shown to lessen psychological morbidity and facilitate adjustment to an altered body image (Al-Ghazal, Fallowfield & Blamey, 2000; Denford, Harcourt, Rubin & Pusic, 2011; Hill & White, 2008). Recent breast reconstruction and mastectomy data indicates the current uptake of breast reconstruction in Australia as 16 per cent of women who have a mastectomy (AIHW & Cancer Australia, 2012). Breast reconstruction decision making is complex, requiring consideration of many personal, clinical and situational factors. Multiple decisions are required over an extended time period, often within the context of a breast cancer diagnosis.

To date, there is very little systematic research into the effectiveness of breast reconstruction patient education. This research sought to develop and implement an evaluation framework for a breast reconstruction decision support tool for women considering breast reconstruction following mastectomy. Developing a decision support tool that provides comprehensive information and supports the decision-making process aims to empower women to participate actively in shared decision

making, facilitate informed consent to breast reconstruction, and support women throughout their decision making and recovery from breast reconstruction.

Evaluation methodology was adopted to guide the three evolutionary phases of the research:

- Phase One undertook a needs analysis; incorporating a literature review, a review of available national sources of breast reconstruction information and focus group interviews; to explore the breast reconstruction decision making experiences and information needs of women who had undertaken breast reconstruction.
- Phase Two, informed by the findings of Phase One, developed a breast reconstruction decision support tool through the implementation of an evaluation framework driven by key stakeholders.
- Phase Three completed implementation of the evaluation framework by conducting summative evaluation of the decision support tool's value using survey and interview methods. Three groups of women evaluated the decision support tool: 1) women who had undertaken breast reconstruction; 2) women who did not have breast reconstruction; and 3) women who had undergone bilateral prophylactic mastectomy and breast reconstruction.

Evaluation of the decision support tool was overwhelmingly positive. The evaluation results clearly identify that: the decision support tool met women's information needs, was perceived to be useful to refer back to throughout a woman's breast reconstruction experience, and would be an acceptable and useful tool to assist women making decisions about breast reconstruction.

The achieved aims of this research culminated in a nationally endorsed and accessible source of breast reconstruction information to assist Australian women with their decision making (www.canceraustralia.gov.au/ breastreconstruction). Not only does this mean women have access to reliable, evidence-based, comprehensive information; but health care professionals can also utilise this resource as a tool for directed discussion about women's breast reconstruction treatment options. Further

research should focus on prospective evaluation of the impact of the decision support tool use on knowledge and decision making outcomes.

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List of Abbreviations

BRCA1 & 2	Breast Cancer Genetic Marker
CIPP	Context, Input, Process, Product
DIEP	Deep Inferior Epigastric Perforator
HREC	Human Research Ethics Committee
IGAP	Inferior Gluteal Artery Perforator
IPDAS	International Patient Decision Aids Standard
LD	Latissimus Dorsi
NBOCC	National Breast and Ovarian Cancer Centre
NHMRC	National Health and Medical Research Council
PAC	Project Advisory Committee
SGAP	Superior Gluteal Artery Perforator
TRAM	Transverse Rectus Abdominus Myuocutaneous
WA	Western Australia

Chapter 1: Introduction and Background to the Research

1.1 Introduction

The increasing incidence of breast cancer across the world, along with significantly improved survival rates, has required both clinicians and researchers to focus on the longer-term consequences that women experience as a result of breast cancer. With 89 per cent of women diagnosed with breast cancer in Australia being cured of their disease, up to 200,000 women at any single time are living with the day-to-day consequences of breast cancer treatment (AIHW & Cancer Australia, 2012). The impact of breast cancer, and its treatments, on a woman's body image, relationships and sense of self has been widely studied. Many factors can affect a woman's recovery from the diagnosis of breast cancer. Breast reconstruction has been shown to lessen psychological morbidity and facilitate adjustment to an altered body image (Al-Ghazal et al., 2000; Denford et al., 2011; Hill & White, 2008). Despite this, there remains a relatively low uptake of breast reconstruction in Australia.

Earlier research undertaken by the researchers explored the impact of breast reconstruction on self-esteem and perceived body image (Hill & White, 2008). This research identified the complex emotional and surprisingly isolated experience for these women in making the decision. Of note, women struggled to find information about breast reconstruction treatment options: details of the different procedures and even practical information to aid recovery were absent. Providing women with access to current, relevant and contextually Australian information about breast reconstruction may assist women with the complexities of breast reconstruction decision making and subsequent adjustment to their reconstructed breast. The research presented in this thesis aims to fill this gap by creating a reliable, comprehensive, evidence-based and user friendly source of information for Australian women to support their decision making about breast reconstruction and meet their ongoing information needs throughout their breast reconstruction experience.

1.2 Aims

This research sought to develop and implement an evaluation framework for a breast reconstruction decision support tool for women considering breast reconstruction following mastectomy. The four main aims of the research were to:

1. explore the decision making experience of women considering breast reconstruction following mastectomy
2. identify the information needs of women considering breast reconstruction following mastectomy
3. develop and implement an evaluation framework for a breast reconstruction decision support tool
4. develop a breast reconstruction decision support tool for women considering breast reconstruction following mastectomy.

Specific objectives guiding the achievement of each of these intended aims are discussed in Chapters Three, Four and Five of the thesis.

1.3 Background to the Research

1.3.1 Breast Cancer in Australian Women

Breast cancer is the most frequently diagnosed cancer in Australian women. The most recent incidence report identified more than 13,567 Australian women were diagnosed with breast cancer in 2008 (AIHW & Cancer Australia, 2012). Developments in population based screening and increased public awareness of breast cancer have led to a rise in incidence rates between 1982 and 2008, with the lifetime risk of developing breast cancer in Australia now one in eight. While breast cancer remains the second leading cause of cancer mortality in women, Australia's five-year survival rate for breast cancer continues to improve; it is most recently estimated to be 89 per cent. Current statistics show that by the end of 2008, 57,300 women who had been diagnosed with breast cancer in the preceding five years were living with the effects of breast cancer and its treatments (AIHW & Cancer Australia, 2012). A number of factors have influenced the high survival rate, including the introduction of a national breast-screening programme, increased community

awareness and treatment developments. However, a key factor is that today more women are being diagnosed with early breast cancer, and are therefore more amenable to cure. The synthesised analysis from a review of current literature on breast reconstruction trends and outcomes follows. The search strategy is detailed in Appendix One. The background to the research will be explained, identifying the significance of this research.

1.3.2 Mastectomy to Treat Breast Cancer

The primary treatment for breast cancer continues to be surgical, either alone or in combination with other treatment modalities such as radiotherapy, chemotherapy and hormone therapy. The psychological morbidity experienced by women associated with breast cancer diagnosis and breast removal has been extensively described in research over three decades (Gilbert et al., 2010; Lasry et al., 1987; Lewis & Bloom, 1978–79; Manderson & Stirling, 2007; Manganiello et al., 2011). This body of research highlighted the need to explore other approaches to the surgical management of breast cancer. As a result, the extent of surgical excision for breast cancer has changed significantly, moving away from extensive resection of the whole breast, axillary nodes, and at times chest wall muscle, towards more limited resection of tumour and surrounding tissue (known as 'breast conserving surgery'). The most significant advances in the surgical management of breast cancer occurred when a number of studies showed no survival benefit from mastectomy over breast conservation surgery with or without radiotherapy for early breast cancer (Fisher et al, 1985; Hwang, Lichtensztajn, Gomez, Foble & Clarke, 2013; Jatoi & Proschan, 2005; Kaviani et al., 2013; Litiere et al., 2012; Pierce et al, 2010), and the more recent evolution of sentinel node biopsy, reducing the requirements for axillary clearance. Surgical advances in breast conserving surgery resulting in improved aesthetic outcomes were shown to have favourable psychological outcomes to mastectomy (Al-Ghazal et al., 2000; Irwig & Bennetts, 1997; Kaviani et al., 2013; Moyer, 1997), including improved body image, self-esteem and social adjustment, early resumption of sexual relationships (Al-Ghazal et al., 2000; Moyer, 1997) and improved global quality of life in women having breast conserving surgery (Kissane, White, Cooper & Vitetta, 2004).

Despite this, mastectomy remains a common procedure for the treatment of breast cancer, for many reasons. While comparative rates for mastectomy versus breast conservative surgery are not reported, it is widely recognised that mastectomy remains one of the key surgical interventions in Australia today. To obtain some guidance on what the proportion might be, recent surgical data was explored. In 2009 to 2010, 10,334 women had a breast lesion excised and 6,148 women underwent mastectomy (AIHW & Cancer Australia, 2012). Based upon the most recent breast cancer incidence figures from 2008, and mastectomy rates for 2009 to 2010, an estimated 45 per cent of women diagnosed with breast cancer had a mastectomy (N=6,106) (AIHW & Cancer Australia, 2012). There are a number of reasons mastectomy may be the surgery selected, including: size or location of the tumour; surgeon or woman's preference; or breast cancer prevention for those choosing prophylactic (preventative) mastectomy. Several recent studies have highlighted an increase in mastectomy rates in western countries, including contralateral mastectomy of the non-diseased breast and bilateral prophylactic mastectomy in the absence of a breast cancer diagnosis (with or without BRCA mutation), considered to be primarily consumer driven (Dragun et al., 2013; Elmore et al., 2010; Jones et al., 2009; Tuttle et al., 2010; Yao et al., 2010; Yi et al., 2010).

1.3.3 Mastectomy to Prevent Breast Cancer

Mastectomy is undertaken to prevent breast cancer in high-risk women who may exhibit a genetic predisposition to breast cancer, or for those who have been diagnosed with breast cancer at some point and elect to remove their other non-diseased breast (termed 'contralateral prophylactic mastectomy'). A systematic review of studies investigating prophylactic mastectomy (both bilateral prophylactic mastectomy and contralateral prophylactic mastectomy) located 25 studies published between 1998 and 2011. Twenty-two of those studies evaluated oncologic outcomes, 16 studied cosmetic outcomes, and two studies explored quality of life and self-esteem. The majority of studies were retrospective; no randomised controlled trials had been performed and studies often utilised non-validated tools to quantify outcomes (McIntosh & O'Donoghue, 2012). The authors of the systematic review indicated the current literature on prophylactic mastectomy did not answer the questions being studied robustly and failed to identify a clear mortality benefit

of contralateral prophylactic mastectomy over breast conserving surgery (McIntosh & O'Donoghue, 2012).

Women who undergo contralateral prophylactic mastectomy or bilateral prophylactic mastectomy are more likely to choose breast reconstruction than women who have a mastectomy to treat breast cancer. A study of 1,635 BRCA mutation carriers from eight countries (60.6% contralateral prophylactic mastectomy and 39.4% bilateral prophylactic mastectomy) identified an overall breast reconstruction rate of 69.5 per cent. However, rates of breast reconstruction varied greatly between countries. The lowest rate of 50 per cent was evident in China and the highest rate of 82.4 per cent was evident in Italy (Semple et al., 2013).

1.3.3.1 Bilateral Prophylactic Mastectomy for High Genetic Risk of Breast Cancer

The identification of genetic mutations BRCA1 and BRCA2, which are passed along family lines, associated with an increased risk of developing breast (and ovarian) cancer has placed a significant focus on prevention of breast cancer in high-risk groups. Carriers of BRCA1 have a 57 per cent risk of developing breast cancer, and BRCA2 a 49 per cent risk. Inherited genetic predisposition for breast cancer is estimated to account for approximately five to ten per cent of all breast cancer diagnoses, although the number of women who have this genetic mutation is not known (Cancer Australia, 2014). Current management includes surveillance or elective bilateral prophylactic mastectomy.

Despite not dealing with the diagnosis of breast cancer, women undertaking bilateral prophylactic mastectomy still confront their own mortality in relation to their potential to develop breast cancer. Due to this differing context surrounding decision making, women choosing bilateral prophylactic mastectomy are making breast reconstruction decisions in different circumstances to a recently diagnosed woman, without processing a breast cancer diagnosis and with no need to consider the impact of breast cancer treatments. As such, the information needs of women considering bilateral prophylactic mastectomy differ from women making decisions within the context of a breast cancer diagnosis and its treatments.

Several Northern European studies have explored women's experiences of bilateral prophylactic mastectomy and breast reconstruction. Two pre-post survey studies identified negative effects on sexuality, but no impairment of overall quality of life. Participants reported decreased sexual pleasure and reduced sensation (Brandberg et al., 2008; Gahm, Wickman & Brandberg, 2010). Women commonly reported body image issues one year after bilateral prophylactic mastectomy, including feeling self-conscious (48%), less sexually attractive (48%), and being dissatisfied with scars (44%) (Brandberg et al., 2008). Another pre-post survey study similarly found that negative breast related body image significantly increased six months post-operatively; however, it had significantly decreased by six to nine years post-operatively. An active approach to coping and seeking social support was associated with less breast related body image disturbance (den Heijer et al., 2012).

In a qualitative study of the long term physical and psychosocial effects of bilateral prophylactic mastectomy and breast reconstruction of 13 women, participants reported being satisfied with their decision and perceived their risk of a breast cancer diagnosis as nil or negligible. Three participants were known BRCA mutation carriers, while the remaining participants had a family history of breast cancer only. Eight women reported that bilateral prophylactic mastectomy did not result in any change to their family life or lifestyle; four women reported it affected their family life positively by providing a sense of security and alleviating their fear of breast cancer; and one woman reported a negative impact on her family life resulting from a disagreement with family members about her choice to have bilateral prophylactic mastectomy. Five women stated their relationship with their spouse was negatively affected, attributing this to decreased breast sensation and a changed body appearance. Nine out of 13 women reported they would recommend bilateral prophylactic mastectomy to other women (Wasteson, Sandelin, Brandberg, Wickman & Arver, 2011).

Despite most women's self-reported satisfaction with their decision to undergo bilateral prophylactic mastectomy and breast reconstruction (Gahm et al., 2010; Wasteson et al., 2011), women are often negatively affected by their experience in some way. While anxiety levels may decrease over time (Brandberg et al., 2008), body image issues may remain (Brandberg et al., 2008; den Heijer et al., 2012; Gahm

et al., 2010; Wasteson et al., 2011). Pre-operative preparation through information may assist this group of women to manage their response to bilateral prophylactic mastectomy and breast reconstruction. Further exploration of women's expectations of bilateral prophylactic mastectomy and breast reconstruction is warranted to determine the appropriate preparatory information and support required. Wateson and colleagues (2011) concluded that counselling and support throughout bilateral prophylactic mastectomy decision making, treatment and follow up might assist women to cope with the changes they experience.

1.3.3.2 Contralateral Prophylactic Mastectomy

A number of recent papers have highlighted a growing trend among women diagnosed with cancer in one breast electing to have contralateral mastectomy of their non-diseased breast, despite no evidence of breast cancer (Elmore et al., 2010; Jones et al., 2009; Tuttle et al., 2007; Yao et al., 2010; Yi et al., 2010). Of note; the evidence around contralateral prophylactic mastectomy among women *without* a genetic predisposition does not support this approach, with a low and declining incidence of contralateral breast cancer (Morrow, 2011). Internationally, contralateral prophylactic mastectomy rates have been reported as increasing from between 13.8 and 23.2 per cent of patients undergoing mastectomy for breast cancer (Dragun et al., 2013; King et al., 2011; Stucky, Gray, Wasif, Dueck & Pockaj, 2010; Yi et al., 2010). Recent data from the United States (US) depicts contralateral prophylactic mastectomy rate increases as high as 188 per cent between 1998 and 2005 (Elmore et al., 2010).

Fear of breast cancer recurrence is an impetus for women choosing contralateral prophylactic mastectomy, with lower recurrence risk and improved survival cited as the most common reasons for choosing contralateral prophylactic mastectomy (Fisher et al., 2012; Rosenberg et al., 2013). Studies investigating the advantages of contralateral prophylactic mastectomy show variable results. Women with BRCA1 and BRCA2 genetic predisposition are at a higher risk of contralateral breast cancer. A 2011 study of 810 BRCA genetic carriers identified an 18.4 per cent risk of contralateral breast cancer (Metcalfe et al., 2011). Bedrosian, Hu & Chang's 2010 population based study, of American women undertaking contralateral prophylactic

mastectomy between 1998 and 2003, identified a 4.8 per cent five year adjusted breast cancer survival advantage for women undertaking contralateral prophylactic mastectomy. Evans and colleagues (2013) compared BRCA mutation carriers who chose contralateral prophylactic mastectomy with those who did not, and identified an 18 per cent ten-year survival advantage with contralateral prophylactic mastectomy. Another study examining data of 385 women who underwent mastectomy and contralateral prophylactic mastectomy between 1971 and 1993, compared to 385 demographically and clinically matched women who underwent mastectomy alone, showed a 95 per cent decreased risk of contralateral breast cancer for those having contralateral prophylactic mastectomy ($p=0.0001$) (Boughey et al., 2010).

However, women with limited or no family history of breast cancer and no genetic predisposition are more commonly choosing contralateral prophylactic mastectomy, often without undergoing genetic testing (Morrow, 2011; Yi et al., 2010). Despite this trend, Rosenberg and colleagues (2013) survey-based study of women under 40 years of age who chose contralateral prophylactic mastectomy showed that, despite a perceived increased risk of contralateral breast cancer, only 18 per cent believed women who underwent contralateral prophylactic mastectomy lived longer than those who did not.

A survey of 81 Australian and New Zealand breast surgeons showed 44 per cent (N=36) perceived rates of contralateral prophylactic mastectomy were rising in their practices. The perceived rises in contralateral prophylactic mastectomy rates were independent of breast surgeon age or gender. In addition to clinical reasons for contralateral prophylactic mastectomy, surgeons acknowledged subjective patient factors such as fear, anxiety and desired breast symmetry also played a part in women's decision making (Musiello, Bornhammart & Saunders, 2012). Beesley, Holcombe, Brown and Salmon's (2013) qualitative analysis of 60 consecutive contralateral prophylactic mastectomy patient records identified that contralateral prophylactic mastectomy was undertaken mostly for psychological reasons, related to fear of recurrence and achieving an optimal aesthetic outcome, rather than risk of contralateral breast cancer.

Recent studies have sought to explore the psychosocial impact of contralateral prophylactic mastectomy. This has proven challenging, as studies are unable to control for the impact of therapeutic mastectomy, distinct from contralateral prophylactic mastectomy, on self-reported quality of life measures. A two-year follow-up study identified no statistically significant differences in quality of life, anxiety, depression or sexuality before and after contralateral prophylactic mastectomy. Health-related quality of life of participants was on a par with the general population of women (Unukovych et al., 2012). Geiger and colleagues' survey exploration of women's quality of life, for those choosing contralateral prophylactic mastectomy and undergoing mastectomy alone, showed high self-reported quality of life for both groups. Both groups expressed self-consciousness about their appearance and avoidance of thoughts about breast cancer. The authors determined no direct association between these reported issues and contralateral prophylactic mastectomy (Geiger et al., 2006). Frost and colleagues' (2011) long-term follow-up study of women undertaking contralateral prophylactic mastectomy identified adverse feelings about body appearance, femininity and sexual relationships. Regardless of women's concerns, high levels of satisfaction with contralateral prophylactic mastectomy decision making was evidenced in both studies (Frost et al., 2011; Geiger et al., 2006).

1.4 Breast Reconstruction Following Mastectomy

Breast reconstruction is surgery undertaken to rebuild breast shape, using breast implants and/or the woman's own tissue from another part of her body. It is one approach available to reduce the psychosocial impact of mastectomy. Breast reconstruction may be undertaken at the same time as mastectomy (termed 'immediate breast reconstruction') or at a later time, months or years following mastectomy (termed 'delayed breast reconstruction').

While breast reconstruction has been shown to lessen psychological morbidity and facilitate adjustment to an altered body image (Al-Ghazal et al., 2000; Denford et al, 2011; Hill & White, 2008); the decision to have a breast reconstruction is not straightforward. This may account for the relative low numbers of women who have

breast reconstruction. In 2009 to 2010, 980 Australian women underwent a breast reconstruction procedure (AIHW & Cancer Australia, 2012). Drawing on recent breast reconstruction and mastectomy data, the current uptake of breast reconstruction is estimated as 16 per cent of women who have mastectomy (AIHW & Cancer Australia, 2012). It must be noted that breast cancer and breast reconstruction statistics are difficult to collate, as incidence data is one to two years older than hospitalisation data. In addition, breast reconstruction hospitalisations may also include breast reconstruction refinement procedures subsequent to initial breast reconstruction surgery, further convoluting interpretation of statistics. Separate to national data collated; variable rates of breast reconstruction are cited throughout the literature, with reports ranging from as little as six per cent, up to 50 per cent, depending on geographical location (Sandelin, King & Redman, 2003; Swan, 2009).

Similar variability in breast reconstruction rates is exhibited worldwide. For example, an American study has reported an increasing national rate of breast reconstruction, from 46 per cent in 1998 to 63 per cent in 2007; however, it also identified variable rates across the states, ranging from 18 to 80 per cent (Jagsi et al., 2013). A 2013 systematic review of the uptake and predictors of breast reconstruction reviewed 28 international studies. Overall, a breast reconstruction rate of 16.9 per cent was calculated, with variable reporting of rates from 4.9 up to 81.2 per cent. Predictive variables associated with breast reconstruction were: early stage breast cancer, no adjuvant therapy, young age, Caucasian, private insurance, higher education and income, availability of breast reconstruction services and residential location (Brennan & Spillane, 2013).

The relatively low uptake of breast reconstruction as a treatment option following mastectomy may be attributed to a combination of complex factors, including: access to breast reconstruction services, due to residential location or health service model (public or private sector); the availability of surgical expertise; financial costs of breast reconstruction; competing treatment priorities; and an individual's personal and lifestyle considerations (Heller & Miller, 2004; Jagsi et al., 2013; Macdonald, Lloyd, Mathur & Ramakrishnan, 2010; Potter, Mills, Cawthorn, Wilson & Blazey, 2013; Preminger, Lemaine, Sulimanoff, Pusic & McCarthy, 2011; Sheehan,

Sherman, Lam & Boyages, 2007). Accessing, processing and interpreting reliable information about breast reconstruction within this context challenges women's decision making about breast reconstruction following mastectomy and may lead to decision regret.

1.4.1 The Complex and Complicated Decisions Surrounding Breast Reconstruction

The decision to have a breast reconstruction following mastectomy is complex, extending beyond a simple 'will I or won't I?' There are many factors that need to be considered and decisions to be made on whether to have immediate or delayed breast reconstruction, what type of breast reconstruction, and additional decisions throughout an extended trajectory of treatment. A number of additional factors impact on women's decision making, including: an individual's priority breast cancer treatments, access to breast reconstruction services, financial constraints, personal values and preferences, and suitability for different types of breast reconstruction (Heller & Miller, 2004). An individual's suitability to undertake the different types of breast reconstruction is dependent upon many factors, including: breast size to be created, available tissue on the body, existing scarring and medical comorbidities presenting surgical risks or impacting on the aesthetic outcome of the reconstructed breast (Rainsbury & Straker, 2008; Steligo, 2005).

For women diagnosed with breast cancer, a sense of urgency regarding breast cancer treatment places time constraints on the decision making imposed by pending mastectomy surgery. In addition, poor retention of information subsequent to a recent breast cancer diagnosis may affect the decision-making process for these women considering breast reconstruction as a treatment option. Women have reported feeling overwhelmed at this time, with their only thought being to deal with the cancer. For those women with a high familial risk of breast cancer, having additional time to consider options and obtain information can make the decision-making process different. Therefore, information and decision support must be tailored to these two different groups of women (Lostumbo, Carbine & Wallace, 2010; Tuttle et al., 2010).

1.4.2 Types of Breast Reconstruction

Breast reconstruction can be undertaken using: implants to recreate breast shape; tissue transferred from another part of the women's own body to recreate breast shape (known as 'autologous breast reconstruction'); or both implants and autologous tissue in some instances, to create sufficient volume of the reconstructed breast/s (Rainsbury & Straker, 2008; Steligo, 2005). The four commonly utilised methods of breast reconstruction currently used in Australia are:

- **Breast reconstruction using implants**—an artificial implant is inserted under the skin and muscle on the chest wall to form a breast shape.
- **Latissimus dorsi (LD) flap**—a flap of LD muscle, skin and subcutaneous fat is moved from the back to the chest wall. Usually a breast implant is also inserted to achieve the required breast size.
- **Transverse rectus abdominus myocutaneous (TRAM) flap**—a flap of TRAM muscle, skin and subcutaneous fat is moved from the abdomen to the chest wall.
- **Deep inferior epigastric perforator (DIEP) flap**—a flap of skin and subcutaneous fat is moved from the abdomen to the chest. No muscle is transferred.

A summary of the advantages and disadvantages of each of the commonly used methods of breast reconstruction in Australia is given in Appendix Two. Other methods of tissue flap breast reconstruction are emerging, where muscle is taken from other parts of the body, such as the buttocks or hips. A superior gluteal artery perforator (SGAP) flap breast reconstruction uses tissue from the upper part of the buttock. An inferior gluteal artery perforator (IGAP) flap breast reconstruction uses tissue from the lower part of the buttock (Rainsbury & Straker, 2008; Steligo, 2005). These methods are in their infancy in Australia; however, they are well developed in other countries around the world.

1.4.3 Breast Reconstruction Outcomes

Breast reconstruction has been shown to lead to improved body image and self-esteem, and enhanced quality of life following mastectomy (Al-Ghazal et al., 2000; Eltahir et al., 2013; Mock, 1993). Reported benefits of undergoing breast reconstruction described by women include: feeling more comfortable in social situations; feeling 'whole'; less emotional distress and fewer thoughts about breast cancer (Denford et al., 2011; Hill & White, 2008). For others, their expectations of the outcome of breast reconstruction are not met and the unexpected psychosocial implications of losing a breast, despite reconstruction, may be a source of additional distress (Hill & White, 2008; Nissen, Swenson & Kind, 2002). Research on the psychosocial advantages of breast reconstruction compared to breast conserving surgery or mastectomy alone show variable results. Some studies identify the advantages of breast reconstruction over mastectomy (De Gournay et al., 2010; Denewer et al., 2012; Eltahir et al., 2013; Rubino, Figus, Lorettu & Sechi, 2007), while others show no statistically significant advantage to reconstructing the breast (Heneghan et al., 2011; Holly, Kennedy, Taylor & Beedie, 2003; Metcalfe et al., 2012; Min et al., 2010).

Many factors can influence breast reconstruction outcomes, making it difficult to generalise the advantages of breast reconstruction over breast conserving surgery or mastectomy alone. Much of the literature is limited: exploration of these complicating factors is lacking; and the use of non-validated outcome measurements, often lack objectivity or subjectivity, as required. When exploring outcomes of breast reconstruction, the aspects of aesthetic appearance, psychological impact, quality of life and patient satisfaction are often investigated separately in the literature, yet they are closely connected.

1.4.3.1 Aesthetic Outcomes of Breast Reconstruction

A systematic review of studies conducted between 1985 and 2009, exploring the aesthetic outcome of breast reconstruction surgery, identified 122 studies. Of the 122 studies, 78.7 per cent were cross sectional studies (primarily recruiting from single institutions), 19.7 per cent were longitudinal assessment and 1.6 per cent case note

reviews. Clinical assessment of the patient was undertaken in 40.2 per cent of studies, photographic assessment in 45.8 per cent and geometric assessment in 12.1 per cent. The authors of this systematic review reported that none of the clinical assessment papers identified their evaluation methods adequately. Photographic evaluation of between one and 16 views of the reconstructed breast took place, with the majority of studies (41.7%) considering three views of the breast: primarily frontal and oblique views. The 13 studies conducting geometric assessment adopted variable assessment methods, including anthropometric measurement, applanation tonometry (to measure inframammary pressure) or volume measurement using casts (Potter et al., 2011).

Both healthcare professionals and patients assessed aesthetic outcome in 42.6 per cent of studies, with healthcare professionals alone participating in 27.1 per cent of studies. In 36.1 per cent of papers, the specific health profession evaluating the aesthetic outcomes of breast reconstruction was not reported. Evaluation took place by a single assessor in 24.7 per cent of studies. Significant risk of bias was identified in 22.9 per cent of studies, with the operating surgeon directly or indirectly involved in the assessment of breast reconstruction outcome. Measurement tools used primarily took the form of three or four point nominal scales and ten point visual analogue scales. Only 12 studies utilised either the Kroll or Garbay-Lowery grading systems specifically developed for breast reconstruction (Potter et al., 2011).

A study of long-term patient and physician evaluation of breast reconstruction was conducted on patients who had delayed breast reconstruction between 1990 and 2005. A sample of 263 women completed a questionnaire, with 180 of those women going on to participate in a clinical follow up for objective evaluation by a single assessor. Women with autologous breast reconstruction were significantly more pleased with their aesthetic outcome than those with breast implant reconstructions. The clinical follow-up assessment concurred that autologous breast reconstructions were aesthetically superior (Christensen, Overgaard, Kettner & Damsgaard, 2011).

A six point scale questionnaire was completed by women who had undertaken implant (N=32), LD flap (N=18) and TRAM flap (N=12) breast reconstructions in Norway between 1992 and 2001. High levels of satisfaction with the cosmetic result

were reported by 75 per cent of TRAM flap breast reconstruction patients, 61 per cent of LD flap breast reconstruction patients and 34 per cent of implant breast reconstruction patients. Differences in satisfaction were statistically significant when comparing TRAM flap and implant breast reconstruction ($p=0.05$) (Kalaaji & Bruheim, 2010).

Variable results of breast reconstruction aesthetic outcomes and difficulty in reducing assessor bias begs the question: what constitutes the ideal breast? Mallucci and Branford (2012) conducted an analysis of the ideal breast to identify the specific proportions of attractive breasts and less attractive breasts. The four key factors identified as 'ideal' were: a 45:55 upper to lower breast pole ratio; a linear or slightly concave upper pole slope; a convex lower pole slope; and an upwards angulation of the nipple 20 degrees from the nipple meridian. The authors concluded divergence from this pattern resulted in a less attractive breast (Mallucci & Branford, 2012). Recent studies investigating technologies for both guiding breast mound creation and subsequent assessment of breast surgery outcomes propose three and four dimensional breast scanning to detail the breast surface, both when still and during movement (Catanuto et al., 2009), along with laser three dimensional images to create a mould of the healthy breast for replication (Ahcan, Bracun, Zivec, Pavlic & Butala, 2012).

Currently, inconsistency in the methods of assessment used and a lack of methodological rigour means that studies of breast reconstruction aesthetic outcomes provide limited valuable information. It must be acknowledged that each woman's perception of the ideal breast and expected aesthetic outcome are likely to vary greatly. Minimising assessor bias, development and use of standardised validated assessment tools, along with incorporation of both objective and subjective aspects of aesthetic outcomes would go a long way to providing useful information about aesthetic outcomes, to inform women making decisions about breast reconstruction.

1.4.3.2 Psychosocial Outcomes of Breast Reconstruction

An integrative literature review and meta-analysis undertaken by Harcourt and Rumsey in 2001 concluded that methodological flaws in the existing research provided inconclusive results regarding the psychological outcomes of breast reconstruction. The authors identified studies as primarily retrospective in design, which could lead to cognitive dissonance, as women attempt to reconcile their past and present situations. Many studies failed to include a control or comparison group and did not assess recognised measures of psychological wellbeing (Harcourt & Rumsey, 2001). Winters, Benson and Pusic's (2010) more recent systematic review concurred that studies assessing patient-reported outcomes and quality of life were primarily retrospective; many included biased patient recall, and lacked methodological rigour and sufficient power to purport generalisable results.

A systematic review of patient-reported outcome measures of breast oncologic surgery, conducted by Chen and colleagues (2010), assessed adherence to international guidelines for health outcome instrument development and validation. Only five of the ten instruments reported an adequate development and validation process (EORTC QLQ BR-23, FACT-B, HBIS, BIBCQ, BREAST-Q); three of those focused solely on non-surgical outcomes (EORTC QLQ BR-23, FACT-B, HBIS). The authors concluded future research would benefit from adopting more current psychometric methods of measurement and should address surgical and non-surgical specific outcomes of oncologic breast surgery (Chen et al., 2010).

Comparison studies of women who have had a mastectomy and breast reconstruction, mastectomy alone, and/or breast conserving surgery have revealed no significant difference in: quality of life (Heneghan et al., 2011; Metcalfe et al., 2012); sexual functioning (Metcalfe et al., 2012); depression and anxiety (Holly et al., 2003; Metcalfe et al., 2012); body image, self-esteem, coping and social support measures (Holly et al., 2003).

Other studies reveal some psychosocial benefit of breast reconstruction over other types of oncologic breast surgery. A 2007 study conducted psychiatric interviews comprising four questionnaire-based scales with 33 breast reconstruction patients,

33 mastectomy patients who were awaiting breast reconstruction and 33 healthy women. The authors found the mastectomy group exhibited worse psychosocial outcomes in the measures of social adaptation (0.0139), quality of life (p=0.0001), depression (0.0047) and sexual functioning (p=0.0002), compared with women who had undertaken breast reconstruction (Rubino et al., 2007). Denewer et al. (2012) compared quality of life outcomes of Egyptian women who had undertaken autologous breast reconstruction and those who underwent mastectomy alone. Participants completed the 'Breast Impact of Treatment Scale' and the 'Body Satisfaction Scale' between two months and two years following surgery. Women who had undertaken breast reconstruction showed higher body satisfaction scores (p=0.003) (Denewer et al., 2012). Zhong and colleagues (2012) questioned 51 women regarding health-related quality of life pre-operatively, at three weeks and three months following autologous breast reconstruction. Breast satisfaction, sexual and psychosocial wellbeing improved significantly post-operatively (p=0.05) (Zhong et al., 2012).

A French study recruited women who had undertaken Lattisimus Dorsi breast reconstruction between 1990 and 2008 (N=193) and a comparison group who had not undertaken breast reconstruction, matched for age at diagnosis and date of mastectomy (N=141). While no difference was noted in quality of life, body image was better in the breast reconstruction group (p=0.0247), particularly for participants less than 60 years of age (p=0.0192) and for women with large breasts (p=0.0197) (De Gournay et al., 2010). A study of 98 women undertaking delayed implant or DIEP flap breast reconstruction evaluated body image and sexuality pre-operatively and at six and 20-month time points. Women's body image and sexual relationship satisfaction improved significantly at 20 months (p=0.001 and p=0.01 respectively). High body image scores were related to better general mental health (p=0.02), less cancer distress (p=0.001) and higher relationship satisfaction (p=0.001) (Gopie, ter Kuile, Timman, Mureau & Tibben, 2014).

While several studies have sought to evaluate the psychosocial outcomes of various types and timings of breast reconstruction, there is a dearth of studies comparing outcomes between these differing types or timings. Metcalfe and colleagues' (2012) comparison study included women who had delayed and immediate breast

reconstruction. The results showed that women who had undertaken delayed breast reconstruction had higher pre-surgical body stigma (p=0.01) and body concern scores (p=0.02); however, no statistically significant difference was evident post-surgery. The authors concluded psychological distress was experienced by women regardless of the timing of breast reconstruction (Metcalfe et al, 2012).

1.4.3.3 Women's Satisfaction with Breast Reconstruction

A critical review of patient satisfaction studies between 1994 and 2006 revealed that the majority of patients were satisfied with their breast reconstruction regardless of age, type of breast reconstruction or timing of breast reconstruction. Asymmetry, complications and scarring were found to affect patient satisfaction negatively, while having nipple reconstruction positively affected satisfaction. Radiation therapy, either before or after breast reconstruction, still yielded satisfactory aesthetic outcomes (Guyomard, Leinster & Wilkinson, 2007). Roth, Lowery, Davis and Wilkins (2007) controlled for socio-demographic factors, surgery type and timing; they concluded that levels of affective distress, depression and anxiety pre-operatively and at one year post-operatively were predictors of decreased satisfaction with breast reconstruction.

Yueh and colleagues' (2010) comparative evaluation of satisfaction with DIEP flap, TRAM flap, LD flap and implant breast reconstruction revealed that DIEP flap breast reconstruction patients had the highest level of general satisfaction and TRAM flap breast reconstruction patients had the highest level of aesthetic satisfaction. Autologous breast reconstruction correlated with significantly higher satisfaction compared to implant breast reconstruction. Of the autologous forms of breast reconstruction, satisfaction with abdominal flap breast reconstruction was superior to LD flap breast reconstruction (Yueh et al., 2010). Colakoglu and colleagues (2011) similarly identified autologous breast reconstruction as a predictor of satisfaction over implant breast reconstruction. Predictors of dissatisfaction included older age, complications and a longer time since breast reconstruction surgery (Colakoglu et al., 2011).

A review of 370 consecutive DIEP (N=365) and superficial inferior epigastric artery (N=5) breast reconstruction procedures reported that aesthetic outcomes, breast symmetry and nipple/areola reconstruction were the most important factors related to patient satisfaction. Seventy-three per cent of patients had secondary surgery following initial breast reconstruction, for aesthetic improvement or treatment of complications. The authors concluded that the need for subsequent operations was an important piece of information that should be provided to patients. (Enajat et al, 2010).

A qualitative study undertook semi-structured interviews with 15 women who had TRAM flap breast reconstructions to explore outcome satisfaction. Women reported their satisfaction with the outcome of breast reconstruction related to relief at not having to wear external breast prostheses and improved confidence with their bodies. However, women also reported having to manage unrealistic expectations about breast reconstruction, including lengthy recovery times and scarring (Abu-Nab & Grunfeld, 2007). This highlights that women's expectations of breast reconstruction are certain to affect satisfaction with their reconstructed breast. Another small qualitative study was conducted in New York at the Memorial Sloan Kettering Cancer Center in 2010, exploring women's met and unmet expectations following implant breast reconstruction. Twenty-eight women were interviewed an average of 13 months after breast reconstruction surgery (range 1–58 months). A wide range of expectations regarding shape, symmetry, scarring and appearance of reconstructed breasts were reported. Women's expectations were unclear and unrealistic, and women were uncertain about how their breast should feel following implant breast reconstruction (Snell et al, 2010). The great variation between breast reconstruction and time of interview (1–58 months) means women would have been at variable stages of their recovery and final breast reconstruction outcome. This may have significantly affected their view of outcome versus expectations.

There has recently been a move to develop more standardised, reliable tools to evaluate the aesthetic outcomes of breast reconstruction (Ahcan, Bracun, Zivec, Pavlic & Butala, 2012; Catanuto et al., 2009). In addition, a 'Breast Reconstruction Satisfaction Questionnaire' (BRECON) was piloted with 128 women demonstrating strong internal consistency, with further validation studies planned (Temple-Oberle

et al., 2013). However, methodological flaws in the current literature have resulted in inconclusive evidence regarding the benefits or pitfalls of breast reconstruction, its timing and types. The lack of conclusive evidence, coupled with the numerous individual and complex clinical factors influencing breast reconstruction outcomes, indicates women considering breast reconstruction may be best served by providing pre-operative information about the variable potential physical, psychosocial and aesthetic outcomes of breast reconstruction. Providing such comprehensive information may assist women when considering their breast reconstruction treatment options.

1.5 Decision Support in Healthcare

Decision support provides clinicians and patients with relevant, appropriately presented information to assist decision making. Decision support may be necessary for persons making complex decisions about their health. A person-centred approach is adopted to support decision makers and improve the quality of healthcare decision making. Decision support may be in various formats including audio, written, computer or web based applications.(O'Connor, Jacobsen & Stacey, 2002; Stacey et al., 2014; https://decisionaid.ohri.ca/odsf.html).

Decision support tools, often referred to as 'decision aids', are defined as evidence-based health information resources designed to support individuals making decisions about their healthcare. Values-based decision making requires the individual to weigh up the pros and cons of each option. Decision support tools aim to facilitate this by engaging the individual in decision making, increasing their knowledge, decreasing their uncertainty and realigning expectations. This results in alignment between their values and their decisions (https://decisionaid.ohri.ca/odsf.html)

Decision support tools are not intended to replace or negate the need for healthcare professional consultation (https://decisionaid.ohri.ca/odsf.html). Rather, decision aids seek to complement healthcare professional consultation by providing information in preparation for decision making. This is achieved by informing

patients of treatment options and potential consequences and supporting the patient to consider the value placed on these options (O'Connor & Edwards, 2009).

A systematic review of decision aids for health and screening decisions showed, when used in conjunction with healthcare professional consultation, decision aids improve patient knowledge, facilitate realistic expectations of outcome, decrease decisional conflict and facilitate shared decision making. In addition, use of decision aids has been shown to lead to patients choosing more conservative treatment options, with some studies demonstrating a resulting decrease in health care costs; although others identify no significant difference in healthcare costs (Stacey et al., 2014). The development and application of decision support tools for health and treatment decisions is discussed further in Chapter Four.

1.6 Significance of the Research

Mastectomy continues to be a mainstay of treatment for women diagnosed with breast cancer. The psychosocial impacts of mastectomy have been well documented in the literature. Breast reconstruction is an option for women undergoing mastectomy to potentially improve psychosocial outcomes; however, it is not frequently chosen by women. Reasons for the relatively low uptake of breast reconstruction may relate to personal issues and considerations, financial restrictions and difficulties experienced in accessing breast reconstruction services. Making decisions about breast reconstruction is complex, requiring women to process a large amount of information on a variety of options. Access to evidence-based information about breast reconstruction options and their implications may go a long way to assist women to make informed decisions about breast reconstruction.

1.7 Research Design

Evaluation methodology was adopted to guide the development and appraisal of a decision support tool for women considering breast reconstruction following mastectomy. Specifically, a decision/accountability-oriented evaluation approach was chosen for its primary focus on stakeholder engagement in the planning and

implementation of evaluation. The complexity of breast reconstruction decision making and the physical, psychological and social implications of such decisions clearly identifies that the women making these decisions are best charged with considering the development of any decision support tool. The input of healthcare professionals is important in navigating women through the context of decision making related to their health and wellbeing, highlighting they are also important stakeholders. The collaborative emphasis of a decision/accountability-oriented approach, aligned with the philosophical underpinning of this research that values the input of key stakeholders (women and their healthcare professionals) ensures breast reconstruction information needs will be met appropriately by the developed decision support tool.

The research was conducted in three distinct, evolutionary phases:

- Phase One explored the breast reconstruction decision making experiences and information needs of women who had undertaken breast reconstruction.
- Phase Two, informed by the findings of Phase One, developed a breast reconstruction decision support tool through the implementation of an evaluation framework.
- Phase Three completed implementation of the evaluation framework by conducting summative evaluation of the decision support tool's value to women considering breast reconstruction following mastectomy.

Project collaborations were formed with Breast Cancer Network Australia (BCNA) and Cancer Australia (previously National Breast and Ovarian Cancer Centre). A Project Advisory Committee of multidisciplinary experts, peak national organisations and consumers from across the country was formed to guide and oversee the implementation of the evaluation framework and development of the decision support tool. The decision support tool took the form of a website and two information booklets: one for women who had been diagnosed with breast cancer and another for women who were considering bilateral prophylactic mastectomy and breast reconstruction.

1.8 Thesis Structure

The thesis is divided into the following chapters:

Chapter 2: Methodology describes evaluation methodology as the research methodology adopted to guide the development and appraisal of a decision support tool for women considering breast reconstruction following mastectomy. The theoretical foundations of evaluation methodology will be introduced, with a particular focus on decision/accountability evaluation research and how it was applied to this research.

Chapter 3: Phase One—Needs analysis of women's decision making and information needs regarding breast reconstruction details the methods utilised to conduct a needs analysis and presents the findings of this scoping phase of the research. A review of breast reconstruction decision making and information needs literature is presented, along with a review of breast reconstruction information currently available to Australian women. How these findings have informed the development of a decision support tool will be discussed.

Chapter 4: Phase Two–Development of a decision support tool for women considering breast reconstruction following mastectomy introduces a conceptual framework utilised to guide the development of a breast reconstruction decision support tool. The development process undertaken within a collaborative evaluation framework will be described. The Project Advisory Committee's role and function in the decision support tool development will be detailed. The format and content of the decision support tool developed will be presented.

Chapter 5: Phase Three—Evaluation of a decision support tool for women considering breast reconstruction decision following mastectomy details the methods used to conclude the evaluation framework. It also presents the results of a summative evaluation of the decision support tool.

Chapter 6: Discussion and conclusion brings together the findings and outcomes of Phases One, Two and Three of the research, discussing the research process and application of the findings within the broader context of relevant literature. The conclusion summarises how the research has achieved its aims and objectives. It then describes the contribution the research has made to the field of breast cancer and breast reconstruction. Limitations of the research are discussed, and opportunities for future research are offered.

1.9 Conclusion

Breast cancer is the most frequently diagnosed cancer in Australian women. Despite surgical advances in the treatment of breast cancer, approximately 45 per cent of women diagnosed will undergo mastectomy. In addition, there is an increasing trend in women opting to undergo contralateral prophylactic mastectomy and bilateral prophylactic mastectomy. All women who have a mastectomy are eligible to consider breast reconstruction. Breast reconstruction can help to improve women's body image, self-esteem and quality of life. It can decrease the emotional distress experienced because of breast cancer diagnosis and treatments. However, the national rate of breast reconstruction is relatively low, at approximately 16 per cent, and the complexities of decision making can be challenging for women.

This research adopts evaluation methodology to explore Australian women's decision making and information needs regarding breast reconstruction. It seeks to develop and evaluate a decision support tool for women considering breast reconstruction following mastectomy. This chapter has introduced the research, detailed the background of breast reconstruction and outlined the structure of this thesis.

Chapter 2: Methodology

2.1 Introduction

Considering breast reconstruction as an option following mastectomy requires women to make a series of highly personal and complex decisions that may have far-reaching effects on their lives. The overarching philosophical approach to this research was that women's needs and preferences would guide all aspects of the research process. In addition, the specialised nature of this surgery, requiring consultation and shared decision making with specialist clinicians, meant healthcare professionals were vital to the stakeholder development of any information resource. This chapter will describe evaluation methodology. This is the research methodology adopted to guide development and appraisal of the decision support tool for women considering breast reconstruction following mastectomy. The theoretical foundations of evaluation methodology, specifically Stufflebeam's decision/accountability evaluation approach, will be examined. Decision/accountability evaluation research was chosen for its primary focus on stakeholder engagement in the planning and implementation of evaluation. The importance of stakeholder engagement in achieving the aims of this research lends itself to a collaborative methodology. This methodology will engage and inform stakeholders, preparing them to make decisions that drive development and evaluation of a decision support tool. The evaluation framework for the research—identifying how decision/accountability evaluation research specifically links to this research—will be presented, and the methods used in each phase of the research will be introduced.

2.2 Evaluation Research

The purpose of evaluation research is to determine the quality and value of something (a programme, product or service), identify areas of potential improvement and inform decision making. The term *quality*, often used interchangeably with the term *merit*, refers to the inherent and fundamental value of

the programme, product or service. In addition to assessing quality, evaluation also seeks to assess the *value* of the programme, product or service to the stakeholders for which it is intended; this is also referred to as *worth*. Typically, evaluation research values the worth more heavily than simply the quality of the product, programme or service (Davidson, 2005). Evaluation research methodology (specifically decision/accountability evaluation research) guided the development and evaluation of a decision support tool for women considering breast reconstruction following mastectomy.

Evaluation allows the value and effectiveness of new or existing programmes, products or services to be assessed; the results can be used to modify the initiative, maximising desired outcomes and minimising undesired outcomes. Evaluation facilitates the evolution, development and subsequent improvement of programmes, products or services by seeking to answer the questions:

- Is it better than what we had before?
- Is it the best option available to us?
- What lessons have we learnt?
- How can we improve it further? (Davidson, 2005)

At its core, evaluation forms a significant part of a healthcare providers' professional responsibility and accountability. Healthcare professionals evaluate individual client's needs, the most suitable treatment options, how to incorporate an individual's needs and preferences into care, and how effective the interventions have been in achieving client goals. As a nurse, practice is guided by a nursing process whereby comprehensive assessment and analysis of assessed findings informs a plan of care to be implemented. Regular and ongoing evaluation of the effectiveness of those interventions is conducted seeking to modify the plan of care to optimise client outcomes. The nursing process is a cyclic process of evaluation aimed at meeting client's healthcare goals. On a larger scale, organisations foster a culture of evaluation to determine efficacy, value and cost effectiveness to the organisation and intended users. Evaluation consequently influences the design and dissemination of programmes, products or services. The examples presented

demonstrate that evaluation can take many forms and be applied in many different ways; as individuals, organisations and in the area of healthcare and service delivery.

Some researchers argue that evaluation is distinct from research, and is not a research methodology in itself (Powell, 2006). Evaluation research, also referred to as 'evaluative research', is not consistently branded as research. Views on the definition of evaluation research are variable, including: an assessment process measuring outcomes against set criteria; the adoption of research methods for the purpose of evaluating something; or a specific research methodology in its own right (Powell, 2006). The foundations of evaluation research come from programme evaluation that seeks to assess the value of a programme in meeting its objectives. The spread of evaluation processes through educational and governmental departments increased the requirement for accountability in evaluation processes; subsequently, rigorous evaluation adopting research methods became the new face of evaluation. The value of evaluation in the social sciences has had great influence on the evolution of evaluation research as a distinct research methodology. Evaluation research is the philosophical approach to a systematic process of knowledge attainment and application (Stufflebeam, 2001).

2.2.1 The Evolution of Evaluation Research

Evaluation research has its origins in sociology, informed by social theories highlighting the importance of contextual influence. Over the last 50 years, schools of social policy, psychology, business and political affairs have influenced the evolution of evaluation research. Stern describes the evolutionary nature of evaluation research as not one single method, but a set of methods and methodologies, each with a distinctive applied purpose that is embedded in a wider institutional/organisational context (Stern, 2005).

Evaluation research has been historically founded on programme evaluation approaches. Programme evaluation became predominant in the Unites States (US) in the 1960s within government and education sectors. Throughout the 1970s and '80s, scholars developed alternative evaluation approaches to programme evaluation. This generation of evaluation research was driven by scholars including

Chronbach, Guba, Lincoln, Scriven, Stufflebeam and Patton (Stufflebeam, 2001). In the 1990s, organisations began to perform structured evaluation to monitor product quality, industry competitiveness and service delivery outcomes.

Alkin and Christie (2004) argue that all evaluation methodologies are underpinned by the concepts of accountability and social inquiry. Social inquiry refers to the study of behaviour of individuals or societies of varying social circumstances, recognising the distinct social dimension of human action and interaction. Social inquiry stems from the desire to adopt a systematic and justifiable methodological approach to demonstrate accountability (Alkin & Christie, 2004). Alkin (1972) divided accountability into: goal accountability (determining if realistic and appropriate goals have been set); process accountability (establishing appropriate processes to achieve nominated goals); and outcome accountability (the degree to which said goals have been reached). To guide understanding of the different evaluation methodological approaches, Alkin and Christie (2004) grouped them according to their distinctive purpose: evaluation that is primarily guided by methods or objectives; evaluation that focuses on valuing the data; and evaluation oriented towards facilitating decision making.

Some evaluation researchers design and execute research emphasising method (Alkin & Christie, 2004). Methods-oriented researchers frequently adopt experimental and quasi-experimental designs. An example of evaluation research guided primarily by method is Ralph Tyler's work since the 1940s, termed 'educational evaluation', which focused on actual educational outcomes compared to intended educational outcomes. Alternatively, other evaluation researchers are strongly objective-oriented, utilising an expanded range of methods to undertake objectives-based measurement. Objectives-oriented evaluation research has been embedded in educational evaluation, leading to the development of Tyler's work into several behavioural and cognitive taxonomies of educational objectives developed and refined over many decades. The pitfall of objective-oriented approaches is the large number of objectives to be achieved within a single evaluation. Objective-oriented theorists have recognised this limitation and the need for a broader scope of objectives, and reduction in the number of objectives for evaluation (Alkin & Christie, 2004).

Scriven (1983) forged the way for evaluation research that focused on valuing the data collected. He described evaluation as the science of valuing. This type of evaluation requires researchers to place value on their findings and fulfil their primary role of serving the interests of all potential stakeholders. Such evaluation researchers must value their findings by making judgements, rather than simply passing their findings to other decision makers. Scriven led a move away from experimental and quasi-experimental design, adopting a method of 'modus operandi' to achieve the desired valuing. The 'modus operandi' method requires the researcher to: develop a complete list of potential causes of the findings; identify which of these were already in existence; and then identify the true cause of the finding, based on the cause/s that fit the chain of events leading to the finding. This enables the researcher to explore causal connections in a systematic manner, to reduce evaluator bias (Alkin & Christie, 2004).

Decision-oriented evaluation researchers strongly value the role of stakeholder engagement to drive evaluation. The role of the researcher is to provide stakeholders with structured processes and information to facilitate decision making. Representative stakeholders are involved in all aspects of the evaluation, including: determining appropriate evaluation questions; planning methods with which to answer those questions; reviewing and interpreting findings; and disseminating findings. Including the perspectives of all potential stakeholders ensures relevant values are presented and comprehensive evaluation is undertaken (Alkin & Christie, 2004).

2.2.2 Application of Evaluation Research Approaches

In 2001, Daniel Stufflebeam published a detailed review of the various evaluation methodology approaches developed over the years. Stufflebeams' aims were to identify and examine the strengths and weakness of the different evaluation methodological approaches, examining conceptual and technical issues associated with their execution. From this review, Stufflebeam identified what was considered robust and rigorous evaluation approaches, and explored how these approaches would be best applied to evaluation research studies (Stufflebeam, 2001). Twenty-

two specific evaluation methodological approaches were analysed and subsequently classified as pseudo-evaluation or quasi-evaluation studies (method/objective-oriented studies), social agenda/advocacy approaches (valuing oriented-approaches), or improvement/accountability-oriented-evaluation approaches (decision-oriented studies) (Figure 2.1).

Pseudo-evaluations are not considered rigorous forms of evaluation research as they often manipulate findings to represent only favourable results and may restrict dissemination of these findings to select groups. Such studies often have a political or marketing nature. Results of such evaluation may be used to mislead people or exert power over more vulnerable populations. Quasi-evaluation studies either seek to address specific questions by employing a diverse range of methods, or focus their evaluation on a particular method. As such, these evaluations narrow their scope, therefore limiting the merit and worth of the evaluation (Stufflebeam, 2001).

Social agenda/advocacy approaches are strongly founded in programme evaluation, with the aim of improving outcomes for socially disadvantaged and vulnerable populations. They focus primarily on promoting access to education and social services and seek to empower individuals and communities. The key limitation of the social agenda/advocacy approach is the risk of not conducting an independent or impartial evaluation (Stufflebeam, 2001).

Improvement/accountability-oriented approaches are comprehensive in their need to evaluate merit and worth. These approaches often use the assessed need of stakeholders as the criteria for assessing merit and worth, along with various methods to undertake evaluation and corroborate evaluation findings. These approaches focus on improvement, by providing stakeholders with information on service options and assisting them to analyse the merits of differing options (Stufflebeam, 2001). The qualities of this approach make it the optimal evaluation methodology approach to provide a systematic framework for stakeholder engagement to best achieve the objectives of this research. The application of this evaluation methodology will be detailed later in this chapter.

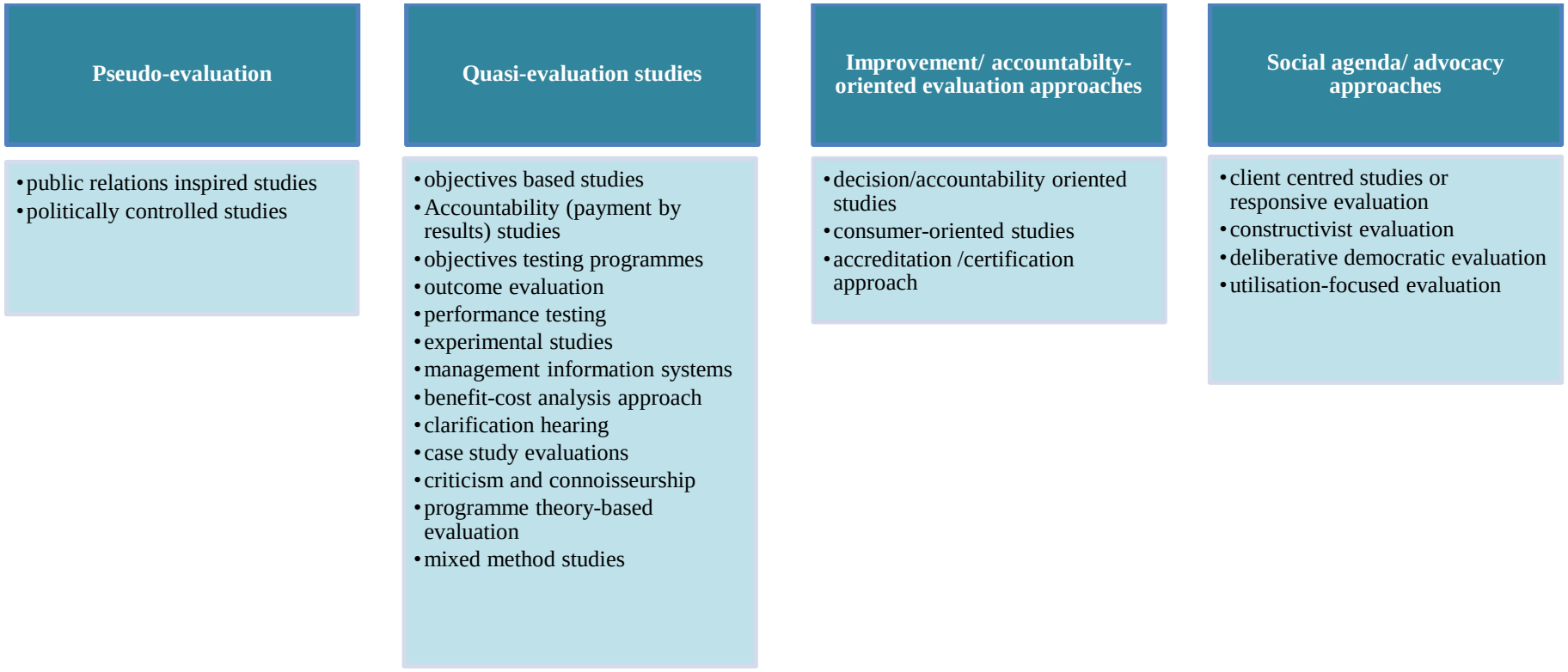

Figure 2.1: Classification of Evaluation Methodological Approaches (Adapted from Stufflebeam, 2001)

Each of the 22 evaluation approaches was evaluated against the requirements of the Joint Committee Program Evaluation Standards (1994) (http://www.jcsee.org/program-evaluation-standards-statements). They were individually ranked poor, fair, good, very good or excellent across five elements of utility, feasibility, propriety, accuracy and overall merit (Stufflebeam, 2001). The Program Evaluation Standards are a publication of the Joint Committee on Standards for Educational Evaluation (Yarbrough, Shula, Hopson & Caruthers, 2011), a coalition of professional associations seeking to ensure the quality of evaluation (http://www.jcsee.org/program-evaluation-standards-statements). The Joint Committee is accredited with the American National Standards Institute, who approved the Program Evaluation Standards becoming American National Standards (http://www.jcsee.org/about).

The Program Evaluation Standards aim to promote stakeholder value of the evaluation processes in meeting their needs (utility); maximise effective and efficient evaluation (feasibility); ensure evaluation processes are proper, legal, fair and just (propriety); and increase the dependability and truthfulness of evaluation outcomes and representations (accuracy) (Yarbrough et al., 2011). Since Stufflebeam's (2001) review of evaluation methodological approaches, the Program Evaluation Standards have been revised (2011) and now incorporate the additional element of evaluation accountability standards, which focus on encouraging adequate documentation of evaluation processes and outcomes to facilitate quality improvement and accountability (Yarbrough et al., 2011). Application of such internationally recognised standards for evaluation has in part addressed some historical concerns about the rigour of evaluation research.

Nine of the 22 evaluation methodological approaches reviewed by Stufflebeam were identified as the most rigorous evaluation methodological approaches. Appraisal of these approaches against the Program Evaluation Standards is presented in Table 2.1. These approaches were characterised by a strong focus on stakeholder engagement and utilised multiple research methods to evaluate. While Stufflebeam's review of evaluation approaches provides valuable insight into the strengths and weaknesses of applying differing evaluation approaches, it must be noted this review was based upon the author's knowledge, years of studying evaluation models and

experience using various evaluation approaches in practice. A structured review process was adopted by appraising evaluation methodological approaches against the American National Standards of programme evaluation (1994), aiming to benchmark how evaluations met the needs the intended users. Such professional standards guide a rigorous approach to implementing a variety of evaluation methodology approaches. The highest ranked evaluation approach was the decision/accountability-oriented approach (Stufflebeam, 2001). It must be noted that Stufflebeam was one of the developers of the decision/accountability approach of evaluation research. The qualities of such an approach made it the optimal evaluation methodology to provide a systematic framework for stakeholder engagement to achieve the objectives of this research. The application of this evaluation methodology will be detailed later in this chapter and in subsequent Chapters Three, Four and Five.

Table 2.1: Evaluation Methodological Approach Ratings (Adapted from Stufflebeam, 2001)

EVALUATION APPROACH	Overall score & rating	Utility score & rating	Feasibility score & rating	Propriety score & rating	Accuracy score & rating
IMPROVEMENT/ACCOUNTABILITY					
Decision accountability	92 (VG)	90 (VG)	92 (VG)	88 (VG)	98 (E)
Consumer orientation	81 (VG)	81 (VG)	75 (VG)	91 (VG)	81 (VG)
Accreditation	60 (G)	71 (VG)	58 (G)	59 (G)	50 (G)
SOCIAL AGENDA/ADVOCACY					
Utilisation-focused	87 (VG)	96 (E)	92 (VG)	81 (VG)	79 (VG)
Client centred/responsive	87 (VG)	93 (E)	92 (VG)	75 (VG)	88 (VG)
Deliberative/democratic	83 (VG)	96 (E)	92 (VG)	75 (VG)	69 (VG)
Constructivist	80 (VG)	82 (VG)	67 (G)	88 (VG)	83 (VG)
QUESTIONS/METHODS					
Case study	80 (VG)	68 (VG)	83 (VG)	78 (VG)	92 (VG)
Outcomes monitoring/value-added	72 (VG)	71 (VG)	92 (VG)	69 (VG)	56 (G)

Ratings: E=Excellent 93–100%, VG=Very Good 68–92%, G=Good 50–67%, F=Fair 25–49%, P=Poor 0–24%.

Approaches were rated against each of the 30 Joint Committee Program Evaluation Standards.

Full details of the comprehensive assessment approach are detailed in Stufflebeam, D. (2001) 'Evaluation Models', *New Directions for Evaluation*, 89, 7–99.

The central elements of decision/accountability evaluation research are engagement of stakeholders at all levels of evaluation, facilitation of timely collaboration to make decisions, and maintenance of a record of accountability (Stufflebeam, 2001). The stakeholder engagement focus of decision/accountability evaluation research strongly aligns with the philosophical approach of this research in valuing the contribution of key stakeholders (women and their healthcare professionals) to ensure women's breast reconstruction information needs are met by the decision support tool developed. The complexities involved in breast reconstruction decision making and the physical, psychological and social implications of such decisions highlights that the women making these decisions are best positioned to guide the development of any decision support tool. The input of the healthcare professionals is also important in navigating women through the context of decision making related to their health and wellbeing.

The main contexts within which decision/accountability evaluation research may be adopted include a projected decision making situation, stakeholder engagement and the need to demonstrate accountability (Stufflebeam, 2001). These drivers are embedded in the aims of this research. Identification of women's needs, conceptualisation and design of a decision support tool, and a process for evaluating the decision support tool required rigorous and transparent decisions over the projected life of the research. Stakeholder engagement was imperative to create a decision support tool that would meet the needs of the women making decisions about breast reconstruction and to ensure the decision support tool was a useful tool for women.

The stakeholder group participating in this research included healthcare professionals involved in the care of women who have breast reconstruction, researchers with experience in the areas of breast cancer research, and consumers affected by breast cancer and/or breast reconstruction. There are different approaches to stakeholder engagement, with varying levels of stakeholder control and participation (Cancer Australia & Cancer Voices Australia, 2011; National Health and Medical Research Council & Consumers' Health Forum of Australia, 2002). This research sought to engage stakeholders at the highest level, by having them direct the development of the decision support tool and plan its evaluation,

rather than a narrower consultative brief. It was important to articulate clearly who the consumers were and how they would be engaged to work collaboratively as equal partners in the research process.

2.2.3 The Context, Input, Process, Product Model

Guided by the principles and characteristics of decision/accountability evaluation, a structured model is important to demonstrate accountability of the research process in producing robust, credible and transferable outcomes. The Context, Input, Process, Product (CIPP) model guided the implementation of this research. The CIPP model was first conceptualised in 1965 by Stufflebeam, in response to an identified need for improvement to the 'gold standard' controlled experimental designs of educational evaluation. Stufflebeam's work recognised that simply focusing on whether measured outcomes correlated with intended outcomes often only identified outcome failure, with minimal valuable information on the improvements required to effect change in these outcomes. Stufflebeam subsequently reconceptualised his view of evaluation, to highlight the importance of appraising not only evaluation outcomes, but also evaluation processes. Focusing an evaluation on poorly designed or articulated goals only sets an evaluation up for failure. Stufflebeam postulated that: the articulation of goals should be based on identified needs (context evaluation); evaluation projects should have well thought out and appraised plans (input evaluation); the implementation of plans should be regularly assessed (process evaluation); and finally, that summative evaluation of the outcomes should take place (product evaluation) (Figure 2.2) (Stufflebeam, 2004).

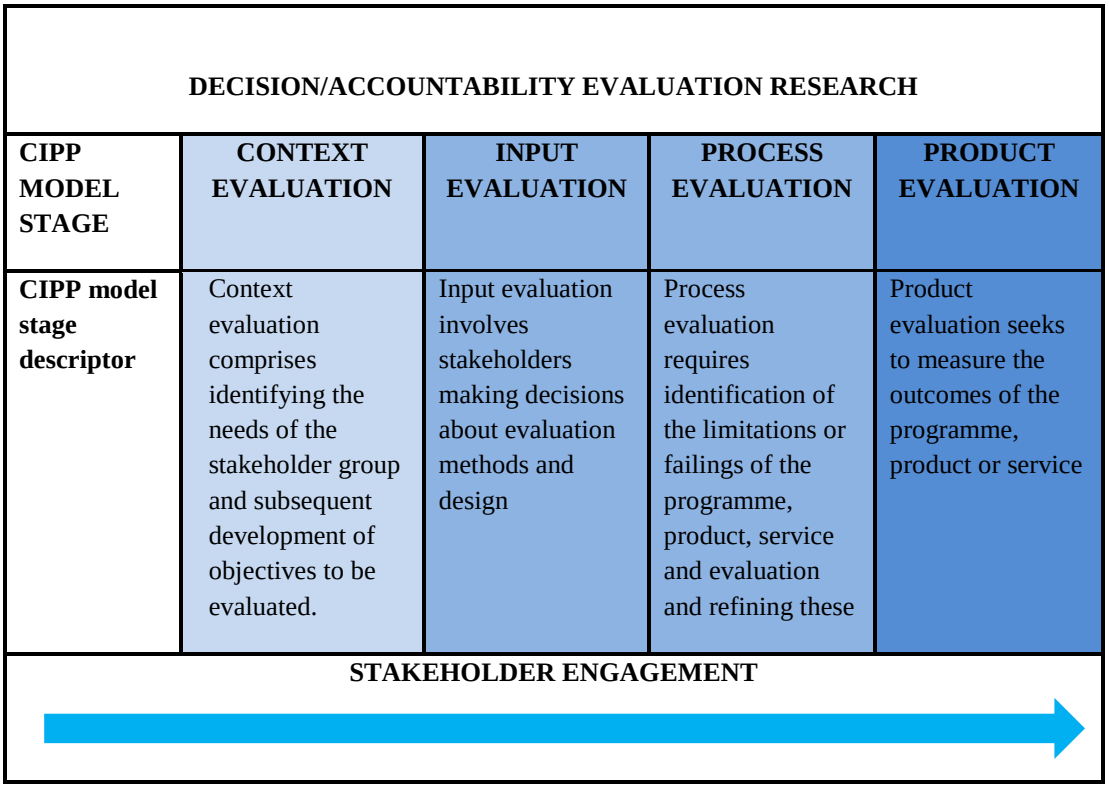

Figure 2.2: CIPP Model (Stufflebeam, 2004)

Evaluation is constant throughout (formative), rather than just focusing on assessment of an end product (summative) (Stufflebeam, 2004). The strength of this approach is that it consistently informs and guides the stakeholder group throughout the project, ensuring transparency.

2.3 Development of a Decision Support Tool Guided by Decision/Accountability Evaluation Research

As outlined in Chapter One, the overarching purpose of this research was to develop and evaluate an evidence-based information resource to assist women who may be making decisions about breast reconstruction following mastectomy. The specific research aims were to:

1. explore the decision making experience of women considering breast reconstruction following mastectomy
2. identify the information needs of women considering breast reconstruction following mastectomy

3. develop a breast reconstruction decision support tool for women considering breast reconstruction following mastectomy
4. develop and implement the evaluation framework for the decision support tool

Based on the CIPP model outlined earlier in this chapter, the research was conducted over three phases. Phase One entailed a needs analysis of the information needs of women in relation to breast reconstruction. Analyses of the results from this phase were combined with a detailed literature review to guide Phase Two, the development of a breast reconstruction decision support tool. In Phase Three, the breast reconstruction decision support tool evaluation was completed. Each phase of the research will be described in detail in Chapters Three, Four and Five respectively.

The selection of research methods was guided by the objectives of each phase, cognisant of the evaluation research design, with data collection approaches selected to maximise comprehensive and rigorous evaluation throughout the research. A continuous evaluation process ensured each phase of the research informed the next, with decisions on the direction and processes of evaluation informed by the stakeholder group. Conducting these three phases, guided by decision/accountability evaluation research, provided an agenda that focused on improvement and guided systematic evaluation and decision making to meet the needs of a targeted population. Figure 2.3 illustrates the evaluation framework guiding this research.

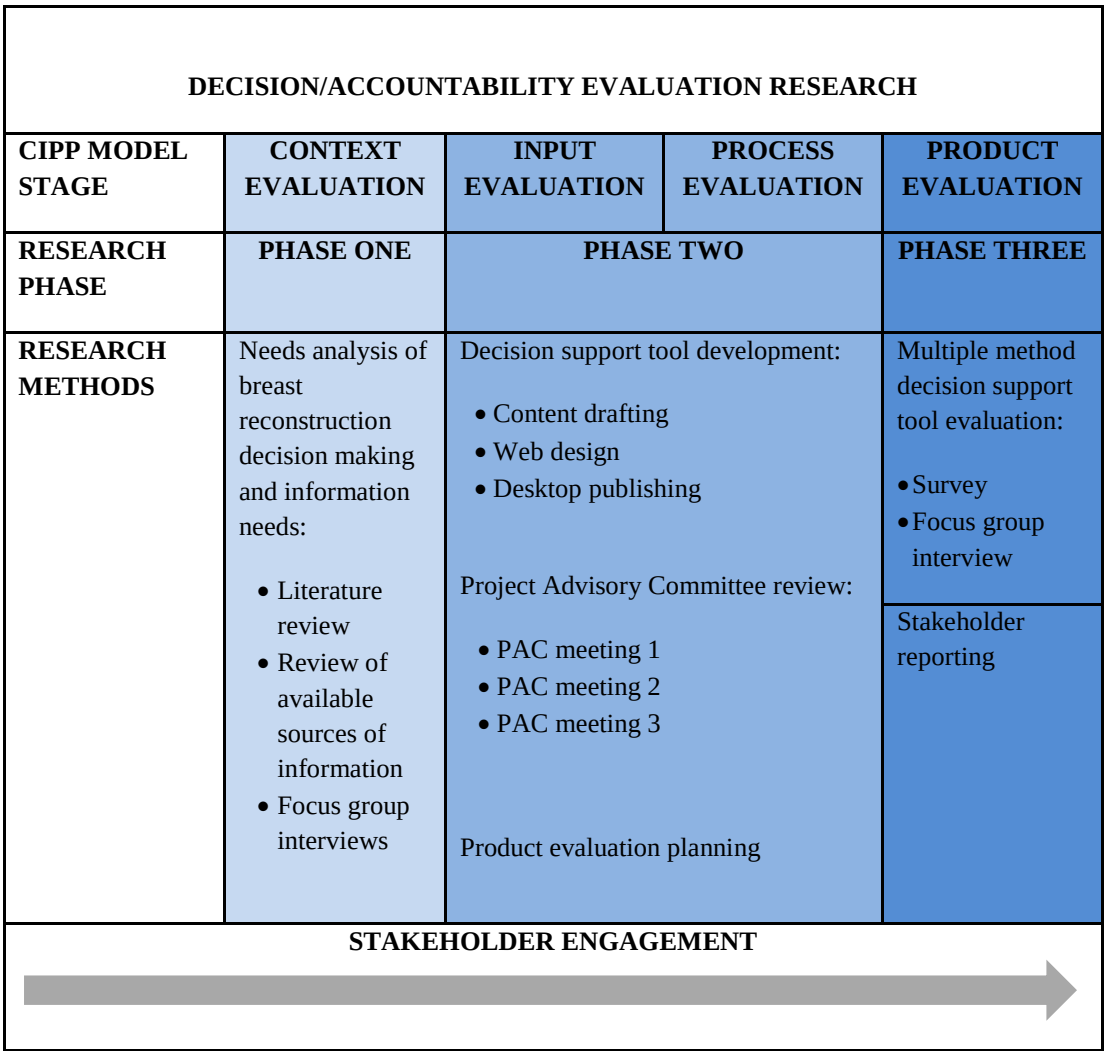

Figure 2.3: Evaluation Framework

2.4 Stakeholder Engagement and Collaboration

The following section details how stakeholders were engaged in this research and the collaborative processes established to facilitate stakeholder contribution. Given the importance of stakeholders in this research process, the process of stakeholder engagement was crucial to ensuring appropriate, relevant, representative and vested stakeholder recruitment.

2.4.1 Identification of Stakeholders

At the outset, it was imperative to identify who the stakeholders were and establish a process to support engagement. Women facing a decision about breast

reconstruction were the primary stakeholders. Given the importance of shared decision making alongside healthcare professionals, to navigate the multiple and sometimes complex clinical considerations of breast reconstruction, medical and nursing personnel were also identified as key stakeholders. These healthcare professionals include: breast surgeons women may interact with at the time of their breast cancer diagnosis and treatment management planning; breast reconstruction surgeons who provide specific information about breast reconstruction options and manage the medical care of women throughout their breast reconstruction experience; breast care nurses who provide women with information, assessment and support before, during and after their breast reconstruction experience; and psychosocial experts who may provide psychological, emotional and social support to women making decisions about, or living through, their breast reconstruction experience.

In addition to these individuals, women may also access peak national breast cancer organisations for information about breast cancer and breast reconstruction treatment options. Cancer Australia (formerly the National Breast and Ovarian Cancer Centre) collaborates and liaises with a wide range of groups, including those affected by cancer, key stakeholders and service providers with an interest in cancer control. Cancer Australia makes recommendations to the Australian Government about cancer policy and priorities. The organisation aims to work towards reducing the impact of cancer and improving the wellbeing of cancer survivors by ensuring that evidence informs cancer prevention, screening, diagnosis, treatment and supportive care. The Breast Cancer Network Australia is Australia's peak national organisation for people affected by breast cancer. The Breast Cancer Network Australia works to ensure these people receive the very best information, treatment, care and support possible. Their website links people to available information on breast cancer and resources available to those people affected by breast cancer.

2.4.2 Recruitment of Stakeholders

2.4.2.1 Healthcare Professionals

To engage healthcare professional stakeholders, the researcher liaised with the peak professional bodies; namely, the Australian Society of Plastic Surgeons and the

Cancer Nurses Society of Australia. The president of each organisation was e-mailed a brief research proposal, requesting nomination of a healthcare professional to represent the organisation in the stakeholder group. Two breast care nurses, one based in Sydney and one in Melbourne, were nominated by the Cancer Nurses Society of Australia, and one breast reconstruction surgeon was nominated by the Australian Society of Plastic Surgeons. An additional two breast care nurses from Perth (where the researcher was based) were directly approached following recommendation of others in the stakeholder group. Their experience in the fields of psychosocial support for women diagnosed with breast cancer and women considering breast reconstruction identified them as valuable contributors to the stakeholder group. All nominated healthcare professionals received a brief research proposal and draft terms of reference for a project advisory committee with the invitation to participate. Once the individuals responded with their willingness to participate, the researcher spoke with each individual on the telephone to provide further detail and answer any questions.

2.4.2.2 Peak National Breast Cancer Organisations

Engaging Cancer Australia and Breast Cancer Network Australia to contribute to the stakeholder group was critical, given that women use these organisations to access some forms of information and decision support about breast cancer and breast reconstruction treatment options. The chief operating officers of each organisation were contacted by e-mail, providing a brief research proposal and details of the requested contribution of an organisational representative to the stakeholder group. Cancer Australia nominated a program officer to collaborate with the stakeholder group and Breast Cancer Network Australia nominated a policy officer. These individuals were contacted by the researcher via telephone to discuss the project in more detail and answer any questions. A brief research proposal and draft terms of reference for a PAC were sent via e-mail. No funding was received from the organisations.

2.4.2.3 Consumers

Consumer representatives, previously identified as the primary stakeholders, were recruited through the Breast Cancer Network Australia's Review and Survey Group. The Review and Survey Group is a database of women who have registered their interest to be involved in research projects in the areas of breast cancer and related issues. The policy manager of the Breast Cancer Network Australia purposively selected two Review and Survey Group members and made contact with them to identify if they were interested in participating. With permission, their contact details were then provided to the researcher, who made contact via e-mail, providing a brief research proposal and later discussed participation over the telephone.

2.4.2.4 Researchers

In addition to this group of stakeholders, research team members were also identified as key to the implementation of this research. The doctoral student's associate supervisors were chosen for their specific expertise and the contribution they could make to the research. Three healthcare professionals involved in the care of women experiencing breast cancer and/or breast reconstruction with research expertise were recruited as associate supervisors to the research.

Professor Phyllis Butow has worked for over 20 years in the area of psycho-oncology and has developed an international reputation in psycho-oncology and health communication. Professor Butow's extensive experience in developing and evaluating communication tools and decision aids added significant expert value to the research. Winthrop Professor Christobel Saunder's experience in both the clinical and psychosocial domains of breast cancer, and as a leader in breast cancer surgery, provided valuable clinical insights to the project. Mr Tony Connell is a senior plastic/reconstructive surgeon specialising in breast reconstruction located in Perth, Western Australia. His research interests include participating in trials of various breast reconstruction surgical techniques.

The stakeholder engagement process described resulted in recruitment of a participant group of 14 healthcare professional, researcher and consumer

stakeholders. This participant group was established as the PAC, charged with providing expert advice and guidance on the implementation of the research. PAC member information is detailed in Table 2.2.

Table 2.2: Project Advisory Committee Members

PAC member	Position & Affiliations at time of participation
Ms Olivia Gallagher	Registered Nurse BN(Hons) Doctoral candidate, University of Sydney
Professor Kate White	Chair of Cancer Nursing, Cancer Institute of New South Wales/Royal Prince Alfred Hospital/University of Sydney (Lead Supervisor)
Professor Phyllis Butow	Co-director of the Centre for Medical Psychology and Evidence-Based Decision Making, University of Sydney (Associate Supervisor)
Winthrop Professor Christobel Saunders	Winthrop Professor of Surgical Oncology, University of Western Australia (Associate Supervisor)
Mr Tony Connell	Plastic and breast reconstruction surgeon, Perth, WA (Associate Supervisor)
Consumer 1	Breast cancer survivor
Consumer 2	Breast cancer survivor
Ms Michelle Marven	Policy Manager, Breast Cancer Network of Australia
Ms Heidi Wilcoxon	Program Manager, National Breast & Ovarian Cancer Centre
Mr David Pennington	Plastic and breast reconstruction surgeon nominated by the Australian Society of Plastic Surgeons
Ms Glenys Longman	Breast Care Nurse, Royal Perth Hospital
Ms Jane Gregson	Breast Care Nurse, King Edward Memorial Hospital
Ms Sue Hutton	Specialist Breast Nurse, nominated by the Cancer Nurses Society of Australia Lismore Community & Allied Health Richmond Network
Ms Danielle Spence	Breast Care Nurse Consultant, nominated by the Cancer Nurses Society of Australia Western Health

2.4.3 Formalising Stakeholder Engagement

Maintaining stakeholder engagement and contribution is an ongoing challenge of collaborative projects. Stufflebeam (2004) identifies a key element of the CIPP model to be the formalisation of stakeholder engagement through written agreements. Having clear, written aims of the collaboration and well-defined

participant requirements for contribution goes some way to establishing the expected standards for collaboration and providing guidance for ongoing collaboration. The difficulties that may be associated with maintaining stakeholder engagement have been identified as a potential limitation of decision/accountability evaluation research. The researcher sought to establish written agreements with the stakeholders through terms of reference for the PAC, seeking PAC members' consent to participate, and establishing memoranda of understanding with peak national breast cancer organisations.

Terms of reference for the PAC (Appendix Five) were drafted by the researcher, based upon the research aims and draft evaluation framework. Providing draft terms of reference was important during the stakeholder engagement phase to provide potential PAC participants with detail on the proposed structure and function of the PAC and the participant contribution that would be required. The terms of reference provided detail of PAC membership, communication processes and anticipated member contribution. The following terms of reference for the PAC were drafted, and later ratified by the PAC:

- to develop a breast reconstruction decision support tool for women considering breast reconstruction following mastectomy
- to develop an evaluation framework within which to appraise the breast reconstruction decision support tool
- to develop the decision support tool in a collaborative manner by involving all stakeholders in the process and using the expertise of these persons to produce a contextually appropriate, accurate, relevant and useful resource for women
- to use national evidence-based best practice to guide the content development of the decision support tool within an evaluation research framework
- adoption of a collaborative approach by the nation's leading experts in the field to reach the outcome of comprehensive information provision that meets the needs of women considering breast reconstruction following mastectomy.

Following review of the research proposal and draft terms of reference, and discussion with the researcher, participants were asked to sign a consent form (Appendix Five). Participants' consent acknowledged that they had been provided with sufficient information about the research and their participation in the PAC, that all questions had been answered by the researcher to their satisfaction, and ratified the terms of reference for the PAC. Gaining consent of the PAC participants formalised the agreed contribution of individuals to the collaboration.

Establishing memoranda of understanding with the national peak breast cancer organisations was important to validate the representation of these organisations on the PAC. Memoranda of understanding were developed and outlined the research aims, research plan, and detailed the agreement of contribution between the researcher and the organisation. The finalised documents were signed by the University of Sydney Research Office, the researcher and a representative of the organisations. The agreements clearly articulated the contribution of each organisation to the research; namely representation of each organisation on the PAC, web design and hosting of the information resource website by Cancer Australia, and recruitment of participants for decision support tool summative evaluation by Breast Cancer Network Australia. Addenda were sent to each organisation if circumstances of the research project changed. An addendum was required to notify Cancer Australia and Breast Cancer Network Australia when a further collaborative partnership was established with Royal Perth Hospital Breast Surgery Gallery, whom assisted the researcher to source consent to include images of women who had undertaken breast reconstruction in the decision support tool. The Royal Perth Hospital agreement detailed the processes to be undertaken to source consent for the images, and responsibilities of each party in gaining this consent and use of the images.

Having written agreements adds to the comprehensive framework intended to implement the CIPP model (Stufflebeam, 2004). A clear and organised approach to stakeholder engagement and ongoing collaboration facilitates a structured process, whereby roles and responsibilities of each party are clearly articulated and coordinated. This formalisation of collaboration also adds rigour to the research by providing an audit trail demonstrating the researcher has met the responsibility of

providing appropriate and sufficient direction to stakeholders participating in an evaluation. The written documents could also be used as a tool to re-focus and re-direct stakeholders who may become too closely involved with aspects of the evaluation, or who are not meeting their agreed responsibilities. Stakeholders could also refer to these written agreements if they had any concern about the researcher's role performance or responsibilities. Having such open and transparent written processes in place provides a safeguard against the identified limitations of decision/accountability evaluation research; namely, maintenance of collaborative stakeholder engagement, decreased stakeholder objectivity and misguided stakeholder contribution (Stufflebeam, 2001).

2.4.4 Facilitating Stakeholder Collaboration

Stufflebeam (2001) emphasised the importance of stakeholders being involved in all aspects of the evaluation and actually driving the evaluation with guidance from the researcher. The stakeholder participants of the PAC were included in all aspects of the evaluation, including ratifying their terms of reference; agreeing upon an evaluation framework; conceptualising what decision support was required and appropriate to meet the needs of women considering breast reconstruction following mastectomy; guiding the content of the decision support tool; having input into the format and design of the decision support tool; and planning the summative evaluation of the decision support tool. The achievement of all these aspects of the research required ongoing engagement and contribution of the PAC members over a 14-month period. Several processes and strategies were used to achieve this goal.

Effective communication and having structured processes to facilitate contribution were crucial to ensuring successful collaboration. Communication with the PAC was maintained via group e-mail to clarify collaborative processes, remind PAC members of specific contribution timelines, and to discuss topics or issues via circulation where appropriate. Over the 14-month period, in between PAC meetings, progress updates were circulated to the PAC via e-mail to maintain impetus of the collaboration. Another important aspect of maintaining collaboration of PAC members was to ensure members felt their contributions were valued. The researcher was responsible for sourcing individual PAC member feedback, collating this

feedback, sharing feedback with the larger PAC group, and facilitating discussion of feedback items affecting the utility, feasibility, propriety, and accuracy of the evaluation research being undertaken.

The PAC meetings provided focused opportunities for face-to-face collaboration. Two to three weeks prior to these scheduled PAC meetings, members were sent pre-reading for consideration and discussion at the meeting and an electronic draft of decision support tool content (when applicable). Project Advisory Committee members were asked to complete a short online structured questionnaire, providing feedback on the draft decision support tool content. PAC members were also given the option of providing electronic feedback as track changes to the document. Questionnaire feedback provided was collated by the researcher and delivered in a presentation at the subsequent PAC meeting. From the analysis of this feedback, the researcher tabled points for discussion as agenda items at the meeting. These processes were effective in maximising PAC member contribution by having a variety of feedback methods available: online questionnaire, electronic editing and PAC meeting attendance. Dependent on PAC member availability, members could contribute as much as they were able via multiple feedback processes. The PAC meetings were held in Sydney and Melbourne to accommodate the majority of PAC member locations. The consumer representatives on the PAC were provided the opportunity to be flown from their place of residence to Sydney or Melbourne to attend the PAC meetings. Teleconferencing facilities were made available to those residing in Perth, Canberra and rural areas of Sydney or Melbourne.

In addition to PAC meetings, individual PAC member expertise was sought, as required, for specific technical aspects of decision support tool content development, either via e-mail or in face-to-face meetings. Any such individual contributions or feedback were reported to the PAC at the next PAC meeting. Examples of such individual consultation included: discussion around surgical complications and side effects with the breast surgeon representative; discussion differentiating between information resources and decision aids as decision support tools with a research expert in the area of decision making and decision aid/information resource development; and specific feedback from the breast reconstruction surgeon representative on the technical aspects of the breast reconstruction images sourced.

Such individual consultation was undertaken to confirm accuracy of the decision support tool content in a way that would conserve the time commitment of the other PAC members.

The researcher maintained an audit trail of all collaborative processes and communications with PAC members in the form of PAC agendas, PAC meeting minutes, PAC feedback presentations, archived versions of each draft of the decision support tool, copies of all e-mail, questionnaire and electronic feedback received from each member, and a record of the contribution of each PAC member. The researcher, as leader of the evaluation research, was always accessible to PAC members via e-mail or telephone and responded to queries in a timely manner. The collaborative processes outlined were well received by PAC members and were effective in achieving the aims of the research.

2.5 Rigour

Rigour involves a structured process of data collection and analysis to ensure that quality research processes are undertaken, confirming a reliable and credible research outcome. Sandelowski (1986) identifies four elements of rigour: 1) credibility; 2) auditability; 3) fittingness; and 4) confirmability. Credibility refers to the degree to which the interpretation of findings corresponds with the lived experience of participants. Auditability is achieved by evidencing a trail of consistent and appropriate research methods and processes. Fittingness is determined by how research findings may be applied to other contexts outside that specific to the research. The ability to confirm research is conducted in an unbiased and neutral manner (confirmability) is determined through demonstration of credibility, auditability and fittingness (Sandelowski, 1986).

Research creditability was demonstrated through seeking to clarify if participants' views and experiences had been accurately interpreted. Phase One member checks were performed by sending participants a written summary of the findings via mail and e-mail for comments, which were then further analysed and incorporated into the Phase One findings. The focus group interviews undertaken in Phase Three also

allowed for survey data analysis to be presented back to the participants through a semi-structured interview schedule, focusing on further exploration of the potential limitations or pitfalls of the decision support tool identified, and any aspects of evaluation that were unclear to the researcher.

Auditability has been achieved by the researcher keeping a set of field notes that documented the researcher's expected and unexpected outcomes during each phase of the research. This assisted conscious auditing and exclusion of the researcher's possible biases, facilitating bracketing practices throughout the research process. A structured data storage system was maintained to ensure all communications, research methods and actions were recorded. This ensured accurate reporting of the research process. Adoption of the CIPP model to guide the research process demonstrates structured, appropriate and thoughtful research progression.

How the outcomes of the research may be applied to other contexts was a key consideration from the beginning. The overall goal of the research was to create a comprehensive, useful and contextually Australian decision support tool to assist women across the nation to make decisions about breast reconstruction following mastectomy. Stakeholder engagement was vital to ensuring the fittingness of the research, and hence was the philosophical approach. Formalised project collaborations were created early on in the research with Breast Cancer Network Australia and Cancer Australia. As well as being involved in the research as key stakeholders and contributing to the development of the decision support tool, both organisations are supportive of applying the research outcomes to the broader national context. Cancer Australia has reviewed a report of the research findings, undertaken its own internal review processes and launched the information resource website on 8 October 2013.

Measures undertaken were able to achieve construct validity and face validity regarding evaluation of the decision support tool. The evaluation survey was constructed against the aims and objectives of the research. The PAC played a part in ensuring the survey designed had validity to evaluate the decision support tool. Validity denotes that a tool measures what it intends to measure. Specifically, the PAC reviewed and appraised whether the survey tool items measured the concepts

they were intended to measure, therefore ensuring construct validity. The incorporation of open-ended survey questions and subsequent focus group interviews ensured the research would provide sufficient information to assist in making improvements to the decision support tool being measured, thus demonstrating formative validity.

2.6 Ethical Considerations

All phases of the research were approved by the University of Sydney Human Research Ethics Committee and, where applicable, the hospital through which participants were recruited (Appendix Three). The research proposal was reviewed and ratified through the peak national body's ethics, or project review, committees. The research complied with the National Statement on Ethical Conduct in Human Research (National Health & Medical Research Council, 2014).

Several strategies ensured the principles of research ethics were upheld. All participants were provided with detailed written information about the research, outlining who was conducting the research, what participation would specifically involve, how much time participation was likely to take, confidentiality of information, benefits of participating, risks of participating, resources available to prevent and manage those risks, how to withdraw from the research, and presenting concerns or complaints. Every person agreeing to participate was contacted by telephone and/or e-mail to confirm participation expectations and answer any queries the person may have. Providing detailed, open and transparent information ensured all participants across all three phases of the research provided informed consent. All participants provided written consent to participate in the research.

No physical risks were identified because of participating in this research. However, due to the personal and somewhat emotive topics for discussion in the focus group interviews of Phase One, it was anticipated some women may experience some level of emotional distress. To address this possible outcome, all women who participated were given access to information on support and counselling services available from the Professional Counselling Service of the Cancer Foundation of Western Australia

(WA) (Karen Anderson, personal communication, August 2007). A process was established whereby if a participant became distressed, the interview would cease immediately. The participant would be given the opportunity to withdraw, recommence after a short break, or on another occasion. This intervention was not necessary during data collection.

Women participating in Phase Three of this research, through survey completion and/or focus group attendance, could experience emotional distress through reliving their experiences at the time of being diagnosed with breast cancer, undergoing breast reconstruction surgery, or dealing with changes in body image resulting from their surgery. Additionally, the decision support tool being reviewed by participants contained photographic images of different breast reconstruction procedures. Women could experience discomfort in reviewing these images, and dissatisfaction with the outcome of their own surgical procedures. The research team has extensive experience in undertaking research with this group of women, and have found that a small number of women experience emotional distress. Women verbalising or appearing to experience emotional distress would be offered to cease participation immediately, resume after a short break or at another time, or withdraw from the research altogether. Women experiencing emotional distress would be provided with information on counselling/support services available through Breast Cancer Network Australia and independent services in their states. No participants expressed emotional distress during this research.

Benefits to the participant were anticipated to be received through discussion of experiences within a supportive and familiar setting in the focus group interviews of Phase One. Several women participating in the focus group interviews verbally expressed this benefit to the researcher. Participants of all phases of the research may benefit from participating in the research, through their contribution to the development of a decision support tool assisting women through the difficult decision making required when considering breast reconstruction following mastectomy.

Participants included people who may have had dependent relationships with healthcare professionals involved in the research. Phase One and Phase Three

participants recruited through their breast reconstruction surgeon's rooms were in a dependent relationship with their healthcare provider. It was necessary to communicate to the women that their declined participation, or withdrawal of participation, would in no way impact the care or services they received from their healthcare professional. This was communicated in the information sheets sent to women and reiterated in the cover letter sent by the breast reconstruction surgeon. To maintain women's confidentiality and reinforce there was no obligation to participate, no participant information was provided to the researcher until an interested participant made contact with the researcher directly. The independence of this recruitment therefore removed the breast reconstruction surgeon from the process at this point, and meant the breast reconstruction surgeon was unaware of who had consented to participate and who had declined.

Maintaining participant confidentiality is important in respecting and protecting participant's rights. All participant information and data collected is stored on a password protected computer and mass storage device securely located in a locked office. The data will be stored securely for seven years after the date of publication of the research, at which time they will be destroyed. The only people having access to the data were the researcher, supervisor to the research, statistician and the transcriber. Participants were also made aware that participation would be confidential, as personal details were coded and pseudonyms were used throughout the transcripts, thesis, reports and any resulting publications.

2.7 Conclusion

Decision/accountability evaluation research, adopting the CIPP model, was deemed most suitable to this research, as it provided a structured and rigorous approach to undertake a longitudinal process of decision support tool development. The personal nature of breast reconstruction decision making and the importance of a shared approach to this complex decision making meant that stakeholder engagement was imperative to the development of a quality resource that would meet the needs of the target population. Involving all key stakeholders in this research facilitated understanding of the product developed and appreciation for the value of the

product, subsequently assisting in disseminating the product to the target population. The development of an evaluation framework to guide this research, incorporating the CIPP model, provided a clear guidance for this stakeholder led research.

Chapter 3: Phase One—Needs Analysis of Women's Information Needs and Decision Making Regarding Breast Reconstruction

3.1 Introduction

Context evaluation was the focus of Phase One of this research and comprised a needs analysis of women's information needs and decision making related to breast reconstruction (Figure 3.1). A detailed review of current research and of nationally available information resources was completed. Focus group interviews with women were undertaken to provide a comprehensive understanding of decision-making processes and the information needs and preferences of women considering breast reconstruction following mastectomy. This chapter reports the methods and findings of this needs analysis The application of these findings in informing the development of a decision support tool for women considering breast reconstruction following mastectomy will be discussed.

<table>
<tr><td colspan="2">DECISION/ACCOUNTABILITY EVALUATION RESEARCH</td></tr>
<tr><td>CIPP MODEL STAGE</td><td>CONTEXT EVALUATION</td></tr>
<tr><td>RESEARCH PHASE</td><td>PHASE ONE</td></tr>
<tr><td>RESEARCH METHODS</td><td>Needs analysis of breast reconstruction decision making and information needs
• Literature review
• Review of available sources of information
• Focus group interviews</td></tr>
<tr><td colspan="2">STAKEHOLDER ENGAGEMENT
  </td></tr>
</table>

Figure 3.1: Evaluation framework (Phase One)

3.1.1 Objectives of Phase One

The aims of Phase One were to:

1. explore the decision making experience of women considering breast reconstruction following mastectomy
2. identify the information needs of women considering breast reconstruction following mastectomy.

The specific objectives of this phase of the research were:

- to explore women's experiences of making decisions about breast reconstruction
- examine the context of breast reconstruction decision making
- identify women's information needs in relation to breast reconstruction decision making.

Three approaches were used to meet these objectives: a review of published studies on women's experiences of breast reconstruction information needs and decision making, a review of existing national information resources available for women, and interviews with women who had breast reconstruction following mastectomy.

3.2 Current Knowledge of Information Needs and Decision Making for Breast Reconstruction

To inform both the development of the decision support tool and identify gaps in current knowledge, an analysis of current literature on breast reconstruction information needs and decision making was undertaken. The review was commenced prior to focus group interviews with women, to inform the qualitative interview questions. Review of the literature was ongoing throughout the project, with searches for recent publications, or to examine specific areas that emerged during the research. The search strategy is detailed in Appendix One.

3.2.1 Information Needs of Women Considering Breast Reconstruction

The information seeking practices of women considering breast reconstruction varied greatly with regard to the volume and detail of information desired by individuals (Brown, Koch & Webb, 2000; Hill & White, 2008; Wolf, 2004b). Warren, Mendlinger, Corso & Greenberg (2012) discuss a model of knowledge acquisition in early stage breast cancer patients, based upon the 2005/2006 knowledge acquisition framework of Mendlinger and Cwikel. Four types of knowledge acquisition are identified: 1) authoritative knowledge imparted by clinicians; 2) technical knowledge detailing procedural information; 3) embodied knowledge gained from personal experience and observation of others' experiences; and 4) traditional knowledge carried through generations (Warren et al., 2012).

The primary source of breast reconstruction information has been identified as reconstructive surgeons (Begum, Grunfeld, Ho-Asjoe & Farhadi, 2011; Brown et al., 2000; Hill & White, 2008; Lee et al., 2011). The Detroit and Los Angeles cancer registries database was used to collect information reported by 1,178 women, to explore the potential impact of breast reconstruction on surgical decision making for breast cancer. Thirty-three per cent of women reported discussing breast reconstruction with their surgeon during their surgical consultation for breast cancer. Surgeons were more likely to discuss breast reconstruction with younger ($p=0.001$) and more educated ($p=0.001$) women. Women who had discussed breast reconstruction with their surgeon were four times more likely to undergo mastectomy ($p=0.001$) (Alderman et al., 2008).

A United Kingdom (UK) study compared satisfaction with breast reconstruction information between women who received information from a plastic surgeon ($N=60$) and a breast reconstruction specialist nurse consultant ($N=59$). Evaluation of women's satisfaction with the information identified no significant difference overall. Women who received information from the plastic surgeon identified receiving information on the surgeon's preferred surgical procedure; therefore, not all treatment options were discussed. Several women felt information was overwhelming and some information was not easily understood (Osborne et al., 2010). This study highlights the surgeon's treatment preference affects the breadth

and depth of information imparted to women about breast reconstruction. As surgeons are the primary source of breast reconstruction information, this poses concerns for the quality of informed decision making and the potential for decision regret.

Written information is a useful supplement to the verbal information provided by clinicians, especially in time-limited consultations (Wolf, 2004a). The qualitative study found surgeons' communication style and manner was both a barrier and facilitator to asking questions. Women reported breast cancer nurses as being more approachable for this purpose. Speaking with other women who had been through similar experiences was valued, acting as a source of support, reassurance and advice. Women also sought to supplement the written and verbal information they received with internet searching (Wolf, 2004a).

Information obtained from internet sites is a common source of information for women considering breast reconstruction (Losken, Burke, Elliott & Carlson, 2005; Macdonald et al., 2010; Sheehan et al., 2007; Wolf, 2004a). McDonald and colleagues examined the quality of web-based information available to patients considering breast reconstruction against the DISCERN grading system (Macdonald et al., 2010). The DISCERN criteria stipulate information should be relevant, reliable, clear, unbiased, achieve its intended aims, refer to additional resources, address areas of uncertainty, outline benefits and risks, address quality of life and shared decision making. The study identified no existing correlation between the Google ranking of the most frequently accessed websites and the DISCERN ranking of websites (Macdonald et al., 2010).

In addition to understanding women's patterns of information seeking and the sources of information they commonly access, it is crucial to identify the content of information required for women to make informed decisions about breast reconstruction. Studies have shown an individual's stage of cancer trajectory will influence their information needs (Adams, Boulton & Watson, 2009; Finney Rutten, Arora, Bakos, Aziz & Rowland, 2005; Heller & Miller, 2004; Vogel, Bengel and Helmes, 2008). In their systematic review of cancer information research, Finney Rutten and colleagues (2005) identified a change in information needs from treatment-related information to recovery-related information.

Wolf's (2004b) qualitative study utilised the focus group method with eight participants to explore the information needs of women who had undergone breast reconstruction. Women concurred they felt overwhelmed by the information provided, expressing that information should initially be sparse, with more detail provided later. The participants valued repetition of information and found bringing questions along to consultations useful. The women felt the information imparted did not prepare them for the length of time taken to complete breast reconstruction, the additional surgeries required, the removal of their nipple/s, how their reconstructed breast/s would look and feel, the lack of sensation in the reconstructed breast/s, the length of recovery time, pain and discomfort experienced, and the complications of breast reconstruction. Some women believed all information on possible complications of breast reconstruction should be offered, while others did not, reporting that this might discourage them from choosing breast reconstruction (Wolf, 2004b). Wolf's (2004b) findings highlight the psychological preparation required to support women in their response to their reconstructed breast/s.

Few sources of visual breast reconstruction information specific to Australian surgical practices exist. However, there are some examples in clinical practice. Breast care nurses at Royal Perth Hospital in WA have developed a computer-based breast reconstruction image gallery displaying variable types of breast reconstructions throughout the surgical recovery trajectory. When women are considering breast reconstruction surgery, they are led through the 'Breast Surgery Gallery' by breast care nurses, who explain the circumstances of each individual outcome. Images selected for viewing reflect the viewer's situation as closely as possible in terms of age and breast size. Audit survey evaluation of the resource revealed 94 per cent of women found viewing the images valuable, 95 per cent reported it assisted their understanding and 84 per cent stated the 'Breast Surgery Gallery' assisted their decision making (Kydd, Reid & Adams, 2010). The 'Breast Surgery Gallery' is one of the few visual breast reconstruction resources available in Australia. The 'Breast Surgery Gallery' resources have been incorporated into the breast reconstruction decision support tool developed and evaluated in this research.

3.2.1.1 Prophylactic Mastectomy

Making decisions about breast reconstruction in the absence of a breast cancer diagnosis presents a different context, requiring modified information to accurately inform this group of women. Women may be considering contralateral prophylactic mastectomy of their non-diseased breast or a bilateral prophylactic mastectomy due to high genetic risk of breast cancer diagnosis in the future.

A qualitative study analysed open-ended survey responses to elicit the information needs of women choosing to undergo either contralateral or bilateral prophylactic mastectomy. Of the 293 women completing the survey, 67.9 per cent had undertaken breast reconstruction. However, presentation of the results did not distinguish whether findings related to those who had or had not undertaken breast reconstruction. Overall, 35 per cent identified they were satisfied with the information they had received about prophylactic mastectomy. Two thirds of participants would have liked more information, with bilateral prophylactic mastectomy participants more likely to desire additional information than those choosing contralateral prophylactic mastectomy. Women commented that information about breast reconstruction was insufficient, specifically in relation to the look and feel, longevity and complications of implants. Twenty-two women identified that information regarding the emotional response to prophylactic mastectomy was lacking, with some commenting they had experienced depression following prophylactic mastectomy, no longer feeling 'whole', 'feminine' or 'sexually attractive'. Recommendations for patient information about prophylactic mastectomy included: potential complications such as pain, numbness and scarring; psychological preparation related to both depression and feelings of relief following prophylactic mastectomy; issues regarding self-esteem, body image and sexuality; aesthetic results, including what to expect and viewing photos of other women who had undertaken the procedure; and follow-up information such as appropriate bras, support groups, post-surgery exercises and future breast-screening practices (Rolnick et al, 2007).

A research team in the US has developed a simulation model as an online tool for patients and their physicians to guide prophylactic surgery decisions of BRCA

mutation carriers. It concludes the greatest life expectancy benefit is achieved by undertaking prophylactic mastectomy and prophylactic oophorectomy immediately after BRCA mutation testing; this highlights that gains vary with age and type of genetic mutation (Kurian et al., 2012; Sigal, Munoz, Kurian & Plevritis, 2012). This statistically based model does not allow for values-based decision making of the individual and, therefore, it may not provide the support women need on its own.

A web-based decision aid for women with the BRCA mutation has been developed, adopting the Ottawa Decision Support Framework as a guide. A focus group needs analysis to determine decision-making needs was first conducted to guide the content and structure of the decision aid. Further focus groups of stakeholders, incorporating breast cancer patients, advocates, geneticists and oncology healthcare professionals, were undertaken to evaluate the content, visual format, application and decision making use of the decision aid. The decision aid presents descriptive risk reduction options for BRCA mutation carriers, numerical presentation of risk reduction, values ranking exercise and summary page identifying the individuals' responses to making decisions between prophylactic mastectomy, prophylactic oophorectomy and Tamoxifen treatment. Most participants noted that using frowning faces as the numerical representation of risk was difficult to understand, preferring graphs, numbers or percentages. Several participants found the icon offensive. Similarly, the use of platinum, gold, silver and bronze ribbons to highlight the level of evidence was reported to be confusing for users. All four groups of participants agreed that users presume the level of evidence included in the decision aid to be appropriate and of a satisfactory standard. This highlights that identifying levels of evidence may be unnecessary. Participants requested more information about the benefits and limitations of options. Significantly, participants identified that information about breast reconstruction was missing. The geneticist and advocate groups felt the decision aid might be overwhelming for users who had recently received genetic results. Use of the decision aid in the clinical setting alongside healthcare professionals was viewed as ideal for the application of this tool. Based on the feedback received, the decision aid is planned to undergo revision prior to pilot testing to assess its application, barriers and usefulness (Culver et al., 2011).

Review of the literature articulates the complexities of breast reconstruction decision making and factors that must be considered by women exploring breast reconstruction options. An obvious gap in relevant and comprehensive information about breast reconstruction exists, complicating women's decision-making process.

3.2.2 Making Decisions about Breast Reconstruction

Breast reconstruction decision making is a complicated process involving numerous decisions, with many variables influencing decision making (Crompvoets, 2006; Heller & Miller, 2004; Wolf, 2004a). Great variation in individual decision-making styles has been identified in the breast cancer literature. The people participating in women's decision making, and women's desired involvement in the decision-making process varies, and is fluid over time (Harcourt & Rumsey, 2004; Lee et al., 2011; Vogel et al., 2008). A study investigating the information needs and decision-making styles of breast cancer patients in Germany identified a varied preference for involvement in decision making. Of the 135 women completing the survey; 38 per cent preferred the clinician to make the treatment decisions, 27 per cent preferred shared decision making with the clinician and 35 per cent preferred to make their decision independently. Twenty-five per cent of women desired greater involvement in decision making at three months. At six months 17 per cent preferred greater involvement, while 13 per cent favoured less involvement (Vogel et al., 2008). Regardless of decision-making style or level of participation in decision making, the vast majority of women who undertake breast reconstruction are generally satisfied with their decision (Alderman et al., 2011; Lee et al., 2011).

Harcourt and Rumsey (2004) explored mastectomy patients' decision making on whether to have a breast reconstruction. Of 93 women recruited, 37 had chosen immediate breast reconstruction and 56 had decided against breast reconstruction at the time of the study. The decision-making style primarily adopted by participants was instant/immediate decision making (N=76). Others were classified as information seekers (N=14) or indecisive decision makers (N=3). Instant/immediate decision makers made their decision with little effort, usually during their surgeon consultation, during which breast reconstruction was discussed. This style of decision making represented 91 per cent of the participants choosing mastectomy

and 67.6 per cent of the participants opting for immediate breast reconstruction. Despite instant/immediate decision making, information seeking commonly continued after the decision was made; however, information that contradicted the decision was avoided (Harcourt & Rumsey, 2004).

Quantitative and qualitative studies have reported women choose breast reconstruction to: avoid body image disturbance (Alderman et al., 2011; Begum et al., 2011; Lee et al., 2011); circumvent the emotional consequences of living without a breast and to avoid thinking about breast cancer (Begum et al., 2011); maintain identity and femininity (Begum et al., 2011; Gopie et al., 2011); and restore a sense of normality following mastectomy (Begum et al., 2011; Gopie et al., 2011). A Dutch study surmised breast reconstruction was seen as a part of the physical and emotional recovery from breast cancer that would help women feel complete (Gopie et al., 2011). Reasons cited for choosing not to have a breast reconstruction include: being focused on breast cancer treatments (Alderman et al., 2011; Begum et al., 2011); being satisfied with using an external breast prosthesis; and not being offered breast reconstruction as an option following mastectomy (Begum et al., 2011).

A UK study interviewed 21 women who had undertaken autologous breast reconstruction surgery to explore their decision to have an immediate or delayed breast reconstruction. Twelve participants had immediate breast reconstruction and nine underwent delayed breast reconstruction. Those choosing an immediate breast reconstruction cited practical issues, including personal commitments and the personal costs of multiple operations, as reasons for choosing immediate breast reconstruction (Begum et al, 2011). Alderman and colleagues (2011) surveyed 384 women five years after breast cancer treatment to explore treatment decisions, factors influencing decision making and decision satisfaction; those women choosing immediate breast reconstruction were less likely to regret their choice about whether or not to have a breast reconstruction than those choosing delayed breast reconstruction, although this difference did not reach statistical significance (Alderman et al., 2011).

Thirty-one women having either implant breast reconstruction (N=15) or DIEP flap breast reconstruction (N=16) at one of six Dutch hospitals were recruited to be

interviewed about their motivations behind their choice of breast reconstruction. Women choosing implant breast reconstruction identified a short anaesthesia and recovery period, avoidance of donor site scars and insufficient autologous tissue as key factors in deciding to undergo implant breast reconstruction. Those opting for DIEP flap breast reconstruction considered the comparatively low risk of complications and perceived long-term benefits, including abdominoplasty and a soft, natural looking breast in their decision to have DIEP flap breast reconstruction. Implant breast reconstructions were not favoured by these women, as implants may require future replacement or because the women had received radiotherapy previously, contradicting implant breast reconstruction as the best option (Gopie et al., 2011).

Damen and colleagues (2011) examined the complexity of women's decisions about the type of breast reconstruction they undertake by administering a discrete choice experiment questionnaire to identify patient preferences for breast reconstruction. The discrete choice experiment identified six attributes of breast reconstruction (material used, operation duration, short-term complications, long-term complications, aesthetic outcome and surgery waiting time). Participants were asked to consider the 18 hypothetical outcomes, even though not all related to a possible breast reconstruction option. A participant sample of 270 women diagnosed with breast cancer was recruited, with 186 of these women having undertaken breast reconstruction. Results identified that women preferred autologous tissue breast reconstruction to methods using breast implants. Women preferred shorter operations and identified a preference for two short operations over one long operation. Women were less likely to choose options listing increased complication rates, with short-term complications being less preferable than long-term complications. Women were also willing to make some trade-offs, with an excellent aesthetic result willing to be traded for a good one in return for a ten per cent decrease in short term complication rates. Autologous material and an excellent aesthetic result were the most important determinants of preference. There were no other statistically significant differences between those who had undertaken breast reconstruction and those who had not. The authors of this study acknowledge that the formal power analysis of this sample was not feasible (Damen et al., 2011). While Damen and colleagues' study provides interesting insights into factors women

consider important when deciding on breast reconstruction, the discrete choice experiment method has its flaws. Further robust and qualitative investigation of the differences in preference, between those who had chosen to have breast reconstruction and those who had not, is warranted.

An Australian single site study examined associations between information satisfaction, psychosocial distress and coping style with decision regret following breast reconstruction. One hundred and twenty-three women completed a survey incorporating the Social Support Questionnaire, Positive and Negative Affect Scale, Information Satisfaction Scale, Depression, Anxiety and Stress Scale, Miller Behavioural Style Scale and the Decision Regret Scale. Of the participant group, 4.9 per cent reported dissatisfaction with the information received at the time of decision making. Women were least satisfied with information about post-operative sensation, outcome expectations and risks or side effects. Overall, 52.8 per cent of women exhibited no decision regret, 27.6 per cent mild decision regret and 19.5 per cent moderate to strong decision regret. Decision regret was found to be strongly associated with low satisfaction with pre-operative information ($p=<0.001$) and depression ($p=<0.01$). There was also an association between decision regret and anxiety ($p=<0.06$) and stress ($p=0.08$) (Sheehan et al., 2007).

The Breast Reconstruction Decision Quality Instrument was developed by Lee and colleagues (2011) in America. The instrument consists of seven multiple choice questions evaluating knowledge about breast reconstruction, 13 items rating goals and concerns on a 0–10 scale, eight multiple choice items investigating involvement in decision making, selection of one out of four possible treatment preferences and a 0–10 scale evaluating the degree to which users felt informed about breast reconstruction. Eighty-four participants from four university medical centres in two states completed the instrument one to three years following breast cancer treatment. Of those participants, 51 had opted for breast reconstruction. Results showed 34 per cent of participants were able to answer at least 50 per cent of the knowledge items correctly. More well educated participants displayed greater knowledge ($p=0.003$); and having undertaken breast reconstruction was associated with greater knowledge ($p=0.0001$). Participants reported feeling well informed about breast reconstruction, with an overall rating of 9.4/10 for this item; however, this was weakly associated

with knowledge scores (Pearson's coefficient 0.28). A larger validation project is yet to be completed (Lee et al, 2011).

3.2.3 Breast Reconstruction Educational Materials

A 2011 systematic review of the literature reviewed studies that had evaluated breast reconstruction educational materials between 1966 and 2009 (Preminger et al., 2011). Of the 497 articles collated, only seven met the review criteria of an evaluation study. The remaining 490 papers were descriptive or commentary papers. Only one of the seven studies evaluated a dedicated breast reconstruction educational resource (Heller, Parker, Youssef & Miller, 2008). Five of the studies evaluated breast cancer educational materials (Chapman, Elstein & Hughes, 1995; Finlayson, MacDermott & Arya, 2001; Goel, Sawka, Thiel, Gort & O'Connor, 2001; Molenaar et al., 2001; Whelan et al., 2004) with only two of these articles specifically mentioning breast reconstruction content (Chapman et al., 1995; Finlayson et al., 2001). The other article administered a survey investigating breast reconstruction information seeking on the internet (Losken et al., 2005).

The authors of the systematic review noted only two of the seven studies employed a needs analysis prior to development of educational materials (Goel et al., 2001; Heller et al., 2008). While three of the studies were randomised control trials (Goel et al., 2001; Heller et al., 2008; Whelan et al., 2004), none addressed statistical power. The format of educational materials evaluated was written, visual and audio, with some combined format educational products. Studies predominantly evaluated knowledge gain, satisfaction and decisional conflict. Most studies only included information about types of breast reconstruction and their associated complications and risks. Only one resource included content addressing expectations of breast reconstruction; another resource included information on satisfaction, with another one discussing social functioning. None of the educational materials developed covered content on sexuality or body image. Preminger and colleagues (2011) concluded further, more robust, studies employing well designed methodologies were required to evaluate the effectiveness of breast reconstruction education materials.

Finlayson and colleagues (2001) sought to explore the impact of a breast reconstruction education and counselling process on the uptake of breast reconstruction. Women diagnosed with breast cancer received a 30-minute surgeon consultation and a written booklet providing descriptions of breast cancer treatments. Plastic surgeon consultation is offered to all women who require, or choose to have, mastectomy. Following consultation women are provided with a video that details breast reconstruction techniques and their outcomes. Mastectomy was undertaken by 43 per cent of the 295 women sampled. Twenty-two of these women were not eligible for breast reconstruction, with the authors citing severe comorbidity, advanced disease and inflammatory breast cancer as reasons for ineligibility. Of the 106 women remaining, 38 per cent took up the offer of plastic surgeon consultation, with 21 per cent ultimately choosing to undergo breast reconstruction. The authors concluded the low uptake of breast reconstruction was more likely due to patient choice than access or lack of adequate information (Finlayson et al., 2001).

A CD-Rom educational resource was developed by Heller and colleagues (2008). This resource contained animated graphics, patient testimonials, photographs and specialist video explanations. Participants of this study were randomised to the educational resource group (N=66) or a control group receiving standard surgeon consultation alone (N=67). Questionnaires assessed knowledge, anxiety and satisfaction before intervention, immediately pre-operatively and one month post-operatively. Those in the intervention group were more satisfied with the sources of information they received ($p=0.03$), demonstrated greater knowledge improvement ($p=0.02$), and were more pleased with their choice of treatment and appearance of their reconstructed breast ($p=0.03$). The resource was accessed by women multiple times and shared with family and friends (Heller et al., 2008). This study was conducted at a single institution, with relatively small participant numbers for a randomised study.

In addition to Heller and colleagues' resource, the literature identified only two other dedicated breast reconstruction education resources: one of French origin (Dravet et al., 2010) and the other American (Lee et al., 2010). Dravet and colleagues (2010) evaluated their interactive DVD plus nurse consultation in addition to standard

surgeon consultation. Half of the 110 women participating learnt additional information from the DVD; however, this did not influence their choice of breast reconstruction technique. Surgeons most significantly affected women's choices, followed by the nurse, then the DVD. The DVD provided additional information to inform women as a complementary source to healthcare professional consultation (Dravet et al., 2010).

Lee and colleagues' (2010) CD-Rom presented information on surgical procedures, interactions with breast cancer treatments, recovery, adverse effects and complications, and institutional and published clinical outcome data. The authors evaluated the decision-making role and satisfaction, with the information provided via mailed questionnaire. The educational resource was reviewed by 168 women, while 87 women had standard surgeon consultation. Participants who received the resource reported being more involved in decision making ($p=0.001$), were more satisfied with the amount of information provided ($p=0.049$) and were able to recall a greater number of breast reconstruction options ($p=0.01$) at a higher rate ($p=0.01$). The authors concluded the improved recall of the intervention group demonstrated that women in this group were more informed about their breast reconstruction options. The authors also recognised the value of an internet-based resource to increase accessibility of such resources, given their resource was only available to women treated within the institution (Lee et al., 2010). It was not identified if the education resource had been updated during the three-year recruitment period and how any modification may have affected the results.

In addition to simply providing information about breast reconstruction, Heller and Miller (2004) argue that healthcare professionals need to assist women to clarify personal goals and priorities to facilitate their decision making, incorporating personal motivations, concerns and lifestyle considerations. The authors concluded it may not be possible to cover all information; however, some information, including the advantages and disadvantages of each option are essential (Heller & Miller, 2004). The literature review has identified a lack of breast reconstruction information resources that meet the information needs of women considering breast reconstruction. In particular, the complex and continuing nature of breast reconstruction decision making has been insufficiently explored. Such investigation

is required to successfully identify women's detailed information needs and develop resources to meet those needs.

3.3 Review of National Sources of Breast Reconstruction Information

A review of Australian breast reconstruction information resources was undertaken to identify current sources of information about breast reconstruction available to Australian women. Internet resources were excluded from this review and only Australian resources were reviewed to identify information relevant to breast reconstruction surgeries available for Australian women. The review revealed dedicated and comprehensive information about breast reconstruction is limited, with few breast reconstruction information resources located. The Cancer Councils of each state in Australia publish a *Breast Reconstruction: Your Choice* pamphlet. A corresponding video is also available for borrowing through Cancer Council support services. Some cancer institutes and cancer service centres have developed their own information pamphlets to provide to their patients. A breast reconstruction booklet has also been developed by a breast implant company.

The *Breast Reconstruction: Your Choice* video was produced in 1997. It provides information about LD flap, TRAM flap and implant breast reconstructions. Due to the production date, the newer technique of DIEP flap breast reconstruction is not included. The video provides information about some practical aspects of breast reconstruction recovery and adjustment, including mobility, activities, sensation of the breast and complications experienced. Several women who have had immediate and delayed breast reconstruction of varying types share their experiences. The video discusses outcome expectations of breast reconstruction, including scarring. The video does not discuss the context of breast cancer diagnosis and treatment, accessibility of breast reconstruction services, financial considerations or the complexities of breast reconstruction decision making. While the video provides valuable information for women about some of the practical aspects of breast reconstruction it does not reflect contemporary experience.

The corresponding booklet does provide further information, including financial issues, available support services, a brief question list to discuss with a surgeon, sexuality following breast reconstruction and a single set of images for each breast reconstruction type and timing. Images provided are not necessarily representative, and broader details of breast reconstruction outcomes are necessary to facilitate realistic expectations of aesthetic outcomes. Few quotes throughout the booklet provide some insight into the experiences of others who have had breast reconstruction. Booklets from each state contain similar material in differing layouts. While the booklet provides a sound overview of breast reconstruction options and some aspects of decision making; further comprehensive information is warranted to ensure women are making soundly informed decisions about breast reconstruction.

Cancer Council Australia has further developed a more comprehensive 76-page information booklet, based on state Cancer Council pamphlets. Approximately half of the booklet is dedicated to external breast prosthesis as an option following mastectomy. Advantages and disadvantages of implant and tissue flap breast reconstruction are tabled. All types of breast reconstruction commonly undertaken in Australia are discussed. Useful websites and contacts for other sources of information are included. While this resource provides more information about breast reconstruction; the detail of advantages and disadvantages of each type of breast reconstruction is still lacking.

The Westmead Breast Cancer Institute has developed a booklet providing brief introductory information about implant and tissue flap breast reconstruction. Details of the types of tissue flap breast reconstruction are not provided in this booklet. Information on recovery and questions to ask a surgeon are included. The implant manufacturing company Mentor also produces a pamphlet that not only covers implant breast reconstruction, but also introduces tissue flap breast reconstruction. Detailed written and pictorial information about tissue expansion and different types of implants is provided; a quality that is often missing in other resources.

Other sources of breast cancer information provide limited information on breast reconstruction. The National Breast & Ovarian Cancer Centre (now Cancer

Australia) published the *Guide for Women with Early Breast Cancer* and the Breast Cancer Network Australia provide the *My Journey Kit*, which contains the *My Journey Information Guide*. The Breast Cancer Network Australia information covers two B5 pages introducing breast reconstruction as an option following mastectomy, describes the common types of breast reconstruction and includes quotations from women about their breast reconstruction experience. The National Breast & Ovarian Cancer Centre resource provides more breast reconstruction information over six pages, including a summary of the advantages and disadvantages of each type of breast reconstruction. An array of books providing information about breast reconstruction is available; however, the majority are American. There are a few Australian books about breast cancer that do contain varying amounts of information about breast reconstruction options.

While some information about breast reconstruction is accessible to Australian women, a void exists between available information and the information needs of women considering the complex decisions around breast reconstruction. The multitude of information available on the internet and in books can provide irrelevant, misleading information to women that may mould their expectations of breast reconstruction. There is a need for comprehensive information that women can access as desired throughout their breast reconstruction experience, information that represents current breast reconstruction practices in Australia. More detail about the different types of breast reconstruction is required so women can make a weighted decision about which type may be best for them. Additional representative and variable images of breast reconstruction are necessary to inform women of potential aesthetic outcomes to aid realistic expectations. Further acknowledgement of the impact of breast cancer and breast cancer treatment on breast reconstruction decision making is imperative. Recovery from breast reconstruction needs to be discussed more comprehensively from both physical and psychosocial aspects.

3.4 Examining Women's Experiences of Breast Reconstruction Information Needs and Decision Making

There were few Australian studies to inform the review of current research. Breast reconstruction techniques and community expectations have changed over the past decade. The review of research conducted and the information resources available delivered information on breast reconstruction options, however, provided limited information about exactly what breast reconstruction would entail. To capture the recent experience of breast reconstruction decision making for Australian women and examine what their information needs were, a qualitative study was undertaken in Phase One.

As the experience of a breast cancer diagnosis, mastectomy surgery and subsequent breast reconstruction may affect all facets of a person's life, it was important to use an approach that enabled the totality of the women's experiences to be explored, from the perspective of these women. Qualitative research approaches give prominence to the voice of those who have the experience. Qualitative methods of data collection acknowledge the complexity and uniqueness of human experience and recognise the need to study people holistically, from a subjective perspective (Merriam, 2009). Phase One of this research sought to explore women's decision making experiences, understand the context of decision making, and identify women's information needs in relation to breast reconstruction.

3.4.1 Participants

Participants were women residing in WA, who had made the decision to undergo breast reconstruction, and had completed their initial breast reconstruction surgery in the preceding 12-month period. The twelve months after initial breast reconstruction surgery was selected as an appropriate time frame. With this time frame, the decision-making period would be reasonably recent to facilitate detailed recall, yet would also provide women with a reasonable period to have reflected on their decision making and breast reconstruction experiences.

Inclusion criteria were women who had undergone TRAM flap breast reconstruction, LD flap breast reconstruction or implant breast reconstruction within the identified one-year period; English-speaking women over 18 years of age, to provide informed consent. These three forms of breast reconstruction were the most commonly used breast reconstruction surgery techniques, both within WA and throughout Australia at the time of recruitment. These inclusion criteria enabled the identification of both women who had been diagnosed with breast cancer and those who had not experienced breast cancer, but had opted for prophylactic (preventative) mastectomy and breast reconstruction. These diverse circumstances provided a different context to the individual woman's breast reconstruction experience. Capturing these varying experiences was important to ensure that any resource developed was appropriate to all women who may consider breast reconstruction as a treatment option following mastectomy.

Women who had undergone immediate breast reconstruction and those who had undergone delayed breast reconstruction were recruited. Although women may be making similar decisions regarding breast reconstruction options, the timing of their breast reconstruction can have a significant impact on contextual considerations at the time of decision making, surgical technique and aesthetic outcomes of the reconstructed breast. To develop a resource that would be relevant to women who may choose either immediate or delayed breast reconstruction, further exploration of decision making experiences in relation to breast reconstruction timing was important.

3.4.2 Recruitment

Participants were recruited from a single metropolitan private hospital in Perth, WA. Given the lower numbers of breast reconstruction undertaken in the public sector, targeted participant numbers may not have been possible without a lengthy recruitment period exceeding 12 months. Information packages inviting women to participate in the research were distributed to the four breast reconstruction surgeons' consulting rooms. These packages contained a cover letter signed by the breast reconstruction surgeon, an information statement, consent form, demographic questionnaire (Appendix Four) and a stamped return envelope for returning the

consent form and demographic questionnaire to the researcher. A list of patients meeting the inclusion criteria was identified and the information packages were mailed by the breast reconstruction surgeon's administrative personnel.

The demographic questionnaire collected information about the participant, including breast cancer and breast reconstruction surgery details, and the individual's nomination of her preferred focus group interview date and time. Collecting information about participant's breast cancer and breast reconstruction surgery was important to record the variability of breast reconstruction experiences that would be captured. Both evening and weekend focus group interview times were scheduled to accommodate varying personal preferences. The participants remained anonymous to the researcher until individual participants made contact with the researcher.

One hundred and eleven information packages were sent out to women from the four breast reconstruction surgeons' consulting rooms. A total of 42 women responded with their consent to participate in the research, indicating a response rate of 38 per cent. Of these 42 women, six women were unable to attend the scheduled focus group interview dates. These six women were contacted by telephone or e-mail to thank them for their interest. A total of 36 women were recruited to participate in this phase of the research. The researcher contacted each participant by telephone to reiterate the aim of the research and their anticipated involvement, confirm the details of the nominated focus group interview and answer any questions the participant may have had.

3.4.3 Data Collection

To explore women's experiences of decision making, focus group interviews were selected, as this allows participants to describe their experiences by expressing their thoughts and reflecting on their actions, using the language they are most comfortable with, and enabling the meaning of their experiences to be examined (Merriam, 2009). Focus group interviews involve a group of participants with a common experience that the researcher is aiming to explore through eliciting thoughts and perceptions of their experiences. Focus group interviews have the

potential to further develop rich data through interaction of participants, stimulating further discussion and debate (Merriam, 2009). The diversity of a group of participants experiencing varying surgical contexts contributed to the richness of experiences and encouraged further exploration through discussion. The process of data analysis was sufficient to extract women's specific and differing surgical experiences.

A total of four focus group interviews were conducted, with 36 women: ten, twelve, ten and four participants in each group respectively. All focus group interviews were audio recorded by two digital voice recorders, to anticipate any equipment malfunction and potential loss of data. All audio recordings were transcribed verbatim by the same transcriber, and the accuracy of each transcript was confirmed by the researcher. Demographic data was collected from a demographic questionnaire mailed to participants (Appendix Four).

Each participant was contacted by telephone or e-mail one to three days prior to the scheduled focus group interview, both as a reminder and to confirm the venue. The focus group interviews were held in a conference room at the private hospital from which the participants were recruited. Commencement of the focus group interview saw the researcher introduce herself and reiterate the aims of the research, prior to commencing questioning and discussion, as guided by the focus group interview schedule (Appendix Four). The interviewer's facilitation of the focus group interview was critical to maintain concentration on the topic, while exploring similarities and differences in participant's thoughts, adding depth to the data. The interviewer must actively involve all participants in the questioning, demonstrating a flexible, non-judgemental approach to encourage effective interaction in a non-threatening environment (Merriam, 2009). Each focus group interview ran for approximately one and a half hours, during which time participants were provided with refreshments.

3.4.4 Data Analysis

Demographic data from questionnaires were entered into the Statistical Package for Social Sciences (SPSS) (version 16). Data entry was checked and confirmed by the

researcher. Frequency calculations were performed on the data. The focus group interview transcripts were initially content-analysed manually, with each listened to a total of three times by the researcher. The first listen enabled the researcher to check the accuracy of transcription and re-familiarise the researcher with the raw data. The second listen was used to make annotations regarding specific topics, discussions and expressions on the transcripts, allowing the researcher to get a feel for the data's meaning. The third listen allowed the researcher to further decipher the meaning embedded within the data, identify key quotations that represented the interpreted meaning of the data, and allowed grouping of common themes throughout the data. Each focus group interview was further thematically analysed within the context of the researcher's notes made during each focus group interview, and field notes made immediately after each focus group interview. Transcripts were analysed separately and then combined to identify common themes.

Data was then analysed within the qualitative analysis software of NVivo (version 7). Transcripts and field notes were entered into NVivo software as source documents. Some nodes were identified from the original manual analysis; however, several others were created upon systematic analysis within the NVivo application. Node housekeeping was performed, where node content and location were reviewed and revised as necessary. Node summaries were written from each tree node, from which the findings resulted. Qualitative data coding and analysis was confirmed by the doctoral research supervisor.

3.4.5 Participant Demographics

Demographic data was collected from all 36 participants. The age of the women ranged from the 30 to 40 year age group (N=2) through to the 71 to 75 year age group (N=1). The majority of women were aged between 46 and 50 years of age (36 per cent). Thirty-six per cent of women had completed secondary education, 33 per cent had attained diploma qualification and 19 per cent had achieved tertiary qualification. One woman had attained less than secondary education and one other had received a Masters qualification. Total combined household income exceeded $100,000 per annum for 50 per cent of women, with the greatest percentage of women (33%) reporting a household income exceeding $150,000 per annum (Table

3.2). A wide variety of occupations was reported, including: architect, fitness instructor, doctor, nurse, secretary, librarian, lawyer and home duties. The majority of women were married (83%), one woman was divorced, one widowed, two separated and two were in de facto relationships. Twenty per cent of women identified as living in a rural location, with the remaining 80 per cent living in the Perth metropolitan area.

Table 3.1: Participant Demographics

Age		Highest level of education completed		Total household income	
Age range	**Frequency N=, Per cent %**	**Level of education**	**Frequency N=, Per cent %**	**Income**	**Frequency N=, Per cent %**
30–40	N=2, 6%	Less than secondary education	N=1, 3%	<$40,000	N=1, 3%
41–45	N=5, 14%	Secondary education	N=13, 36%	$40,000–$54,999	N=5, 14%
46–50	N=13, 36%	Diploma	N=12, 33%	$55,000–$69,999	N=3, 8%
51–55	N=5, 14%	Tertiary degree	N=7, 19%	$70,000–$84,999	N=5, 14%
56–60	N=6, 17%	Masters degree	N=1, 3%	$85,000–$99,999	N=4, 11%
61–65	N=3, 8%	Doctoral degree	N=0, 0%	$100,000–$150,000	N=6, 17%
66–70	N=1, 3%	Professional degree	N=0, 0%	>$150,000	N=12, 33%
71–75	N=1, 3%	Other*	N=2, 6%		
Total	**N=36, 100%**	**Total**	**N=36, 100%**	**Total**	**N=36, 100%**

Percentages rounded to the nearest whole number

* Other identified as a hospital based nursing course and a technical college course

The majority of women had undertaken mastectomy and breast reconstruction as their only breast surgery experience (56%, N=20), while others had undertaken previous surgery to treat breast cancer and had subsequently undergone further breast surgery, including breast reconstruction in the last 12 months (N=16). Previous breast surgery performed in the past was reported to be breast conserving surgery (N=8) and mastectomy only (N=8). Twenty-one women (58%) had opted for prophylactic mastectomy and immediate breast reconstruction. Two out of these 21 women had never had a breast cancer diagnosis and had undergone genetic testing

for breast cancer, while the other 19 women had a previous diagnosis of breast cancer and had since decided to preventatively have a contralateral mastectomy to remove their non-diseased breast. For those women who had been diagnosed with breast cancer, the time elapsed since diagnosis ranged from five months to 15 years; however, the majority of participants (62%) had been diagnosed in the last two years. Time lapse between diagnosis and the date of initial breast cancer surgery ranged from four days to seven months, with the majority of women (67%) undergoing surgery within 28 days of diagnosis.

Four women underwent implant breast reconstruction and 32 women underwent LD flap breast reconstruction. Seventy-eight per cent of women opted for immediate breast reconstruction (N=28), with eight women having delayed breast reconstruction (22%). Four of the 32 women had also undergone a previous breast reconstruction surgery; specifically TRAM flap breast reconstruction. One of these four women had a second breast reconstruction due to a failed breast reconstruction, while the other three women had the opposite breast reconstructed later. The time lapse between multiple breast reconstructions was between two and ten years.

Twenty women (56%) experienced post-operative complications following breast reconstruction surgery, with five women experiencing multiple complications. The types of complications experienced were mostly seroma/haematoma (N=14), infection (N=5) and skin necrosis (N=4). Thirty-nine per cent of women had their complications treated with surgical procedures requiring hospitalisation (Table 3.2).

Table 3.2: Post-operative Complications

Number of complications*		Type of complication		Treatment required	
Number of complications	**Frequency N=, Per cent %**	**Post-operative complication encountered***	**Frequency (N=)**	**Treatment**	**Frequency (N=)**
0	N=16, 44%	Infection	5	None	11
1	N=15, 42%	Seroma/ haematoma	14	Antibiotics	5
2	N=3, 8%	Skin necrosis	4	Surgical procedure NOT requiring hospitalisation	1
3	N=2, 6%	Injury to site	1	Surgical procedure requiring hospitalisation	10
Total	**N=36, 100%**	Keloid scarring	1	**Total**	**27**
		Pulmonary oedema	1		
		Leaked tissue expander	1		
		Implant capsular contracture	0		
		Partial flap loss	0		
		Full flap loss	0		
		Abdominal weakness/ hernia	0		
		Donor site necrosis	0		
		Total	**27**		

Percentages rounded to the nearest whole number

* Complications refer to the most recent or only breast reconstruction procedure.

Twenty-four of the women (67%) received adjuvant therapy, with nine of those women (38%) reporting having more than one type of adjuvant therapy. Chemotherapy was undertaken in 19 instances, radiotherapy in four instances and 11 women received hormone therapy. The duration of adjuvant therapy ranged from 12 weeks to five years.

3.4.6 Women's Experiences of Breast Reconstruction Information Needs and Decision Making

Content analysis of the focus group interviews identified four main themes of women's experiences: confronting cancer, seeking information, multi-layered decision making and the breast reconstruction marathon (Figure 3.2).

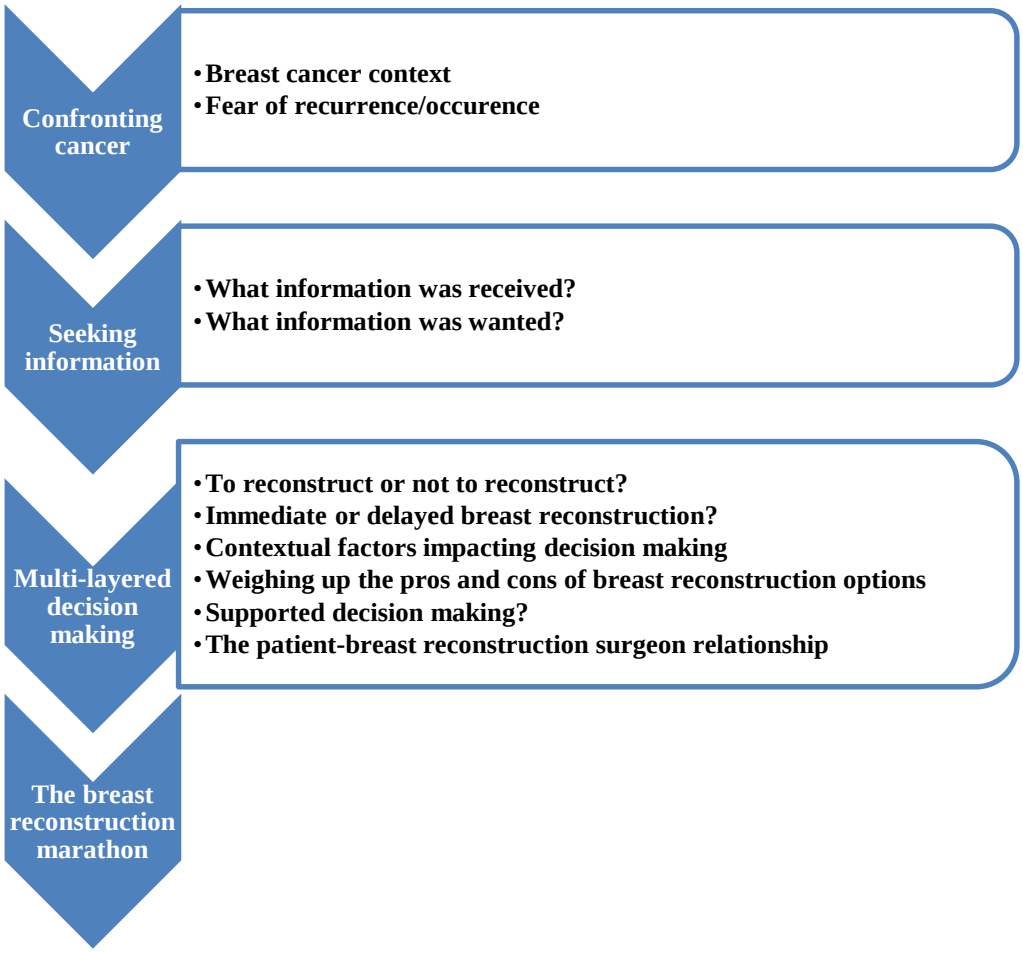

Figure 3.2: Thematic Schema of Women's Experiences of Breast Reconstruction Information Needs and Decision Making

3.4.6.1 Confronting Cancer

Thirty-four of the 36 women had been diagnosed with breast cancer. For these women the dominant context surrounding breast reconstruction decision making and information seeking was their cancer diagnosis. Women's initial thoughts following

diagnosis centred on being confronted with their own mortality; the possibility this disease may end their life; and how this would affect their family, in particular their children:

> If you've got young kids, or any family I suppose... it's kind of; 'Am I going to get to see them grow up? Is my husband still going to love me after I've had a breast off? How am I going to feel about myself and my own image when I look in the mirror? Am I going to survive? Am I going to be here in ten years time? Do I need to start doing, you know, all those little tidy up things?'
> (Linda)

> How do I look at the face of my eight year old and think, 'Mummy may not be here anymore'?
> (Mary)

Undergoing adjuvant therapy was a reminder of the cancer and its impact on the woman's body. 'Coming through' adjuvant therapy was highlighted as the true battle of the breast cancer experience for these women, while the breast reconstruction experience almost paled into insignificance:

> I just think it's (breast cancer and breast reconstruction) a dog of a trip, but at the end of it, if we can all get to the end of it, and we've got a supporting person or friends … you can learn so much from it. It's tough, but I found the chemical side (chemotherapy) much tougher than the surgical side (mastectomy and breast reconstruction)
> (Carol)

Despite the hardship of dealing with breast cancer diagnosis and undergoing breast cancer treatment, for some women, an enlightened perspective on life came from this experience:

> I remember running around the corner as fast as you can; on chemo, no hair, no boob; and I thought, 's**t that's ugly'. Put my beanie on and had a shower. That was the only thing I could do to sort of change, 'cause I was very grey looking and horrible. But what chemotherapy and everything else taught me … is it's what's on the inside. What's on the outside; whether I've got one boob, two boobs, no boobs—and I've had all of that; doesn't change who I am. This is just the vessel that I've been given to do this journey which is life; and one boob, two boobs, no boobs, doesn't change who I am.
> (Linda)

Women's fear of cancer triggered a sense of urgency for some women, wanting to eradicate the cancer from their bodies as soon as possible:

> I felt like I was a ticking time bomb as soon as I found out, and I just wanted it all done and gone. I just couldn't wait to get going into surgery, I didn't really want to spend time on second opinions, I just wanted the surgery to get rid of the cancer. I was really afraid of dying.
> (Barbara)

The issue of the women's mortality continued long after initial diagnosis through a strongly embedded fear of recurrence. This fear may have lessened over time, but it never went away. It increased at times, such as routine follow ups:

> It just seemed to be always at the back of my mind.
> (Susan)

> Each time I'd go back yearly for examinations and tests and whatever ... there was a problem, so I said 'Take it off' and had them both reconstructed at the same time.
> (Carol)

Fear of recurrence was a key factor for those who elected to have a contralateral prophylactic mastectomy, despite no evidence of malignancy in that breast:

> This just isn't good enough. What happens if it comes back on the other side? I had all these … doubts coming into my head. And I said, 'Is this my best option?', and he (breast surgeon) said 'No, your best option is mastectomy'. I just said 'Well I'll have mastectomy then, in fact I'll have a double mastectomy', and he said 'Right okay, if that's your decision then', and that was it.
> (Deborah)

Several women noted that the decision to remove their healthy breast was very straightforward and logical to them, considering that recurrence of cancer was the other possible alternative:

> But I think when you're thrown with life and death, my kids won't see me when they're ten ... you make the decision so quickly.
> (Susan)

For others, the decision to act preventatively was too difficult to make within the context of a recent breast cancer diagnosis:

> If I hadn't been conquered with the cancer thing, trying to get over that, and was thinking clearly, I probably would have had them both done at the same time. But I was just trying to deal with cancer at the time.
> (Susan)

The cosmetic outcome of having only one reconstructed breast was a consideration in opting for contralateral prophylactic mastectomy. Removing both breasts and having them reconstructed at the same time was seen by some women to maximise aesthetic outcome by ensuring both breasts and nipples would look similar.

Women who made the decision to remove the healthy breast at a later time after mastectomy experienced body image issues related to asymmetry:

> My younger sister said 'Why don't you have them both done at the same time?' and I just looked at her in horror and said 'Why would you be bothered messing with something that's fine?' But in retrospect after having had one done, my right breast looked so abnormal, 'cause I've breast fed three kids and it's (breast) down here. This one's sitting up here like this, happy as Larry and I'm thinking 'This doesn't look good'.
> (Sandra)

Two women opted for bilateral prophylactic mastectomy and breast reconstruction due to a strong familial history and positive results from genetic testing. The decision for these women was driven by an understandable fear of breast cancer, and the need to prevent this occurring; prophylactic bilateral mastectomy was a practical and proactive step. Their stories depict an experience of breast cancer in the absence of a breast cancer diagnosis. Both women having bilateral prophylactic mastectomy opted for immediate breast reconstruction. The decision to reconstruct their breast was inherent in their decision to have bilateral prophylactic mastectomies. Preventative mastectomy was seen as an attempt to preserve their lives and bilateral breast reconstruction was seen as an obvious subsequent decision.

One of these women noted that an added incentive to undertake bilateral prophylactic mastectomy was to avoid the perceived impact of adjuvant therapy if a diagnosis were to eventuate:

> I was between [an] eighty-five and ninety-five per cent chance of getting it (breast cancer) … and they said 'You're most probably going to have a mastectomy whether you want it now without chemo or down the track with chemo', so…
> (Kathleen)

While the focus of this research was the breast reconstruction experience, not the breast cancer experience, it became clear the breast cancer experience was the unwavering context within which women lived their breast reconstruction

experience. For these women, the breast cancer experience was not separate from the breast reconstruction experience, but was part of one ongoing journey. The diagnosis of breast cancer raised the issue of mortality for these women, which they had to digest and continue to grapple with throughout their breast cancer and breast reconstruction experience. Several women commented that due to the flurry of decision making about, and protracted recovery from, breast reconstruction, they had never adequately processed and dealt with having a diagnosis of breast cancer. This was often something that returned to the forefront of their minds once the breast reconstruction process was complete.

For the two women who chose to undergo bilateral prophylactic mastectomy, breast cancer also played a significant part in their decision making, but had less of a part in their ongoing breast reconstruction journey. Whether experiencing a fear of recurrence or a fear of occurrence, confronting breast cancer was the first in a long line of challenges for these women.

3.4.6.2 Seeking Information

Information seeking practices varied among the women interviewed. Some women wanted as much information as they could get, while others wanted minimal information on specific breast reconstruction topics. While all women stated that they were supplied with pamphlets, and had discussed breast reconstruction with their breast reconstruction surgeons, all women sought further information to meet their needs. The information provided by the breast reconstruction surgeons focused on the surgical procedure, post-operative recovery and surgical complications. Women described breast reconstruction surgeons were open to providing any information when requested; however, time-restricted consultations limited the volume and breadth of information imparted. Some women who had recently been diagnosed with breast cancer commented that information given by the breast reconstruction surgeon during these consultations was often not retained:

> It was really hard. I was in shock really. I had to go back and see both of them (breast surgeon & breast reconstruction surgeon) a week later because I couldn't remember even being there very much.
> (Barbara)

For other women who had pending mastectomy surgery, there was a short period for decision making, which the women described as ‘frantic’ and ‘rushed’:

> I felt it was really frantic. I was trying to get as much information as I could. I didn’t know anything.
> (Susan)

> My husband tried to sort of slow the process down because he said, ‘We just can’t absorb this’.
> (Patricia)

During this period, some women ‘wanted to know everything’, while others ‘didn’t want to know too much’:

> You need as much information as you can possibly get, if you don’t want to read it you don’t have to. It just needs to be there and I think you select what you want to read.
> (Sandra)

> I just decided that I did trust my surgeons and I found them very accessible and easy to talk to, and once I had left their surgery I wouldn’t think about it anymore and I tried not to.
> (Sharon)

Sources of information included the internet, national and state-based cancer organisations, videos and books. The women expressed concern regarding the variability of the quality of these resources, the lack of credibility of web-based material, the predominance of American information and currency of information:

> Not being a medical person, there was a lot in it (organisational report) that I sort of couldn’t really decipher anyway.
> (Nancy)

The most useful source of information for women was talking to other women who had experienced breast reconstruction. Several women were put in touch with other women who had previously undertaken breast reconstruction by their breast reconstruction surgeon. Women found this information source most valuable to gain insight into the procedure and recovery itself, the outcomes of the surgery and the emotional and physical consequences of the experience:

> (Woman who had breast reconstruction) phoned me up … and I was able to speak to them and I found out what they’d gone through. And although our backgrounds were slightly different, it was still really interesting for me just to find out what they had gone through and their procedures … So that was really helpful, just to hear to a human voice on the end of the phone and even to talk about some of the emotions. We didn’t know one

> another well enough to kind of go into the real nitty gritty stuff, but it was reassuring just to hear a voice at the end of the phone who'd gone through what I was about to go through.
> (Deborah)

Most women felt that the information received and sourced was sufficient to make the initial decisions surrounding breast reconstruction. For others the volume, detail or clarity of information made comprehension difficult. However, it was clearly articulated by women that the information received focused on the clinical, with little information provided on the practical and emotional aspects of the breast reconstruction experience:

> What I wasn't informed about was the emotional side, or how you're going to feel afterwards, what your limitations are, you know.
> (Karen)

Women wanted more practical information on day-to-day activities that they would, and would not, be able to do, and how long this extended physical recovery might take (particularly for breast reconstruction surgeries where muscle had been moved). This would provide women with a clearer recovery trajectory and enable them to plan their recovery and better accommodate family life for that period.

Other topics that women stated were lacking included: sensation of the breast, arm movement and strength; rebuilding/strengthening the remaining muscle; difficulty positioning; and subsequent impact on other areas of life such as sleep, child care duties, driving, leisure activities and sports:

> I think for me it was more post-op that I most probably needed help with. To make the decision to be reconstructed was easy because I still wanted two boobs, but you know the dressings, the infections...
> (Donna)

> There's no new information. The brochures are very good in describing what they will be performing on you but I certainly found trying to seek out any other information as to, well, how long will I be tight across the back? and … what should I be feeling in two months time, three months time, four months time? I found there was very little information on that and where to go for it.
> (Brenda)

The women identified a lack of visual information regarding what their breast might look like, not simply when healed, but a longitudinal visual representation throughout stages of recovery and surgical refinement, as a significant unmet need in the decision-making process:

> But the number one thing I wanted was pictures. I really, really wanted pictures to see what it was going to be like and I could hardly find any.
> (Susan)

Not only did women want to know what the breast would look like and how they could manage their recovery, but also how they would or should be feeling about their new breast. Women felt that follow up of a psychosocial nature was required, but was lacking:

> There is not enough information for women as to how they should be feeling, what to expect.
> (Diane)

> There's not enough psychological and emotional support and I don't even think when you're in hospital that you get that.
> (Linda)

Women also felt that some form of information was required for partners, who do the best they can to support the women, yet also do not know how they should be feeling or reacting to the women's breast reconstruction experience:

> I think … just all the different aspects. I think it needs to cover sexually for them (partners), I think it needs to cover what our emotions are going to be like, you know. They (healthcare professionals) say six weeks; they think that in their head we're going to be perfect after six weeks. I've got a fantastic supportive husband but I think he had to deal with it more than what I did, because I was in control of the situation. Like, get 'em off, let's move on. Whereas for him, he's a bit of a thinker and I'm impulsive so, I don't know, I just think just a male lingo is what they need more so.
> (Susan)

Some women wanted to know more about complications than other women. For those who had experienced moderate to severe complications they felt if they had known more about what to look out for, their complications may not have progressed so far and they may not have suffered so much. These women described this as 'education on how to care for their new breast'.

While information was primarily provided by the women's breast reconstruction surgeons focusing on the physical aspects of breast reconstruction, all women sought further information. Missing information included aspects of the long-term practical and emotional recovery from breast reconstruction. There were often time restrictions on decision making when mastectomy surgery was pending, which gave some women little time to process the information they had received and consider their breast reconstruction options.

3.4.6.3 Multi-layered Decision Making

Overall, the decision of whether to undergo breast reconstruction or not was a significant, yet somewhat 'easy' decision for these women:

> I think making the decision to have the reconstructions was most probably one of the easiest bits because … it's your vanity.
> (Donna)

Women described the decision making experience as a 'process': it was not simply a single decision, but encompassed multiple decisions made over an extended period. The decisions surrounding breast reconstruction included not only whether to have a breast reconstruction or not, but when to have a breast reconstruction (immediate or delayed), what type of breast reconstruction to have (TRAM, LD or implant breast reconstruction), what size to make the reconstructed breast, and whether further procedures should be undertaken, such as nipple and areola reconstruction, or additional procedures to refine both breasts to a symmetrical pair.

The motivation to reconstruct was similar for those who had immediate breast reconstruction and those who had delayed breast reconstruction—not wanting to live without a breast. Those choosing to have immediate breast reconstruction simply did not want to experience living without a breast, while those women who had initially undertaken mastectomy alone described the difficulties resulting from living without a breast. Most women (78%) underwent immediate breast reconstruction. These women described the advantages foreseen with having an immediate breast reconstruction, including one surgery and therefore one general anaesthetic and one subsequent recovery (albeit a longer recovery). Women were also advised by healthcare professionals that immediate breast reconstruction, particularly where

skin sparing and nipple preservation were possible, might result in a more symmetrical and superior aesthetic outcome:

> You're going through hell anyway, so to have it all done at the one stage you don't have to go back and go through the whole lot all over again.
> (Janet)

There was consensus among women choosing immediate breast reconstruction that waking up with something was better than waking up with nothing. Women wanted to avoid the anticipated psychological distress of living with mastectomy. In some instances this resulted from hearing about the experiences of close friends and loved ones:

> For a long time she (friend) had one completely flat side of her chest and the other a normal breast. And I saw the difficulties she had as far as swim suits and then, you know, little things floating in the pool afterwards and she'd grab it and shove back in. And I just thought 'No, I don't want to do that'. If, when they come off, it was always a when they come off, I'm going to have a reconstruction at the same time.
> (Shirley)

> I don't think I could have coped as well if I hadn't had an immediate reconstruction. I think you go through so much with your self-esteem anyway ... when you go through the cancer treatment, with losing your hair and everything. When I had my operation and I woke up afterwards and I kind of looked under my gown and it just looked like I still had breasts ... I didn't feel any grief for losing my breast.
> (Carolyn)

Several women reported thinking that they would not feel 'normal' living with mastectomy, describing concerns surrounding their body image and self-esteem. These scenarios often focused on functionality, cleavage and femininity. How they would appear to others affected how they felt about themselves:

> Come hell or high water I wanted a reconstruction, because something has got to be better than nothing. Jumping into the ocean and have a prosthesis float off towards Rottnest (coastal island) was not in the equation.
> (Janice)

> You know I was born with two and I want to go to my grave with two, even if the silicone sits on top.
> (Mary)

Some women who opted for delayed breast reconstruction did not feel they were ready to make decisions about further surgery at the time of their diagnosis, identifying this was not a priority for them:

> A lot of women do have the mastectomy, see how it goes, the site sort of actually gets better and then make your decision in good time, rather than be rushed into having the mastectomy as well as the reconstruction at the same time. And I think that's probably, from my experience ... a good thing to do.
> (Nancy)

Other women described the impact of mastectomy on their self-image as the driver in their decision to undergo delayed breast reconstruction:

> I was always big busted. At first, when I had it (mastectomy) done I thought 'Yeah, I'm quite happy with little boobs'. But the longer it went on, it's not normal for me. That's why to me it wasn't an option; basically reconstruction was going to be done.
> (Kathleen)

Some women were advised by healthcare professionals against having immediate breast reconstruction, due to the urgency of adjuvant therapy as a treatment priority. In some cases, adjuvant therapy was expected to be detrimental to the reconstructed breast and therefore surgery was delayed until cancer treatment was completed.

In addition to the context of a breast cancer diagnosis and the multiple decisions that women make about breast reconstruction, other individual factors influenced women's decision making. The contextual factors incorporated personal, familial, financial and residential considerations. In most instances, women's breast reconstruction options were limited due to these factors.

Seven participants resided a significant distance from Perth and had to travel to Perth for breast reconstruction surgeon appointments and breast reconstruction surgery. Breast reconstruction surgeons were scarce in these areas:

> I know in (town name) no-one has a Lat Dorsi or a TRAM flap ... I don't know whether the surgeons can't do it, but everyone there gets implants and the biggest implant they go to is a B.
> (Susan)

> I did sort of say 'You know, a TRAM flap', and he (breast reconstruction surgeon) said "Well…if we were in New York or Europe perhaps, but I have a lot of success with Lat Dorsi'. I went 'Okay'.
> (Linda)

Financial implications also played a part in women's decision making. Several women noted breast reconstruction was not covered under their private health insurance, as it was considered 'aesthetic'; therefore, leaving women to cover the costs of the surgery:

> And when we looked into this (private health insurance), they (private health insurer) said 'however, if I could have myself certified as being psychologically damaged and that the reconstruction was because I was suicidal then it would be free, or it would be covered by Medicare'. And I don't think that that's exactly right. I mean having a reconstruction following cancer and surgery is quite a different matter to just having a breast (augment).
> (Sharon)

Women without private health insurance struggled with the surgical waiting lists in the public sector. As a result of not wanting to wait the anticipated several years, some women funded their surgery and hospitalisation outright within the private sector, where breast reconstruction was readily accessible.

The type of breast reconstruction being considered also had financial implications, with some women stating they could not afford the larger bill from a longer post-operative recovery period in hospital and away from work. Once women had acknowledged these hurdles of inequity, they could then begin to weigh up their decision within the context of their personal lives.

Family was a large part of the decision, with regard to time away from the family and organising the care of children not to disturb family routines. The longer the physical recovery, the greater the impact on family lifestyle:

> I need to get on with my life and get my family prepared and ready for whatever's coming next and I need to take this little kid to year two and make everything absolutely as normal as possible for as long as possible.
> (Shirley)

> It was really helpful to me to be able to plan how disabled I was going to be following the operation in terms of child care, work, what care I needed,

> to help around the house, that sort of thing. It just made the planning part of it much easier.
> (Sharon)

Work commitments meant women often had limited time to recover before they needed to return to work:

> I mean I was running a business. I didn't have time to be messing around with long recovery periods and things.
> (Cheryl)

Women retrospectively identified physical limitations of some surgical options interfering with their ability to interact with their family day-to-day:

> To me, I'm finding being a young mother … I was right into sports, I've got boys, and I can't do the things I used to be able to do. I used to play baseball with my boys, I used to do flying fox. So there's a lot of things that I'm restricted to do now and I would have liked to have more information on that.
> (Dianne)

Women reported weighing up the perceived positives and negatives of the differing types of breast reconstruction surgery available, using the information they received and the personal experiences of family, friends and acquaintances who had previously experienced breast reconstruction.

Two women had previously undertaken TRAM flap breast reconstruction, subsequently having a second type of breast reconstruction (one woman due to a failed TRAM flap, while the other woman had her other breast reconstructed). These women discussed the advantages of TRAM flap breast reconstruction being use of the body's own tissue, avoiding a foreign material being inserted into their body, and the added bonus of a simultaneous 'tummy tuck'. Information resources informed women that TRAM flap breast reconstruction often gave superior aesthetic results to the other surgical options available. The disadvantages of TRAM flap breast reconstruction included it being the most invasive surgical procedure with the longest physical recovery period. The recovery was viewed as taxing, disabling the woman for a lengthy period of weeks to months. Some women retrospectively spoke about their unawareness of the immensity of the TRAM flap breast reconstruction operation:

> I had such a big shock about the whole thing. I just did not have my head around what a big operation it was. The doctors were good and they explained the procedures and all that, but I just thought 'Oh yeah, they'll cut you here … and they'll do this'. But I just didn't have my head around that it was a six hour operation.
> (Brenda)

Thirty-two women underwent LD flap breast reconstruction. The LD flap breast reconstruction was favoured as it was a shorter operation with a shorter recovery than the TRAM flap breast reconstruction, yet was still an autologous form of breast reconstruction, using the woman's own body tissue. Disadvantages to the LD flap breast reconstruction included the inconvenience and uncomfortableness of the tissue expander expansion process:

> When I was having the tissue expanders done, I was going to (breast reconstruction surgeon) twice a week. I mean, the pain was excruciating, it was like having children that you haven't breast fed for like a year.
> (Gloria)

Women having LD flap breast reconstruction described the functional difficulties of having surgery on the back and front of the body:

> If you've had the LD done, you know, your back muscle's sore so you can't lie on your back and then when you tip over, boobs … and it's like killing you. And if you're a tummy sleeper well that goes out the window'.
> (Donna)

Impaired arm movement was an issue for several women undertaking LD flap breast reconstruction; however, some women noted that they regained full arm function after some months with exercise and, in some instances, physiotherapy.

Some women identified that neither LD, nor TRAM flap breast reconstructions were an option, as they did not want their muscle interfered with in any way. Four women underwent implant breast reconstruction:

> I didn't want TRAM flap or Latissimus Dorsi because, well, my body is my tool, so to sort of interfere with muscles that I use while I'm teaching and exercising was not really an option.
> (Beverly)

Implant breast reconstruction was favoured by these women as it has the shortest operation and physical recovery time of the three breast reconstruction surgical options. Some women also commented they were not eligible for TRAM or LD flap

breast reconstruction, as they did not have enough tissue to create a breast mound; therefore, implant was the only feasible option for them. Disadvantages to implant breast reconstruction were identified as the implants not looking or feeling natural and resulting in obvious asymmetry with the natural opposing breast:

> I needed to know that information before, that the implants were so hard and it wasn't so much the look it was how I'd feel with them, the uncomfortableness of them.
> (Sandra)

Women generally described wanting to make the decision of whether to undergo breast reconstruction independently. Although their partners were very supportive throughout the decision-making process, they were not actively involved. Once the decision to have a breast reconstruction was made, subsequent decisions in the process were heavily guided by the breast reconstruction surgeon.

> The other decisions depended on their (breast reconstruction surgeon) expertise and education. You rely on them ... especially when you're feeling you're so vulnerable.
> (Pamela)

> They (breast reconstruction surgeon) know the best surgery to give, I mean a plastic surgeon it's all about the result isn't it? So I think yeah, they will recommend what's going to give the best result. I mean it may not always be what you think is best for you.
> (Catherine)

Other women were told by their breast surgeon that they would have a breast reconstruction, what type they would have and when they would have it. In these few instances shared decision making was not undertaken and these women's consideration of treatment options was limited by their surgeons.

> (Breast surgeon) 'And you will have reconstruction'. I went 'What does that mean?' He said 'Oh well, we'll send you off to a plastic surgeon, but basically he'll take a muscle out of your back and make another breast and when you wake up you'll have two breasts'.
> (Donna)

Women reported both strong support and, in some instances, a lack of support from those around them. Women described instances where family and friends distanced themselves from the decision-making process, as they felt it was a personal and individual decision only the woman herself could make, yet remained supportive of whatever the woman's decision was:

> All they (children) could just sort of say ‘Oh whatever you decide Mum we’ll support you’. That was what they said and that’s what my husband said as well, you know ‘Whatever you decide we’ll support you’. But they can’t cope with that sort of thing as well because they’re emotionally involved too.
> (Nancy)

Women undertaking bilateral prophylactic mastectomy described a lack of support, feeling others did not believe their decision making experience was difficult, as they did not have a cancer diagnosis.

> [B]ecause I was young, I was fit, I should be all right to cope with it. I didn’t have cancer so I didn’t need any support?.
> (Kathleen)

Several women also described that others lacked of understanding of women’s reasoning behind both deciding to have a breast reconstruction and the type of breast reconstruction chosen. This resulted in additional pressure on women. One woman described having to reassure others about her decision, rather than having others support her decision:

> But she was saying ‘Oh you don’t need to do it, if you’re just doing it for, you know, vanity and for your husband, don’t do it, he’ll still love you the same’ and da, da, da. And I’m saying ‘Well it’s not for him, it’s for me’. I mean it was, you know, he was happy that I did it, but it was for me’.
> (Sandra)

A recurring theme for most women seemed to be friends and family sharing second hand horror stories of others breast reconstruction experiences. Women found this frustrating and unhelpful to their decision making:

> Please don’t tell me anymore stories about your second cousins’ wife’s sister. I don’t want to hear anymore, just do not give me any more information.
> (Shirley)

> But sometimes you get misinformation because they haven’t really had it themselves but they’ve heard their neighbour or whatever and they love to share it with you.
> (Mary)

Through women’s accounts of their breast reconstruction decision making, it became clear that their relationship with their breast reconstruction surgeon held great importance. All women expressed the need to have a breast reconstruction

surgeon they trusted with this very important aspect of their lives. It was imperative women were confident in their surgeon's knowledge of what was best for them:

> You have to pick the one (breast reconstruction surgeon) that suits you. They're operating on an intimate part of your body so you've really got to feel that they've got your best interests at heart. It's not about their agenda or what they're trying to achieve, it's about what you want and you've got to put your whole, one hundred and ten per cent trust in them.
> (Linda)

> They're (breast reconstruction surgeon) not just treating the cancer, they're treating the whole person and your family.
> (Elizabeth)

Breast reconstruction surgeons played a significant role in women's decision making. Women held great respect for their breast reconstruction surgeons and generally felt exceptionally supported by them. There was an essence of 'surgeon knows best' expressed throughout women's decision making. Some women were minimally involved in the decision-making process about their breast reconstruction.

Women described two types of breast reconstruction surgeon consultation: those who encouraged shared decision making and ensured the woman was comfortable with the agreed option; and those who restricted women's choice and impressed certain options upon women with minimal discussion or consultation. Women felt obliged to go with the recommendations of their breast reconstruction surgeon, leading to a positive outcome for most; but this left a few others feeling unsure of the outcome they had achieved:

> And you sort of go with the surgeon. If he says 'No, for best results go this way', but I'd made my mind up when I walked into the surgery that I didn't want (Lat dorsi). I just wanted implants, I didn't want the Lat Dorsi 'cause I didn't want the scarring down my back, I was scarred enough … And when he walked in, I said 'I don't want it, I don't want it'. He just went 'it just won't look good'. Then he showed me pictures … so he talked me around to it because he said it would give the best results, whether that's now true or not? But he's reconstructive surgery, so I sort of thought 'if he's pushing me down that avenue then it must be the best way to go', as reluctant as I was.
> (Brenda)

> He (breast reconstruction surgeon) came in and he grabbed it (body part) and he said 'Oh yeah, I think that'll be enough' and … he said 'I'll tell you why I did that when you're dressed' and I'd already guessed why he did it. He grabbed this one and he said 'See that? I've got to be able to get that

> from here', he said 'It's not going to happen', so you just get reduced to a piece of meat.
> (Shirley)

Women experienced the extremes of support throughout their breast reconstruction decision making, which was on occasion complicated by unhelpful information or input from family and friends. While partners were not actively involved in decision making, they were very supportive of the women's decisions. Many women sought support for their decision making from their breast reconstruction surgeon.

3.4.6.4 The Breast Reconstruction Marathon

Overall, women described their breast reconstruction experience as a 'process' or 'journey'. This was not just a single surgery, but an ongoing experience affecting every facet of their lives, with multiple treatment decisions to be made along the way. The recovery from breast reconstruction was voiced as the 'rehabilitation', demonstrating the magnitude and meaning of the experience for women. Women's breast reconstruction surgeries often involved multiple surgeries, having significant effect on the financial, familial, physical and emotional aspects of their lives:

> I had to come up (to Perth) three or four times for the expander to be enlarged and then the second op after that and then, you know, another one maybe if I have a nipple tattooed.
> (Nancy)

> And by definition, the conditions that we have or had or continuing to have, whatever, they necessitate lots of visits to different medical practitioners, So I think it's something that actually develops as you go along and bit by bit, you're stronger and you're knowing more about what's happening and what to expect.
> (Shirley)

Of those women who have experienced breast cancer, several felt breast reconstruction was a positive result from the negative experience of breast cancer:

> I would really have to say that I don't know how I could have looked in the mirror, grey skinned, bobble eyed, no hair with only one breast. I think I would have just fallen into a hole, crawled back into bed, pulled the doonas over my head and just not bothered to get out. So that was a really tough time, at least it was made better by having two breasts. At least I still felt like a woman.
> (Ruth)

> And this (breast reconstruction) is a really positive thing for you, whereas the actual cancer and chemotherapy and all the follow-up treatments is a real negative drag and you sort of think 'Oh, how did I get so lucky'. This is positive'.
> (Judith)

However, some women described that the enormity of the breast reconstruction experience detracted from dealing with the personal experience of breast cancer:

> I've finished all the reconstruction and the day it finished, I then can concentrate on having breast cancer. So I realised that the last eighteen months I haven't come to grips with the fact of having breast cancer.
> (Janet)

Throughout the interviews, women discussed different aspects of the impact of breast reconstruction from an emotional and psychosocial perspective. One woman expressed her journey to the group through her poetry, *'The Reconstruction Marathon'*. Undertaking breast reconstruction was a profound experience for the women. The breast reconstruction experience extended over a prolonged period of one to two years, raising issues of self-esteem, body image and emotional recovery. Breast reconstruction affected all facets of the woman's life. It became clear that women were not adequately prepared to navigate this experience. Breast reconstruction was seen as a positive experience by the majority of women, with no women identifying any regrets about their decision to have a breast reconstruction.

3.5 Discussion

Women experienced breast reconstruction information seeking, decision making, procedures and recovery within the context of breast cancer diagnosis and treatment. Women's lived experience of breast reconstruction was not separate from this context. Breast reconstruction was perceived by women as a positive outcome of breast cancer; however, the 'marathon' of breast reconstruction surgeries and physical and emotional recovery often detracted from women dealing with the psychological implications of a breast cancer diagnosis. Any resource developed must acknowledge this entwined experience and provide information on the psychosocial aspects of breast reconstruction within this context.

Women expressed the initial decision of whether to undergo breast reconstruction was an 'easy' one. The main driver in deciding to undergo breast reconstruction was fear; whether this was a fear of breast cancer recurrence for those who had already been diagnosed once, or a fear of an initial breast cancer diagnosis for those who chose bilateral prophylactic mastectomy. Another factor reported to weigh heavily in women's decision to reconstruct their breast/s was body image concerns, experienced in anticipation of mastectomy (for those choosing immediate breast reconstruction) or as a result of having lived with mastectomy (for those opting for delayed breast reconstruction). Women's concerns focused on wanting to feel 'normal'; how they appeared to others, but also to themselves; and how their breasts made them feel about their femininity and role identity. Similar motivations for choosing breast reconstruction have been identified in other studies (Alderman et al., 2011; Begum et al., 2011).

The majority of women chose to undergo immediate breast reconstruction to avoid living with mastectomy and to maintain their feminine identity and appearance; this has been commonly identified in other studies (Alderman et al., 2011; Begum et al., 2011; Gopie et al., 2011; Lee et al., 2011). Those opting for delayed breast reconstruction felt they were not ready to make such a big decision, and chose to focus on breast cancer treatment as their priority. The need for women to focus on their breast cancer treatments and avoid other complicating decisions or treatments during this time is a rationale expressed in other research (Alderman et al., 2011; Begum et al., 2011). A Cochrane Collaboration intervention review comparing outcomes of immediate and delayed breast reconstruction found only one randomised control trial. This 1983 study by Dean, Chetty and Forrest demonstrated less psychiatric morbidity with immediate breast reconstruction compared to delayed breast reconstruction; however, the study was considered methodologically flawed due to limited data, high risk bias and inadequate reporting of outcomes (D'Souza, Darmanin and Fedorowicz, 2011). Despite the immediate replacement of the breast, a woman may still grieve for the loss of a breast even after a breast reconstruction (Hill & White, 2008; Nissen et al., 2002).

The information seeking practices of women varied, with some women wanting to know everything about breast reconstruction and others wanting to know very little.

Such variation has been reported in the breast reconstruction literature (Brown et al., 2000; Hill & White, 2008; Wolf, 2004b). Previous studies have also identified breast reconstruction surgeons as the primary source of information (Begum et al., 2011; Brown et al., 2000; Hill & White, 2008; Lee, Gray & Lewis, 2010). Warren and colleagues' (2012) discussion of knowledge acquisition in early stage breast cancer patients, based upon the work of Mendlinger and Cwikel (2005/2006), is reflected in these findings. The primary knowledge acquisition exhibited by these women was authoritative knowledge imparted by clinicians pertaining to technical knowledge detailing procedural information. Another type of knowledge acquisition—embodied knowledge gained from personal experience and observation of others' experiences—was desired by women in the form of information imparted by women who had previously undertaken breast reconstructions. Women reported this to be a most valuable source of information.

Women expressed concern about the relevance and reliability of information on the internet. The internet is a common source of information for women considering breast reconstruction (Losken et al., 2005; Macdonald et al., 2010; Sheehan et al., 2007; Wolf, 2004a). Women's concerns about accessing the internet for breast reconstruction information are warranted. A study by Macdonald and colleagues (2010) identified the most frequently accessed sites were not necessarily evaluated as quality sources of breast reconstruction information. Unguided access to internet information is fraught with potential misinformation. Information on the internet is not regulated, may not be reliable or current, and may provide information that is not applicable to the information seeker; for example, specific breast reconstruction techniques that are not commonly performed in the country the woman lives in. While the internet provides an easily accessible wealth of information, women accessing breast reconstruction information on the internet should be guided to use reliable and relevant sources.

Information that was found lacking encompassed practical and psychosocial information, including: the impact of breast reconstruction on day-to-day activities in the short, medium and long term; visual information about breast reconstruction surgery and recovery; and information on the emotional implications of undergoing breast reconstruction, including how women should feel about their reconstructed

breast/s. A small qualitative study found that women often struggled to comprehend how they were, and should be, responding to their reconstructed breast/s (Wolf, 2004b). A systematic review of breast reconstruction educational materials acknowledged the lack of comprehensive information about breast reconstruction, with most resources reviewed only containing clinical information about breast reconstruction. Only one resource included content addressing expectations of breast reconstruction; one other included information on satisfaction; and another discussed social functioning. None of the educational materials developed covered content on sexuality or body image (Preminger et al., 2011).

For the two women who had chosen bilateral prophylactic mastectomy and breast reconstruction, their decision making and information seeking was equally difficult, for different reasons. Their decisions were made in the absence of a breast cancer diagnosis; yet breast cancer was the significant factor in their decision making. The available information was not specifically tailored to their circumstances, with the majority of information specific to women diagnosed with breast cancer requiring mastectomy. Women who undertake prophylactic mastectomy and breast reconstruction have slightly different information needs to those who have a breast cancer diagnosis. Information should be tailored to this group of women's specific situation to ensure they are receiving relevant, accurate and realistic information about breast reconstruction options.

While the initial decision to have a breast reconstruction was described as 'easy', subsequent decisions about breast reconstruction options were more challenging. A series of decisions was required over an extended timeframe. Consideration of options for each of these decisions was confounded by multiple complicating factors. This convoluted and multi-layered decision-making process is widely acknowledged in the literature (Crompvoets, 2006; Heller & Miller, 2004; Wolf, 2004a). Factors affecting decision making included: a restricted timeframe within which to make these decisions; access to breast reconstruction services; limited comprehensive information available; financial considerations; breast reconstruction surgeon advice; and the physical implications of surgeries and how these may affect lifestyle. Heller & Miller (2004) have been previously identified that these multiple factors influence decision making. Several Australian and

international studies have also identified issues with accessing breast reconstruction services (Hall & Holman, 2003; Heller & Miller, 2004; Potter et al., 2013; Sandelin et al., 2003).

Two distinct types of decision making were prevalent in this group of women: shared decision making in consultation with the breast reconstruction surgeon, or detached decision making with the responsibility for decision making left up to the breast reconstruction surgeon. Women who described participating in shared decision making articulated consultation with anyone other than their breast reconstruction surgeon was neither necessary nor desired. Women did not describe an independent style of breast reconstruction decision making, as identified in another study exploring breast cancer decision making (Vogel et al., 2008). However, women's preferences for decision-making styles have been found to change over time (Harcourt & Rumsey, 2004; Lee et al., 2011; Vogel et al., 2008).

Women described an intense relationship with their breast reconstruction surgeon, perhaps due to the extended time of the relationship, over one to two years, and the intimate nature of this relationship. Women's vulnerability throughout their breast cancer and breast reconstruction experience may also contribute to this valued relationship, which was almost perceived as a personal relationship by some women. Some women perceived their breast reconstruction surgeon imposed decisions on them; with women either not feeling confident to challenge their surgeon's direction or believing the surgeons would make the right decisions for them. While breast reconstruction surgeons' role in decision making has been identified in the literature (Vogel et al., 2008), the dynamics of the ongoing patient-breast reconstruction surgeon relationship has not been studied.

Women's decision making was supported by partners, managed by breast reconstruction surgeons to varying degrees, and confounded by others' breast reconstruction stories or opinions. Women's experience of breast reconstruction was described as a 'marathon', during which women required ongoing information to support their decision making and adjustment following breast reconstruction. Previous studies have shown an individual's stage of cancer trajectory will influence

their information needs (Adams et al, 2009; Finney Rutten et al., 2005; Heller & Miller, 2004; Vogel et al., 2008).

3.5.1.1 Complexities of Breast Reconstruction Decision Making

Making choices about breast reconstruction requires multiple decisions. Firstly, a woman must decide whether she would like a breast reconstruction or would prefer a mastectomy, possibly with use of external breast prostheses. Secondly, a woman must consider whether her breast/s will be reconstructed at the same time as the mastectomy (immediate breast reconstruction), or at a later time (delayed breast reconstruction). Thirdly, the woman must decide which type of breast reconstruction will best meet her needs and preferences. In addition to this initial series of decisions, subsequent decisions may need to be made in the future. Once breast reconstruction surgery has been completed, women may consider whether any further breast refinement surgery is desired to improve aesthetic outcome, through restoring breast symmetry and reconstructing the areola and nipple (Heller & Miller, 2004).

Complicating women's decision-making process are the clinical and personal factors that may influence their breast reconstruction options and preferences. Clinical factors include: access to breast reconstruction services, surgical suitability for different types of breast reconstruction, and the potential effects of priority breast cancer treatments. Personal factors may include: the individual's values and preferences, ability to finance breast reconstruction, effect of different types of breast reconstruction surgeries on lifestyle and the effect of surgery on the family (Heller & Miller, 2004).

The decision whether to have an immediate or delayed breast reconstruction has implications for the accessibility of breast reconstruction services, cost of breast reconstruction, outcomes of breast reconstruction and impact on breast cancer treatments (Heller & Miller, 2004). An immediate breast reconstruction requires only one operation. It may be possible for the surgeon to keep the skin, nipple and areola intact so that the look of the reconstructed breast is more natural (Heller & Miller, 2004). Despite the immediate replacement of the breast, a woman may still

grieve for the loss of her breast even after a breast reconstruction (Hill & White, 2008; Nissen et al., 2002).

Immediate breast reconstruction requires coordination of two surgeons (one to perform the mastectomy and one to perform the breast reconstruction). Few surgeons perform both breast removal and breast reconstruction procedures; those that do are generally limited in the types of breast reconstruction they offer. For those who choose delayed breast reconstruction, waiting lists may be unavoidable. Women having breast reconstruction in a private hospital do not experience these difficulties (Heller & Miller, 2004; Sandelin et al., 2003).

Radiotherapy is another key factor to be considered when deciding on the timing of breast reconstruction. Radiotherapy after breast reconstruction is likely to affect the look and feel of the reconstructed breast (Heller & Miller, 2004; Lam, Hesieh & Boyages, 2013). This is particularly an issue following breast reconstruction using implants. It may be recommended that breast reconstruction is delayed until after radiotherapy is completed, to ensure that treatment can start as soon as possible and the outcome of breast reconstruction can be optimised. An alternative is to have implant breast reconstruction at the same time as the mastectomy. Then following radiotherapy, the 'sacrificial' implant is removed and another breast reconstruction procedure can be done. These decisions are complicated by the fact that the need for radiotherapy may not be known until after a pathologist has examined the tissue removed during mastectomy (Heller & Miller, 2004).

Women must consider the financial costs of breast reconstruction when making their decisions. Breast reconstruction is an expensive procedure. In Australia, Medicare covers most of the breast reconstruction. However, individual claims are reviewed by a Medicare claims review panel, and the woman may be required to pay for the costs of a breast implant. Breast reconstruction undertaken as a private patient attracts a 75 per cent Medicare rebate on the schedule procedural fee. However, breast reconstruction surgeons commonly charge above the scheduled fee. There are also additional costs that must be covered, including: anaesthetist fees, equipment and medications (personal communication, Medicare Australia, 21 April 2010). It is not uncommon for a privately insured patient to have up to $10,000 out-of-pocket

expenses to undertake the more complex types of breast reconstruction (personal communication, D. Pennington, 6 April 2010).

Those living in rural and remote regions of Australia have less access to breast reconstruction services near where they live. Few breast reconstruction surgeons are located in rural and remote areas of Australia, meaning women most frequently travel to major city centres for extended periods to undertake breast reconstruction (Hall & Holman, 2003; Sandelin et al., 2003). While some travel assistance may be accessible (http://www.ruralhealthaustralia.gov.au/), this extended time from home adds further financial strain to breast reconstruction costs. In addition, women are away from their family and friends throughout their surgery and immediate post-operative recovery.

Potter and colleagues' (2013) qualitative study using interviews with patients and healthcare professionals identified similar inequalities in the access and provision of breast reconstruction in the UK. Options for breast reconstruction were restricted, due to surgeon expertise or preference, and women felt comprehensive information was lacking. This resulted in unrealistic expectations of their surgical experience and its outcomes. Women believed providing balanced and unbiased information about all types of breast reconstruction would facilitate informed and considered decision making about breast reconstruction (Potter et al., 2013).

3.5.1.2 The Importance of Shared Decision Making

The nature of breast reconstruction decision making clearly identifies a need for shared decision making alongside healthcare professionals. Healthcare professionals are crucial in providing individualised information to women regarding medical factors impacting breast reconstruction options, accessibility of breast reconstruction services and probable outcomes of breast reconstruction. The individual and personal nature of such information means skilled healthcare professionals are best equipped to assist women to navigate a large volume of information when making decisions about breast reconstruction.

Patient involvement in decision making has become more prominent in healthcare decision making over the last 50 years, with a move from a paternalistic approach, to a person-centred approach of increased patient involvement, thereafter expanding into a shared decision making model. Charles, Whelan & Gafni's (1999) conceptual framework of decision making models distinguished between paternalistic, informed and shared decision making; identifying a fusion of these different models dependent upon patient preference for involvement and medical factors impacting treatment options. A 2002 systematic review of patient involvement in healthcare concluded higher levels of patient involvement led to improved care quality, increased satisfaction of both the patient and healthcare professional and improved patient self-esteem (Crawford et al., 2002).

Shared decision making places emphasis on enabling informed consent by empowering the patient to be an autonomous decision maker. Shared decision making requires a plan to be developed by the patient and healthcare professional and exploration of the patient's values in relation to their situation. The health professional's role is one of advisor, not paternalistic decision maker. Barriers to shared decision making include patient preferences for shared decision making, healthcare professional attitudes and skills, and time available for the patient and healthcare professional to communicate. Patients should be involved in decision making to the extent they desire. This requires a skilled healthcare professional to take the time to identify the patient's preferred level of involvement and negotiate a plan to achieve this (Edwards & Elwyn, 2009).

Shared decision making necessitates two-way communication between healthcare professional and patient, whereby the healthcare professional informs the patient of treatment options, risks and benefits and the patient informs the healthcare professional of their existing knowledge of treatment options, personal values and beliefs, lifestyle, and preferences. This ensures both the healthcare professional and patient consider all relevant options within the context of the patient's situation. Fundamental to shared decision making is the provision of health information to enhance decision making. Decision support tools are a useful tool to support shared decision making, particularly within the constraint of limited time healthcare professionals have available to consult with patients (Edwards & Elwyn, 2009)

3.6 Conclusion

Breast reconstruction is a complicated decision. It is important for healthcare professionals to acknowledge the complexity of decision making and the volume of information required to make informed decisions. Making quality decisions about breast reconstruction requires women to weigh up the information they have sourced, and align options with their personal values and goals. Information needs do not come to an end once the decision to have a breast reconstruction has been made; instead, they evolve as women experience breast reconstruction procedures and outcomes. Women will have differing information needs as they progress through the different stages of their breast reconstruction experience.

Breast reconstruction information available to women undergoing mastectomy is limited. To date, there is very little systematic research into the effectiveness of breast reconstruction patient education. Several studies describe benefits with no evidence of effects. This may be one factor contributing to the relatively low uptake of breast reconstruction nationally, and has the potential to impact quality decision making and lead to decision regret. Comprehensive information about breast reconstruction treatment options and potential outcomes is required to better inform and prepare women faced with decisions about breast reconstruction. Information should be longitudinal, spanning decision making, surgery and physical and emotional recovery in the short, medium and long term. Information must be reliable and contextually Australian to guide women through realistic options and outcomes of breast reconstruction. The information provided should incorporate the practical, physical, visual and emotional aspects of breast reconstruction surgery and recovery. The differing information needs of women who have been diagnosed with breast cancer, and women who choose to prophylactically remove and reconstruct their breasts, must be considered when developing appropriate information about breast reconstruction.

While informing and empowering women to make choices about breast reconstruction is vital, shared decision making is an imperative component of breast

reconstruction decision making. This ensures that women are appropriately guided through the convoluted factors impacting various breast reconstruction treatment options. Developing a decision support tool that provides comprehensive information and supports the decision-making process aimed to empower women to actively participate in shared decision making, facilitate informed consent to breast reconstruction as a treatment option, and support women throughout their decision making and recovery from breast reconstruction. Phase Two of this research used the findings of this needs analysis to inform the development, content and format of a decision support tool to meet women's information needs, and assist them with decision making about breast reconstruction.

Chapter 4: Phase Two—Development of a Decision Support Tool for Women Considering Breast Reconstruction Following Mastectomy

4.1 Introduction

Phase Two, informed by Phase One, undertook input and process evaluation to develop a decision support tool for women considering breast reconstruction following mastectomy (Figure 4.1). Phase Two saw a group of key stakeholders direct the creation of a decision support tool and plan its evaluation. This chapter will detail these methods. The Ottawa Decision Support Framework was adopted to guide the decision support tool development process; this will be introduced and discussed, and the developed decision support tool will be described.

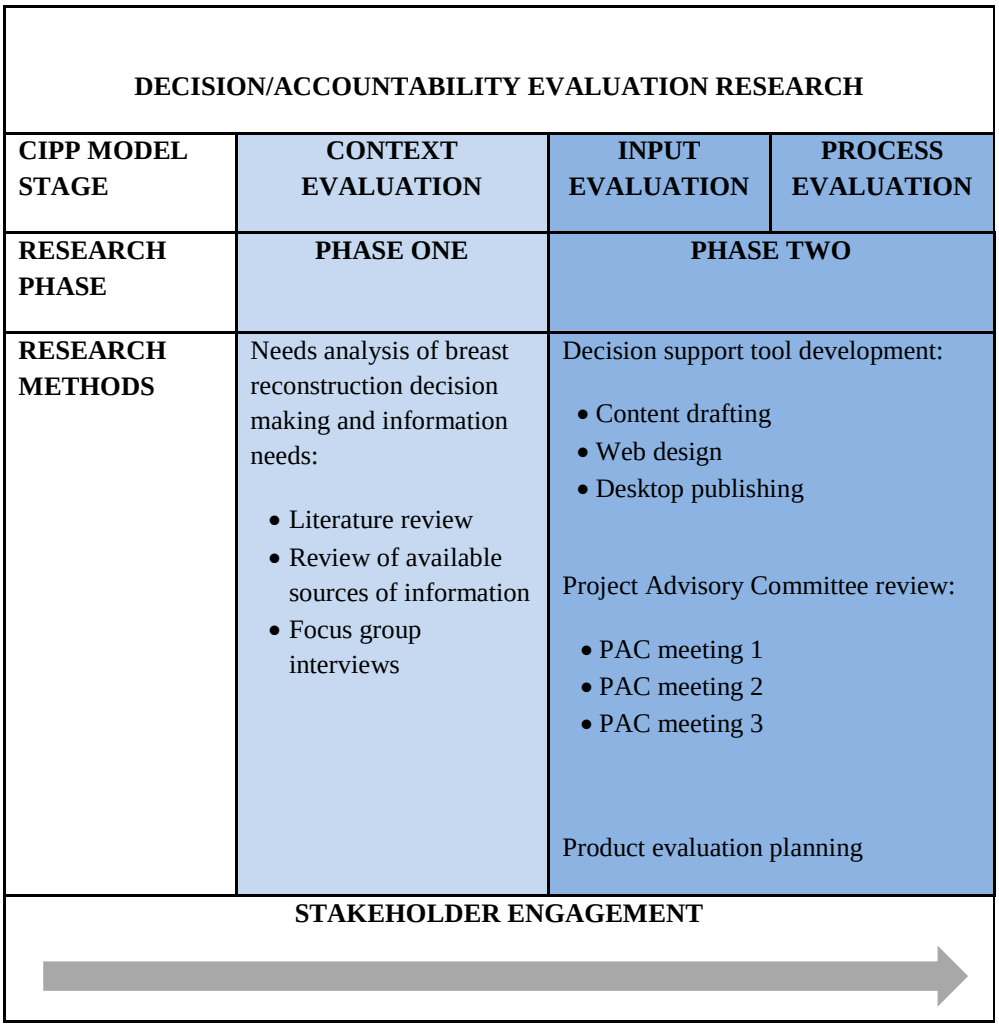

Figure 4.1: Evaluation Framework (Phases One & Two)

4.1.1 Objectives

The aim of this phase of the research was to develop and implement an evaluation framework for a breast reconstruction decision support tool for women considering breast reconstruction following mastectomy. Key to this phase was development of a decision support tool. The specific objectives of this phase of the research were to:

- develop an evaluation framework to guide the development and evaluation of a decision support tool
- create a decision support tool to meet the information needs of women considering breast reconstruction following mastectomy
- produce a resource that would be useful for women to refer back to throughout their breast reconstruction experience

- develop a summative evaluation plan to evaluate the decision support tool developed.

4.2 **Conceptual Framework**

The conceptual framework adopted to guide the development of a decision support tool was the Ottawa Health Research Institute's Decision Support Framework (Figure 4.2). The Ottawa Decision Support Framework uses assessed decision support needs to tailor the development of a decision support tool, and evaluate the application of this tool (https://decisionaid.ohri.ca/odsf.html). The Ottawa Decision Support Framework is an evidence-based conceptual framework, derived from the theories and concepts of psychology, decision analysis, decisional conflict, values, social support and self-efficacy (Ajzen & Fishbein, 1980; Bandura, 1982; Fischhoff, Slovic & Lichtenstein, 1980; Janis & Mann, 1977; Keeney, 1982; Norbeck, 1988; Orem 1995; Tversky & Kahneman, 1981). The premise of this framework asserts that a person's decisional needs will affect the quality of their choices. The degree to which the decisions made are informed and values-based influences the person's health behaviours, health service use, health outcomes and decision regret. Addressing the person's decisional needs through decision support can facilitate optimal decision quality (https://decisionaid.ohri.ca/odsf.html).

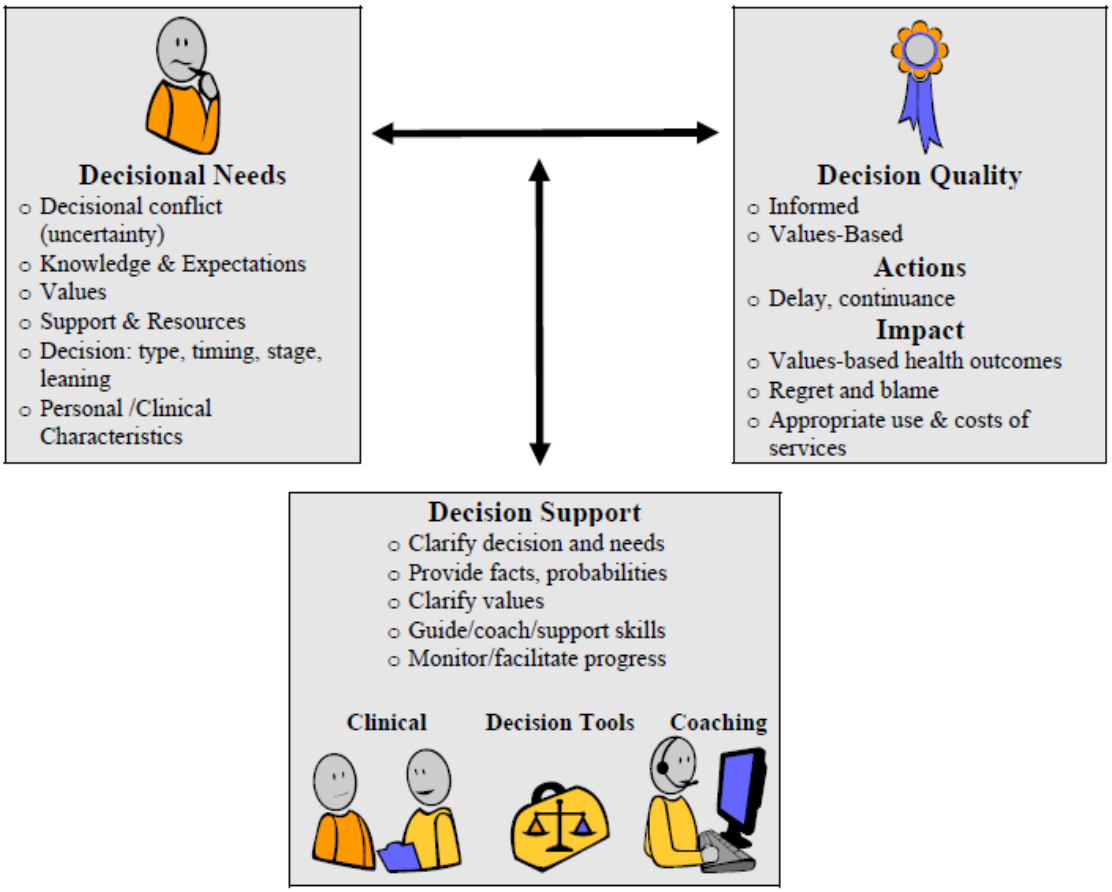

Figure 4.2: Ottawa Decision Support Framework

(http://decisionaid.ohri.ca/docs/develop/ODSF.pdf)

4.2.1 Foundations of the Ottawa Decision Support Framework

Several well-established theories discussing the complexities and processes of decision making form the foundations of the Ottawa Decision Support Framework; including Orem's theory of self-care (1995), Janis and Mann's model of decision conflict (1977), Tversky and Kahneman's articulation of decision making psychology (1981), Keeney's work on decision analysis (1982) and Bandura's perspective on self-efficacy (1982). Nursing theorist Dorothea Orem described the context of nursing practice through a theory of self-care; this identified *universal self-care* requirements associated with life processes, *developmental self-care* requisites related to developmental processes associated with a condition or event,

and *health deviation self-care* required during illness or injury leading to a modified self-concept to an ill state. Her complementary theory of self-care deficit identified when care was necessary due to a reduced ability to self-care, through five methods of assistance: doing, guiding, supporting, promoting self-development and teaching. Orem's theory is founded on the concepts of health promotion and health maintenance (Orem, 1995).

The literature clearly demonstrates that a person's self-concept may be affected by a diagnosis of cancer. The removal of a woman's breast/s may affect what this means to her sense of femininity and the roles she plays in the world. Women adjust to this modified self-concept in different ways over time. Breast reconstruction may assist women living with mastectomy to restore their self-concept to a sense of normality, while women who have immediate breast reconstruction may experience an altered self-concept in response to the perceived loss of their breast, despite reconstruction. Orem's self-care theory (1995) highlights the developmental requisites associated with breast reconstruction decision making and the self-care deficit women must consider because of breast reconstruction surgery and recovery.

Irving Janis and Leon Mann's model of decision conflict asserts the level of stress associated with a decision may affect decision quality. Decision outcomes depend upon the demands of the environment within which the decision is being made and the personal resources available to facilitate the decision-making process. The decision mediation process is structured around four levels of questions: are the risks serious if I do not change?; are the risks serious if I do change?; is it realistic to hope to find a better solution?; and is there sufficient time to search and deliberate? Five patterns of decision making were determined: namely, unconflicted adherence, unconflicted change, defensive avoidance, hypervigilance and vigilance. Janis and Mann's model addresses important life decisions, acknowledging that a person's fear of making the wrong decision deters the person from making a decision. People adopt the mechanisms of rationalisation and procrastination in decision avoidance. The model developed allows for comparison of alternative options and the incorporation of values and morals in the decision-making process (Janis & Mann, 1977).

Making decisions about breast reconstruction can be very stressful for women. Some women are processing a recent diagnosis of breast cancer and may need to make decisions within a restricted time frame, identified by Janis and Mann (1977) as the single most important factor affecting decision making. There are multiple options for breast reconstruction and multiple decisions that need to be made across a decision making trajectory. In these circumstances, women consider their personal values in relation to the perceived risks and benefits of breast reconstruction treatment options. Janis and Mann's model of decision conflict (1977) represents the patterns of decision making women may adopt within the often stressful context of breast reconstruction decision making.

Tversky and Kahneman's 1981 article explores the psychology of decision making. Decision making is founded on the premise of rationality, whereby consistency and coherence are key components. The decision maker's perception of actions and their outcomes is influenced by the decision problem itself and the decision maker's personal characteristics. The author's statistical analysis of the probabilities and outcomes of decision making highlights a shift in preferences when the same problem is framed in different ways. Rationality stipulates that option preference should not alter with changes in decision framing. Alteration of preference can occur simply when the wording of options is changed, even where the actual options remain the same. This reframing may lead to risk aversion or risk taking. The postulated theory of decision making identified two phases: 1) framing of acts, outcomes and contingency of options; and 2) evaluation of these options within this frame. It is proposed that while subjective decisions cannot produce quantifiable probability outcomes, the principles of this decision-making theory can be applied (Tversky & Kahneman, 1981).

Women considering breast reconstruction are framing their decision making within the challenging context of breast cancer diagnosis, often restricted by a limited time within which to make decisions about breast reconstruction. The decisions required are multiple and influenced by a multitude of personal, practical and clinical factors, only some of which are within the individual's control. Someone's ability to rationalise their preferred breast reconstruction treatment options may be affected by their emotional wellbeing, accessible information and support resources in place

at the time of decision making. A decision support tool may assist women to frame their decisions rationally, coherently and consistently.

Keeney's overview of decision analysis discusses the complexity of the decision environment. Factors recognised to contribute to this complexity include: the need to achieve multiple objectives from the decision; intangibles (often subjective factors) that are difficult to quantify and measure; risks and uncertainty; and interdisciplinary input into decision making. A single alternative will not achieve the multiple objectives of decision making. Achievement of multiple objectives requires assessment of how multiple alternatives may achieve these various objectives. There will always be some level of risk or uncertainty with each option, as it is impossible to predict all outcomes of each alternative precisely. Decisions may be characterised by high stakes, complicated structures and a need for the decision maker to justify decisions. Considering potentially negative outcomes in the decision-making process may be difficult for the decision maker. Professional expertise must be considered a critical part of a person's decision analysis for major decisions. Decision analysis is a complex process that requires gathering and collating the available information to weigh up the pros and cons of alternatives, while recognising the uncertainty of these alternatives. Keeney's model of decision analysis is described in four steps: 1) structure the decision problem; 2) assess the possible impacts of each alternative; 3) determine preferences or values of the decision maker; and 4) evaluate and compare the alternatives (Keeney, 1982).

The complexity of important life decisions that surround breast reconstruction are highlighted by Keeney (1982). The subjective nature of breast reconstruction decision making and the multiple decisions to be made regarding multiple options requires information to be made available to women making these decisions. A decision support tool can provide such information, weighing up the potential advantages and disadvantages of each option, while encouraging values-based judgement of these options. The importance of shared decision making with the healthcare professional team is also an imperative component to breast reconstruction decision making. It can go a long way to establishing realistic expectations and avoiding decision regret.

Bandura (1982) explores the impact of self-efficacy on human behaviour and action, based upon the premise that an individuals' perception of their own capabilities to execute an action and cope with a specific situation affects the choices they make. People generally will only choose a course of action they are sure they can manage; however, people who exhibit strong self-efficacy will apply greater effort to achieve challenging outcomes. An individual's self-efficacy is influenced by their perceptions of previous successes. Microanalysis between perceptions of self-efficacy and actioning of tasks identifies that inherent self-efficacy improves with improved enactive mastery. Self-evaluation of one's own capability is important in decision making, as misjudgement of self-efficacy may lead to a course of action that produces adverse consequences. The self-efficacious person is likely to put little effort into preparing for action; some uncertainty of self-efficacy may have benefits in preparatory knowledge acquisition behaviours. However, those who perceive themselves as inefficacious may focus on this perceived deficit and place greater value on potential adverse consequences of an action than is realistic or reasonable (Bandura, 1982).

Committing to undertake breast reconstruction is a significant decision that will demand physical, emotional and social resilience of the individual. How an individual believes they will cope with varying breast reconstruction options will be a factor in their decision making. The circumstances of their lives, such as financial, family, recreational, social and work situations, may restrict or facilitate their perceived ability to cope with certain situations. Considering one's self-efficacy is an important factor in breast reconstruction decision making. Development of a decision support tool that provides women with comprehensive information about breast reconstruction options, outcomes and preparation may meet the needs of women with varying levels of self-efficacy and resulting information seeking behaviours.

These theories, forming the basis of the Ottawa Decision Support Framework, highlight the psychological, social and emotional complexities associated with decision making. This structured framework, within which to explore decisional needs, consider decision quality and provide decision support, was useful to assist stakeholders in the development of a breast reconstruction decision support tool.

4.2.2 Components of the Ottawa Decision Support Framework

4.2.2.1 Decisional Needs

When adopting the Ottawa Decision Support Framework, it is necessary to first articulate the type and context of the decision being made. In this research, women are making treatment decisions regarding breast restoration. These decisions may be made within the context of a breast cancer diagnosis, or as a preventative action to reduce breast cancer risk. The decisional needs of these two groups of women differ somewhat. The timing of a decision is also important. Women who require a mastectomy to treat breast cancer need to make a decision if they desire an immediate breast reconstruction (or not) before mastectomy surgery is scheduled. This can often be a matter of days or weeks, adding a sense of urgency to this important decision.

As there are multiple decisions to be made along a treatment trajectory often extending over several years, women are making specific decisions at different stages of their breast reconstruction experience. At all stages of the decision-making trajectory women have the option to decide not to choose any of the treatment options available. In leaning towards a particular option, women may be seeking further information, clarification of information or alignment of their option with their personal values.

Decisional conflict occurs when the person is uncertain about which treatment option to choose, when these choices carry risk, loss, regret or impact on the individual's personal life and values (https://decisionaid.ohri.ca/odsf.html). Factors contributing to decisional conflict include the inherent difficulty of the decision to be made, lack of knowledge about options, unrealistic expectations about option outcomes, unclear personal values of the decision maker, perceived social pressure and lack of resources. To manage decisional conflict, the individual needs to comprehend information about each option and its probable or potential outcomes, have realistic expectations of the likelihood of outcomes of each option, and seek clarity of their personal values (how desirable or important the outcomes of each option are to the personal self) (https://decisionaid.ohri.ca/odsf.html; O'Connor et al., 2002).

The support and resources accessible to the decision maker also influence their decisions. Others' opinions of what treatment option should be selected may support or conflict with the decision maker's personal values, either supporting or confusing the individual's decision-making process. Opinions may come from the person's family, friends or colleagues, or from health care professionals. The decision maker may feel coerced into choosing one option over another. If this option does not align with the person's values, or they are not satisfied with the outcome of the option, decisional regret may eventuate.

Preferred roles in decision making can differ between individuals. While some prefer to share decision-making responsibilities, others prefer to make the decision themselves after considering the options; still others prefer someone else to make the decision on their behalf. While involving others in decision making, or having someone else make the decision, are legitimate personal preferences, it is important the person has the opportunity to be informed about their options and the reasoning behind the decisions made.

Individuals' past experiences of decision making or perceived outcomes of previously chosen options influence decision making. Additionally, an individual's motivation and readiness to make decisions and their confidence in their decision-making abilities are factors that need to be considered as part of decisional needs analysis. Factors external to the personal, such as access to information, advice, emotional or financial support may be contributors to either decision quality or decisional conflict. Personal characteristics including age, gender, ethnicity, educational level and health status also influence decision making. While control of all these factors is not achievable to eventuate decision quality, decision support tools are designed to prepare people to participate in decision making and consider their options within the context of the individual's personal situation, values and information needs (https://decisionaid.ohri.ca/odsf.html).

4.2.2.2 Decision Quality

Quality decisions are informed and values-based, where the chosen option best aligns with the individual's values. To achieve this, a quality decision-making process must have occurred. The quality of the decision-making process is determined by the extent to which the individual acknowledges a decision is required, is aware of available options and the benefits and harms of each, aligns their preferred option with their personal values, discusses this with their healthcare professional and is involved in decision making according to their preferred role in decision making (https://decisionaid.ohri.ca/odsf.html).

Breast reconstruction treatment options are multiple and varied, requiring the decision maker to have a sound understanding of surgical processes, potential physical consequences and outcomes of each surgical option, and the emotional impacts of breast loss and restoration. Given the volume and complexity of the information required to make an informed decision about breast reconstruction, women would benefit greatly from a comprehensive decision support tool that clearly identified available options and the benefits and harms of each, framed within the context of shared decision making with healthcare professionals, to avoid unrealistic expectations and subsequent decision regret.

Optimal decision support sees the decision maker guided through four steps: 1) clarifying their decision; 2) identifying their decision-making needs; 3) exploring their needs; and 4) planning the next steps of their decision-making process. Clarifying the decision involves prompting the individual to identify the decision to be made, the timing and stage of decision making they are at, and their inclination towards an option. When identifying decision-making needs, the individual should identify if they have sufficient support, knowledge of the options and the risks and benefits of each option, clarify if this knowledge aligns with their values, and question their certainty about their decision. The individual should consider others who are involved in their decision making, if they are feeling pressured by this involvement, and what role they are comfortable to undertake in the decision-making process. Planning the next steps involves summarising the individual's perception of their support, knowledge and values, and considering the next steps in

the decision-making process (http://decisionaid.ohri.ca/docs/das/opdg.pdf). These steps towards decision quality have been formalised in the Ottawa Personal Decision Guide, which is available in practitioner and patient versions; however, further research on the self-implementation of this tool for patients is required (O'Connor et al, 2002).

4.2.2.3 Decision Support

The need for a decision support tool arises from a desire to meet person-centred care needs, an identified complexity of decision making, and recognition that decision support tools facilitate high quality decisions. More than 30 decision support tools have been developed using the Ottawa Decision Support Framework, with studies demonstrating that decision support tools improve knowledge, produce realistic expectations and ease decisional conflict. More simplified decision support—in the form of information only—has been shown to be just as effective at improving knowledge (O'Connor et al, 2002).

The first step towards the development of decision support tools is to understand information and decision-making needs. Existing decision support tools should be reviewed to determine how they might meet decisional needs and promote decision quality. A collaborative development process involving all key stakeholders is imperative to ensure decision support skills and tools will be enhanced. Implementation and evaluation of the developed decision support tool must be undertaken to determine the quality of decision support provided by the tool. These process steps towards developing decision support tools are based upon the Knowledge-to-Action Cycle, as depicted in Figure 4.3.

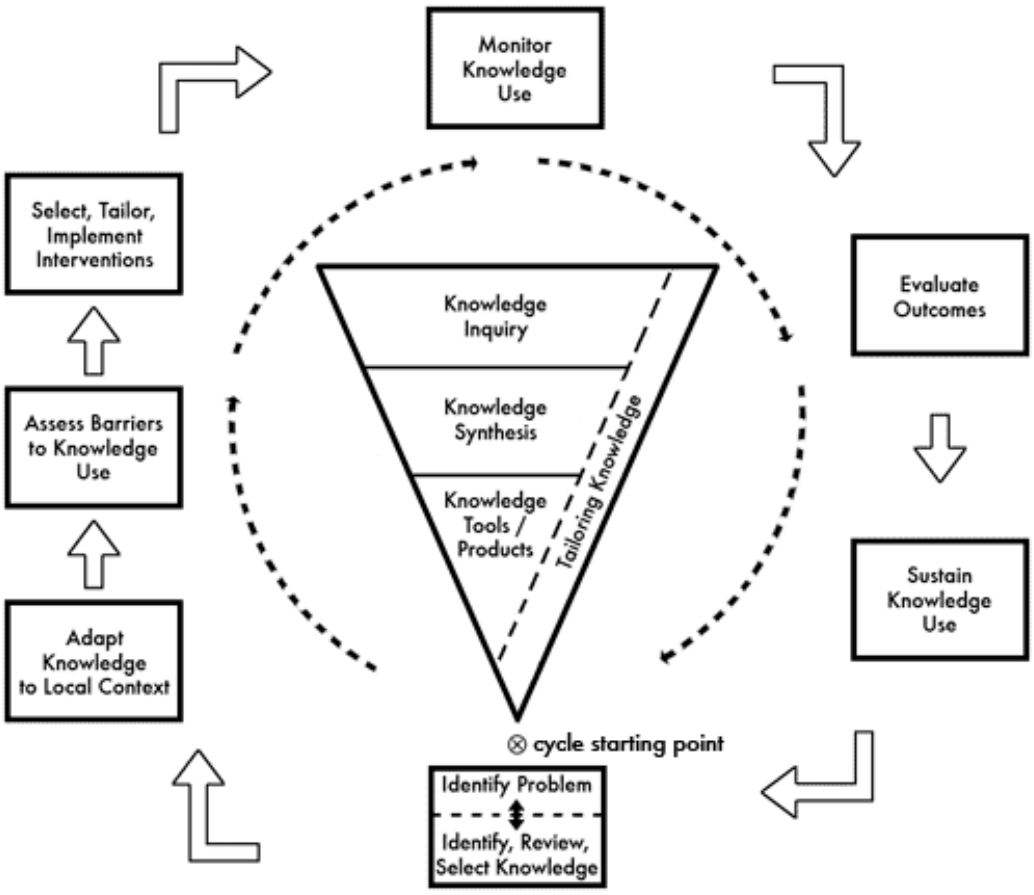

Figure 4.3: Knowledge-to-Action Cycle

(http://ktclearinghouse.ca/knowledgebase/knowledgetoaction)

The Knowledge-to-Action Cycle was developed by the Canadian Institute of Health Research, depicting a model for knowledge translation. The Canadian Institute of Health Research defines knowledge translation as a dynamic and iterative process that includes synthesis, dissemination, exchange and the ethically sound application of knowledge. This provides more effective health services and products, improves health and strengthens the health care system (http://ktclearinghouse.ca/knowledgebase/).

4.2.2.3.1 Knowledge Funnel

The knowledge funnel represents the refinement of knowledge, and tailoring that knowledge to meet the needs of the intended user, incorporating the processes of knowledge enquiry, synthesis and tool or product generation. Knowledge enquiry refers to the unrefined collation of studies and other information on the particular topic, also termed 'first generation knowledge'. Knowledge synthesis is the process of reviewing and summarising the multitude of information gathered. This comprehensive literature review and critique is also termed 'second generation knowledge'. Knowledge synthesis should not only incorporate systematic reviews where possible, but also an exhaustive literature search of both published and unpublished works. Knowledge tools and products, also termed 'third generation knowledge', involve formatting refined knowledge in a clear, concise and user-friendly design. The resulting tool or product should facilitate the application of knowledge (http://ktclearinghouse.ca/knowledgebase/).

4.2.2.3.2 Action Cycle

The action cycle outlines the process by which the knowledge generated is implemented. The action cycle is based upon planned-action theories, whereby the process of knowledge application will generate change in groups or settings. In the case of this research, knowledge application aims to improve women's decision quality about breast reconstruction treatment options. There are seven phases of the action cycle: 1) identifying the knowledge action gaps; 2) adapting knowledge to local context; 3) assessing barriers to knowledge use; 4) selecting, tailoring, implementing interventions; 5) monitoring knowledge use; 6) evaluating outcomes; and 7) sustaining knowledge use (http://ktclearinghouse.ca/knowledgebase/).

The Ottawa Health Research Institute's Implementation Toolkit assists navigation through the steps of the Knowledge-to-Action Cycle. The implementation toolkit is aligned with the International Patient Decision Aids Standard (IPDAS) Collaboration, which provides an internationally recognised set of clear criteria for

judging the quality of decision aids developed (http://decisionaid.ohri.ca/implement.html).

4.2.3 Application of the Ottawa Decision Support Framework to this Research

The table overleaf outlines the Ottawa Health Research Institute's steps of implementing decision aids, how these align to the Knowledge-to-Action Cycle, and specific research methods undertaken to achieve each step (Table 4.1).

Table 4.1: Application of the Ottawa Health Research Institute's Patient Decision Aid Implementation Toolkit to the Development of a Breast Reconstruction Decision Support Tool

OHRI Patient Decision Aid Implementation Toolkit	Knowledge-to-Action Cycle	Application to this research
Step 1: Identify the decision	Phase 1: Identify problem	Phase One—needs analysis Literature review Review of available national information resources Focus group interviews
Step 2: Find patient decision aids	Phase 1: Identify, review and select knowledge Phase 2: Adapt knowledge to the local context	Formation of a national PAC Exploration of the needs analysis Conceptualisation of a breast reconstruction decision support tool
Step 3: Identify barriers and explore ways to overcome them	Phase 3: Assess barriers to knowledge use	Stakeholder engagement Establishment of collaborations Phase Two—creation of a breast reconstruction decision support tool
Step 4: Implement decision aids/decision support with training	Phase 4: Select, tailor and implement interventions	Phase Three—multiple method evaluation of the breast reconstruction decision support tool, using survey and interview methods
Step 5: Monitoring use and outcomes	Phase 5: Monitor knowledge use Phase 6: Evaluate outcomes Phase 7: Sustain knowledge use	Analysis of multiple method evaluation of the breast reconstruction decision support tool Report evaluation of the breast reconstruction decision support tool to stakeholders Initiation of the Cancer Australia review and dissemination process

This research aimed to develop, implement and evaluate a decision support tool for women considering breast reconstruction following mastectomy. Input and process evaluation was guided by the Ottawa Decision Support Framework. The development of the decision support tool was driven by a project advisory committee of key stakeholders, including women who had, and had not, undertaken breast reconstruction. Figure 4.4 demonstrates the application of the Ottawa Decision Support Framework to this research.

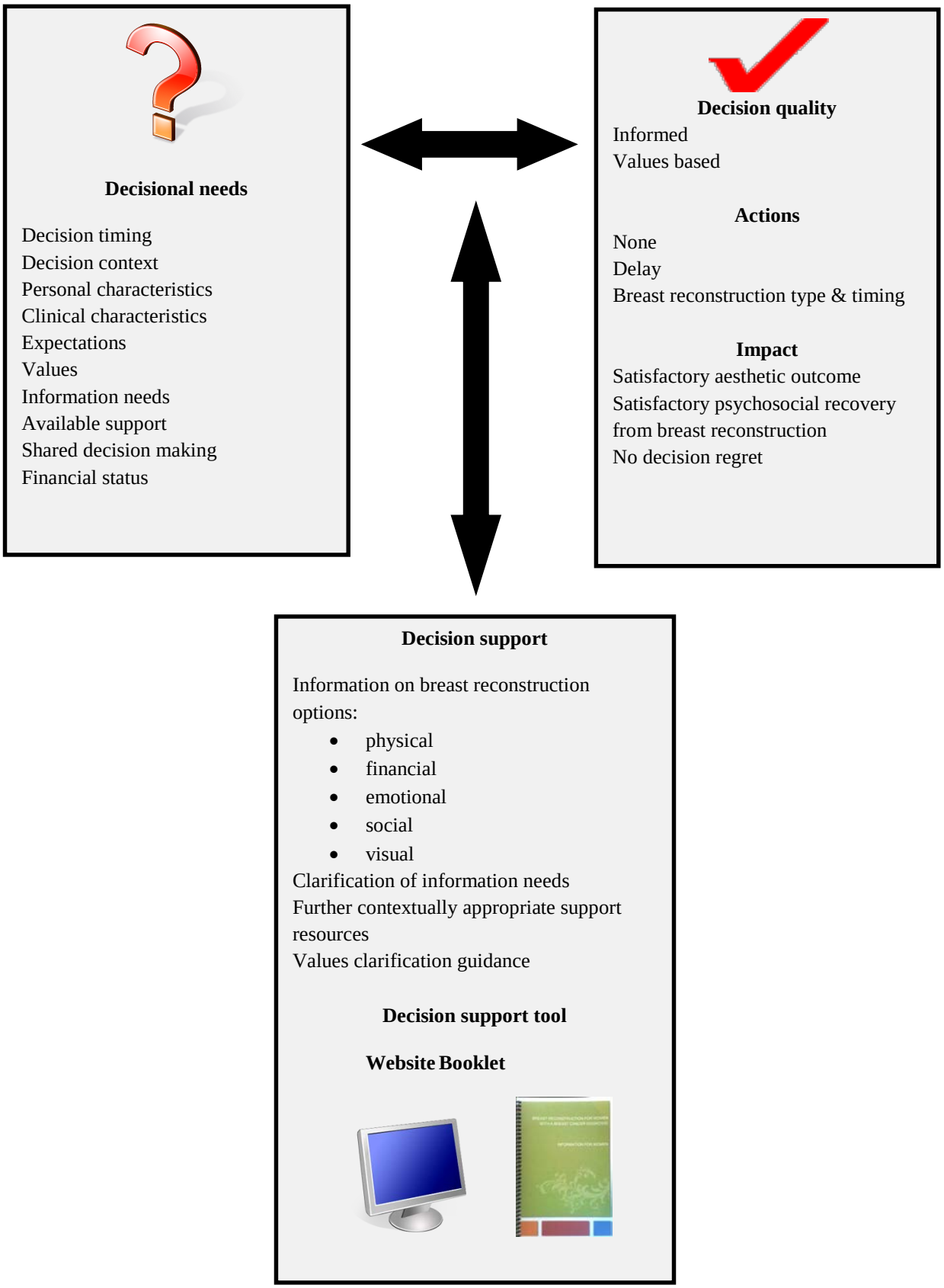

Figure 4.4: Application of Ottawa Decision Support Framework to the Development of a Breast Reconstruction Decision Support Tool

4.2.4 Alignment of Decision/Accountability Evaluation Research with the Ottawa Decision Support Framework

The Ottawa Decision Support Framework was chosen as the overarching conceptual framework to this research, as it is a well-developed model of decision support tool development. What the Ottawa Decision Support Framework does not provide is a research methodology. This research applied evaluation methodology, specifically decision/accountability evaluation research, using the CIPP model to guide the research process. The conceptual framework of the Ottawa Decision Support Framework aligns well with the chosen methodology and further supports the development of a robust decision support tool. A basic element of the CIPP model is identifying core values as the foundation of an evaluation (Stufflebeam, 2004). These core values of this research have been identified as the elements of the Ottawa Decision Support Framework decisional needs, decision quality and decision support.

The Ottawa Decision Support Framework identifies the importance of first identifying decisional needs and also recognising the impact of the decision making context on information needs (https://decisionaid.ohri.ca/odsf.html). The Phase One context evaluation undertakes this needs analysis, adopting various data collection methods to gain a comprehensive and holistic understanding of the complex decision making context of breast reconstruction. Decision quality within the Ottawa Decision Support Framework refers to quality decisions being informed and values based. Poor decision quality may lead to decision regret (https://decisionaid.ohri.ca/odsf.html). The Phase Two input and process evaluations are imperative to ensure the decision support tool is informative and values based, to maximise facilitation of decision quality. The ongoing formative process of evaluation allows for identification of areas of deficit to make improvements to the decision support tool. The final component of the Ottawa Decision Support Framework is decision support, which may take various forms (https://decisionaid.ohri.ca/odsf.html). The Phase Three product evaluation utilised multiple methods to evaluate if the decision support tool developed met the needs of women making decisions about breast reconstruction.

The above description of how the Ottawa Decision Support Framework aligns with the methodology of this research incorporating the CIPP model, highlights that rather than complicating the research process, adopting the Ottawa Decision Support Framework as a conceptual framework complements and reinforces the research process. Aligning with a well-developed model of decision support tool development that has been used widely and researched extensively further contributes to the rigour of this research. Figure 4.5 depicts how the Ottawa Decision Support Framework aligns with the evaluation framework of this research.

<table>
<tr><td colspan="5">DECISION/ACCOUNTABILITY EVALUATION RESEARCH</td></tr>
<tr><td>CIPP MODEL STAGE</td><td>CONTEXT EVALUATION</td><td colspan="2">INPUT EVALUATION | PROCESS EVALUATION</td><td>PRODUCT EVALUATION</td></tr>
<tr><td>RESEARCH PHASE</td><td>PHASE ONE</td><td colspan="2">PHASE TWO</td><td>PHASE THREE</td></tr>
<tr><td>RESEARCH METHODS</td><td>Needs analysis of breast reconstruction decision making and information needs:
• Literature review
• Review of available sources of information
• Focus group interviews</td><td colspan="2">Decision support tool development:
• Content drafting
• Web design
• Desktop publishing

Project Advisory Committee review:
• PAC meeting 1
• PAC meeting 2
• PAC meeting 3

Product evaluation planning</td><td>Multiple method decision support tool evaluation:
• Survey
• Focus group interview

Stakeholder reporting</td></tr>
<tr><td>OTTAWA DECISION SUPPORT FRAMEWORK ELEMENT</td><td>DECISIONAL NEEDS</td><td colspan="2">DECISION QUALITY</td><td>DECISION SUPPORT</td></tr>
<tr><td colspan="5">STAKEHOLDER ENGAGEMENT</td></tr>
</table>

Figure 4.5: Evaluation Framework Incorporating Application of the Ottawa Decision Support Framework

4.3 Methods

Phase Two aimed to develop a decision support tool for women considering breast reconstruction, and plan summative evaluation of the tool developed. During this phase, a decision support tool was drafted. This incorporated regular review by PAC members.

4.3.1 Participants

Participants in Phase Two of the research were PAC members. The stakeholder engagement, recruitment and collaboration processes undertaken were detailed earlier in Chapter Two, Section 2.4. Members of the PAC are reiterated below.

Table 4.2: Project Advisory Committee Members

PAC member	Position & Affiliations at time of participation
Ms Olivia Gallagher	Registered Nurse BN(Hons) Doctoral candidate, University of Sydney
Professor Kate White	Chair of Cancer Nursing, Cancer Institute of New South Wales/Royal Prince Alfred Hospital/University of Sydney (Lead Supervisor)
Professor Phyllis Butow	Co-director of the Centre for Medical Psychology and Evidence-Based Decision Making, University of Sydney (Associate Supervisor)
Winthrop Professor Christobel Saunders	Winthrop Professor of Surgical Oncology, University of Western Australia (Associate Supervisor)
Mr Tony Connell	Plastic and breast reconstruction surgeon, Perth, WA (Associate Supervisor)
Consumer 1	Breast cancer survivor
Consumer 2	Breast cancer survivor
Ms Michelle Marven	Policy Manager, Breast Cancer Network of Australia
Ms Heidi Wilcoxon	Program Manager, National Breast & Ovarian Cancer Centre
Mr David Pennington	Plastic and breast reconstruction surgeon nominated by the Australian Society of Plastic Surgeons
Ms Glenys Longman	Breast Care Nurse, Royal Perth Hospital
Ms Jane Gregson	Breast Care Nurse, King Edward Memorial Hospital
Ms Sue Hutton	Specialist Breast Nurse, nominated by the Cancer Nurses Society of Australia Lismore Community & Allied Health Richmond Network
Ms Danielle Spence	Breast Care Nurse Consultant, nominated by the Cancer Nurses Society of Australia Western Health

4.3.2 Data Collection

Data was collated from PAC meeting minutes, electronic feedback questionnaires, documented feedback and feedback communicated via e-mail. As versions of the decision support tool were drafted, PAC members completed questionnaires, providing feedback on the content and format of the decision support tool. It should be noted that while the researcher attended all PAC meetings, as the collator and developer of the content under review, she did not participate in the survey reviews. Questionnaires were followed by PAC meetings, where survey findings were presented to the group and further discussion ensued. Project Advisory Committee members were also invited to provide documented feedback on decision support tool

drafts and expert opinion was sought from PAC members as required, through minuted meetings or via e-mail. All records of feedback provided were managed, stored and compiled by the researcher. Contributions of PAC members are depicted in Table 4.3.

Table 4.3: Project Advisory Committee Member Contribution

	PAC review 1	PAC review 2	PAC review 3
PAC contribution	**Number of PAC members contributing**	**Number of PAC members contributing**	**Number of PAC members contributing**
Track change edits/comments to draft document	5	5	0
Online review questionnaire	4	2	10
E-mail comment	1	4	3
PAC meeting attendance	6	11	8
Total contributions	**16**	**22**	**21**

4.3.2 Data Analysis

Questionnaire data were analysed manually to report frequencies and open-ended comments. Written feedback provided via e-mail or to draft documents was also incorporated into a feedback report that was presented to the PAC. Based on the manual content analysis of feedback, points of discussion were tabled as agenda items for the subsequent PAC meeting. The PAC meeting minutes provided another source of data to be considered and actioned in the successive draft of the decision support tool. This analysis process was followed through eight drafts of the decision support tool over a 14-month period.

4.4 Decision Support Tool Development Results

The findings from Phase One concluded that any decision support tool developed would contain comprehensive, reliable information; in particular psychosocial, visual and practical information about breast reconstruction. The resource needed to be contextually relevant to Australian women, and also meet the needs of women

choosing to have bilateral prophylactic mastectomy and breast reconstruction in the absence of a breast cancer diagnosis. The collaborative input of key stakeholders was fundamental to developing a resource that would meet the needs of the end users. The content of the resource developed must support women's individual decision making by providing them with valuable information to assist them with clarifying personal values and making informed decisions.

4.4.1 Project Advisory Committee Meeting One

The first steps for the PAC in undertaking input evaluation were to review and ratify the draft evaluation framework and review the findings from the Phase One needs analysis, to progress the research forward, as deemed appropriate. Project Advisory Committee meeting one took place on 19 February 2010 in Sydney. One month before the scheduled meeting, PAC members were e-mailed pre-reading in the form of a summary of Phase One findings and a skeletal outline of the potential decision support tool content, based upon Phase One findings. Twelve PAC members contributed to the review process. Agenda items included:

- introduction of PAC members
- research overview in line with the PAC terms of reference
- Phase One findings presentation
- decision support tool proposed content
- decision support tool format.

Table 4.4 presents a summary of the discussion that ensued.

Table 4.4: Project Advisory Committee Meeting One Summary

Agenda item	PAC Summary of Discussion
Decision support tool proposed content discussion	*Volume of information* Project Advisory Committee members agreed the comprehensive nature of a decision support tool for breast reconstruction meant a large volume of information would be imparted to women. Discussion centred on how best to present this information so as to not overwhelm or confuse the decision support tool user. The PAC felt the clarity of language used and the format of the decision support tool would be significant factors in achieving this goal. The aims identified included to ensure the information would be user friendly, understandable to the minimum education level demographic, and not lead the decision maker or appear to be advocating specific options. *Duplication of information* Another suggestion to minimise the volume of information contained within the decision support tool was to omit information that was already reliably and comprehensively provided by other national resources, rather than simply refer to such resources. Examples included information about breast cancer management and prophylactic mastectomy. *Values clarification exercises* The PAC members debated the advantages and disadvantages of including values clarification exercises into the decision support tool. While acknowledging values-based decision making is critical for each individual to make quality decisions, the need to foster realistic expectations through a shared decision making framework is also crucial for women considering breast reconstruction. The PAC members agreed that decisions about breast reconstruction could not be made by the individual woman in isolation, due to the impact of clinical characteristics and breast cancer treatments on breast reconstruction options available to women. It was felt it would be misleading to provide information to women about all types of breast reconstruction accompanied by values clarification exercises to reach individual decisions. Women may develop unrealistic expectations, becoming confused when consulting with healthcare professionals about their options, or experiencing decision regret at their breast reconstruction outcomes as a result. It was agreed the decision support tool developed should aid decision making by providing comprehensive information about breast reconstruction treatment options and identifying factors influencing decision making, within the context of a shared decision making model alongside healthcare professionals. Hence, the decision support tool developed must also meet the needs of healthcare professionals contributing to women's decision making around breast reconstruction. It was anticipated this would be achieved through the contribution of such healthcare professionals on the PAC. Values clarification could be prompted throughout the decision support tool, but with an understanding of factors affecting decision making and the need for shared decision making. *Missing information* Information content that PAC members identified as lacking included: • the financial costs of breast reconstruction to be considered when making decisions • the grief that may be experienced following breast reconstruction (particularly for women undertaking immediate breast reconstruction) • greater focus on the impact of breast reconstruction on sexuality;

Agenda item	PAC Summary of Discussion
	• what women should do if they are unhappy with their breast reconstruction outcomes.
Decision support tool format discussion	*Information medium* Discussion around the format of the decision support tool considered women's preferred options for information and also the cost effectiveness of resource production to ensure resources developed are accessible to women making decisions about breast reconstruction. A website was acknowledged as a cost effective and accessible option to maintain, as opposed to a written resource. Website navigation was also proposed to provide greater opportunity for clear sequencing of information through use of web links. However, it was acknowledged some women may prefer hard copy resources. It was agreed that both a website and booklet format would be produced. Evaluation of the resources would incorporate women's preferred option between these two formats. Survey data collected would also include information on women's internet and computer skills to ascertain the information technology skills and preferences of the target demographic. *Meeting differing information needs* Certain information relevant to women with a breast cancer diagnosis is not relevant to women choosing bilateral prophylactic mastectomy and breast reconstruction. The PAC members suggested separation of information for these two groups of women may provide greater clarity and direction to necessary information. Much of the key information was identified as applicable to both groups; however some of the information is different, particularly with regard to timing of breast reconstruction, impacts of breast cancer treatments on breast reconstruction, surgical techniques utilised, expected aesthetic outcomes and emotional response and adjustment to breast reconstruction. For the booklet format this would be achieved by producing two separate booklets. Web links and navigation panes would be utilised to separate necessary information for the two groups of women on the website.

As a result of PAC meeting one, the following key amendments were made to the second draft of the decision support tool content:

- reviewing and revising the terminology used
- including greater information about the need for shared decision making, framing the purpose of the decision support tool within this context
- introducing the need for values clarification for the individual
- reframing content headings as questions
- splitting initial information between two groups of women (women with a breast cancer diagnosis and women considering bilateral prophylactic mastectomy and breast reconstruction)
- including information on the financial implications of breast reconstruction, including rebates and assistance available
- selecting visual images of breast reconstruction to be inserted into the decision support tool
- creating a table comparing breast reconstruction types with regard to surgery time, physical recovery time, post-operative experience, complications, limitations of each type, advantages and disadvantages of each type
- including additional detail on planning to undergo breast reconstruction, pre-operative experiences, post-operative experiences, and impact of breast reconstruction on psychosocial wellbeing
- detailing the steps women may take if they are unhappy with the outcome of their breast reconstruction
- expanding nationally available sources of information
- including notes pages in the booklet.

4.4.2 Project Advisory Committee Meeting Two

Project Advisory Committee meeting two took place in Melbourne on 7 April 2010. Prior to the meeting, PAC members were circulated draft two of the decision support tool content for review, along with a flowchart of the decision support tool structure. Thirteen PAC members contributed to the review process. Agenda items included:

- breast reconstruction images

- decision support tool content
- decision support tool format and production.

The presentation for PAC meeting two commenced with a summary of the contribution made to the previous review process and a summary of key amendments made to draft two of the decision support tool content. Next, the decision support tool structure flowchart was discussed. This document outlined the revised structure of the decision support tool, separating information to relevant groups and identifying common information to both groups. It was proposed the beginning of the decision support tool would contain generic information relevant to both groups, aimed at setting the scene and outlining the purpose of the decision support tool. Subsequent information would then be split into sections: one for women who had been diagnosed with breast cancer and another for women who were considering bilateral prophylactic mastectomy and breast reconstruction. Further information providing detail about breast reconstruction surgical options, preparing for breast reconstruction and living with breast reconstruction, would then be combined for both groups.

Table 4.5 presents a summary of PAC meeting two discussions.

Table 4.5: Project Advisory Committee Meeting Two Summary

Agenda item	PAC summary of discussion
Breast reconstruction images discussion	Much discussion occurred around the breast reconstruction images that had been selected for inclusion in the decision support tool. A synopsis of each woman's surgical experience only was provided to the PAC members for comment, as all image consents had not yet been sourced. The description accompanying each image aimed to provide information about the different stages of breast reconstruction the woman is at; explaining all scars, dressings, and complications. Discussion focused on if these series of images were appropriate, representative and provided meaningful information to women considering breast reconstruction following mastectomy. Comment from the PAC members was positive, with suggestions being to source additional images of an older woman and also to source DIEP flap breast reconstruction images, as this was an increasingly common surgical technique used in Australia. Consented breast reconstruction images would be included in draft three of the decision support tool.
Decision support tool proposed content discussion	Project Advisory Committee members expressed confidence that the content of the decision support tool was now appropriate and comprehensive to meet the needs of women considering breast reconstruction following mastectomy. *Breast reconstruction statistics* The researcher identified difficulty in accessing statistics of breast reconstruction complication rates. Liaison with the Australian Society of Plastic Surgeons had confirmed no such comprehensive data on breast reconstruction complications is collated. Surgical representatives of the PAC expressed the complication rates discussed in the information resource were representative of current trends observed. *Level of language* While PAC members acknowledged the language used within draft two of the decision support tool content was much improved, there still needed to be some work done to set the language at a minimum grade eight reading level. It was agreed the time was right to have the next draft of the decision support tool content reviewed by a professional editor to achieve this outcome. *Sharing women's experiences of breast reconstruction* All PAC members agreed the inclusion of women's quotes detailing their personal experiences of different aspects of breast reconstruction would provide useful information women could relate to. The PAC felt it was important to ensure a balance of quotes were included, so as to provide women with comprehensive information about the varying and individual experiences of women, not just promotion of positive breast reconstruction experiences. *Glossary of terms*

Agenda item	PAC summary of discussion
	The PAC members also provided feedback on a glossary of terms to facilitate understanding of some of the health and medical related terminology used in the decision support tool. The glossary would be located at the back of the booklet, with terms found in the glossary identified throughout the booklet, and formatted as hover definitions on the website. Defining the roles of members of the healthcare team and surgical complications were agreed to be necessary.
Decision support tool format discussion	The revised structure of the decision support tool was felt to have neglected a third distinct group; women who have had a breast cancer diagnosis and undergone mastectomy some time ago and may be considering delayed breast reconstruction. The specific information needs of this group may be slightly different to those who have been recently diagnosed with breast cancer; however the context of their experience may still be affected by having been diagnosed with breast cancer and undergoing breast cancer treatments. Rather than a distinct third group, it was agreed the navigation built into the design of the decision support tool could adequately direct this group to relevant information. The PAC also discussed the appeal of the decision support tool, considering it was very text dense. The inclusion of quotation and breast reconstruction images would go some way to break the text up. Other suggestions were made, including adding figures of breast reconstruction procedures to compliment the technical text explanations.

As a result of PAC meeting two, the following key amendments were made to draft three of the decision support tool content:

- relevant quotes from women who had undergone breast reconstruction were added to relevant sections
- additional breast reconstruction images were sourced, consents finalised, and images inserted
- diagrams of breast reconstruction surgery techniques were sourced and incorporated
- 'questions to ask your breast reconstruction surgeon' were moved to the end of specific sections of relevance in the booklet. Links to the list of questions to ask your breast reconstruction surgeon were added to the end of each relevant section on the website.

Once these amendments were made, further consultation with PAC members was undertaken to finalise draft three prior to professional editing. The decision support tool structure flowchart was revised to incorporate the third group of women requiring specific information about delayed breast reconstruction. This structure flowchart provided sequencing of information for each group to assist with booklet formatting and website navigation. Feedback on the revised structure was received from three PAC members via e-mail. Glossary terms were also revised and circulated to PAC members via e-mail, with three feedback replies received. A meeting was called in Perth, with the researcher and surgeon members of the PAC, to undertake final discussions on the technical content of surgical procedures presented in the decision support tool. Two of the three surgeon PAC members were able to attend.

Approximately one year lapsed between PAC meeting two and three. A significant volume of work was required to produce booklet and website prototypes for PAC review. Multiple drafts and reviews of these prototypes were undertaken by the researcher during this period. Additionally, ethics approval for breast reconstruction image consents was pending, as were diagram permissions from Oxford University Press.

4.4.2.1 The Booklets

The decision support tool booklet content was split into two discrete documents: one for women diagnosed with breast cancer and the other for women considering bilateral prophylactic mastectomy and breast reconstruction. These versions were sent to a professional editor. Two rounds of professional editing were undertaken and reviewed by the researcher. Navigation through the booklet copy was facilitated by symbols to: identify terms defined in the glossary at the end of the booklet, refer to further information on specific topics using 'more information' boxes, and summarise the key content of each section for consideration by the reader, using 'questions to ask your breast reconstruction surgeon' boxes. The edited versions were sent to a desktop publisher, with whom the researcher discussed specific design components. In particular, consumer PAC members had mentioned a desire to avoid the stereotypical pink badging of breast cancer related information. The desktop published booklets were reviewed once by the researcher with minor amendments; following this, the decision support tool booklets were finalised for PAC review. The content outline of the booklets can be viewed in Appendix Seven.

4.4.2.2 The Website

The same professional editor also undertook webpage copy edit. Part of the collaboration with Cancer Australia was an agreement for the website to be hosted on the Cancer Australia website for the purposes of summative evaluation. The professional editor employed had previously worked with Cancer Australia, assisting to streamline the web development process. Two versions of the webpage copy edit were reviewed by the researcher with amendments made. Specific focus was placed upon the navigation links and structure of the levels of headings, to ensure information was appropriately sequenced and accessible to the intended user groups. Cancer Australia web production staff then created the website. The website prototype was not a live website and was password protected. The researcher reviewed the website twice, with ongoing liaison regarding amendments with the web production staff. Following this process, the decision support tool website was finalised for PAC review. The website can be accessed at www.canceraustralia.gov.au/breastreconstruction It must be noted that minor

modification of the website has taken place since completion of this research, as part of Cancer Australia processes.

4.4.3 Project Advisory Committee Meeting Three

Project Advisory Committee members met in Sydney on 8 April 2011. Two weeks prior to this date, PAC members were e-mailed the link and password to the prototype website for review, and were asked to complete an online questionnaire prior to attending the PAC meeting to facilitate focused discussion. The researcher collated these responses to present at the PAC meeting, identifying issues for further clarification and discussion. Eleven PAC members contributed to the review process. Agenda items tabled for discussion included:

- website review questionnaire results
- complications and side effects
- breast reconstruction images
- evaluation framework.

Table 4.6 presents a summary of the discussion that ensued.

Table 4.6: Project Advisory Committee Meeting Three Summary

Agenda item	PAC summary of discussion
Breast reconstruction images discussion	*Quality and representation of breast reconstruction images* Concerns were highlighted by one member of the PAC regarding the quality and representation of the images on the website. The concern was that women may develop a negative perception of breast reconstruction by viewing some of these images. During PAC meeting one, members agreed the images should reflect a variety of ages, body shapes, breast sizes and aesthetic outcomes. The purpose was to show a representative variation of breast reconstruction aesthetic outcomes, not the extremes of 'excellent' or 'poor' aesthetic outcomes. It was deemed important to show both 'good' and 'average' aesthetic outcomes, to provide women with a view of the variable and individual results of breast reconstruction. Detailed descriptors of the individual woman's surgery were provided for each image, to set the context of the individual woman's surgical experience, reiterating this individual variability. It was agreed that depicting some commonly occurring minor complications and their resolution over time would be valuable and representative of breast reconstruction outcomes. It was agreed it would not be representative to show major complications. Consensus of the PAC members attending the meeting was that the images currently on the website were appropriate and representative and met the objectives of the project. However, attendees suggested adding more DIEP flap breast reconstruction images.
Decision support tool proposed content discussion	All questionnaire respondents agreed the information was clearly explained and easy to understand. Project Advisory Committee members commented that the editing process had contributed greatly to achieving this outcome. All PAC members responding to the questionnaire agreed the information content was appropriate to meet the purposes of the resource in providing women with information about breast reconstruction to aid decision making and also meet information needs during physical and psychosocial recovery from breast reconstruction. However, it was suggested the front page of the website include an introductory statement outlining the purpose of the resource rather than beginning with breast reconstruction information straight away. *Volume of information* One PAC member responding to the questionnaire disagreed the volume of information presented on the website was appropriate. However, PAC members attending the meeting did not believe the volume of information was an issue due to the clear navigation of the website and the view that users would likely navigate to desired information, rather than review the website in its entirety. It was agreed women evaluating the website in Phase Three of the research would determine if the volume of information was too large. *Complications and side effects* One PAC member believed information displayed regarding side effects and complications of breast reconstruction surgery should be revised to ensure accuracy. A separate meeting had been scheduled with this PAC member to discuss further, after which revised text would circulated to the PAC via e-mail for feedback. *Missing information*

Agenda item	PAC summary of discussion
	Project Advisory Committee members were asked if any gaps in information existed. One of the PAC members identified information about options for women who choose not to have a breast reconstruction were lacking. It was suggested the inclusion of visual images of use of external breast prosthesis would provide useful information to identify this as a real option for women following mastectomy and diffuse some of the myths around unpleasantness associated with using external breast prosthesis.
	In addition, several PAC members suggested more positive comments about breast reconstruction experiences would add value to the website and did not feel adding more positive comments would affect the balanced view presented.
Decision support tool format discussion	While 100% of PAC members responding to the questionnaire agreed the website layout facilitated navigation through the information, the researcher identified there had been restrictions to just three levels of headings which had posed difficulties during the web design phase. A slight variation of headings was proposed to make navigation even clearer for website users.
Evaluation framework	The evaluation framework of the research was revisited with particular reference to Phase Three, where summative evaluation of the decision support tool would be undertaken by women whom the decision support tool were developed to assist. The PAC members discussed the planned recruitment processes through the Breast Cancer Network Australia Review and Survey Group, identifying participants as those who had already undertaken breast reconstruction, those who may be considering breast reconstruction, and those who had already made a decision that breast reconstruction was not for them. The researcher had also liaised with some members of the PAC to enable recruitment of women who had undertaken bilateral prophylactic mastectomy and breast reconstruction also. It was deemed this recruitment would provide a comprehensive evaluation from the varying perspectives of the distinct groups targeted by the breast reconstruction decision support tool.
	The content of the summative evaluation surveys to be implemented in Phase Three was discussed. Survey items would be derived from the research aims. It was agreed components of information technology use, breast cancer and breast reconstruction experiences and information seeking would be included in the survey to provide some contextual background to the evaluation results. The researcher would circulate draft surveys for comment.

As a result of PAC meeting three, the following key amendments were made to the decision support tool content:

- photographs of a woman using an external breast prosthesis were taken and inserted into the decision support tool
- heading levels of the website navigation pane were amended
- an introductory statement was developed for the front web page
- side effect and complication information content was revised
- additional breast reconstruction comments were inserted
- breast reconstruction images were edited with regard to lighting, magnification and consistency of sequencing
- additional DIEP flap breast reconstruction images would be sought.

Several of these amendments were actioned via e-mail circulation. Feedback was received from three PAC members regarding the revised heading levels for the website navigation pane. Seven PAC members provided comment on the introductory statement drafted for inclusion on the front page of the website. The information on side effects and complications of breast reconstruction were revised as per PAC member feedback. Each of the surgeon PAC members approved the revised version as accurate for inclusion in the decision support tool. The revisions to breast reconstruction images were discussed with the PAC member voicing concern. These revisions included adjusting the lighting of the shots, cropping and zooming shots so that there was some uniformity, and decreasing the sequence of shots from nine images per woman to five images per woman at key points in time during recovery from breast reconstruction surgery. These revisions were accepted by the PAC member. All amendments were made to both the web copy and the booklet versions, and were sent through to the desktop publisher and web production staff for actioning. Both formats were reviewed by the researcher to confirm these amendments had been actioned.

4.4.4 International Patient Decision Aids Standard Collaboration Checklist

Aligned with the Ottawa Decision Support Framework is the International Patient Decision Aids Standard (IPDAS) Collaboration checklist, which provides an

internationally recognised set of quality criteria to guide both developers and users of decision aids (http://decisionaid.ohri.ca/implement.html). These standards were developed through a two-stage evidence informed Delphi consensus process. The IPDAS Collaboration agreed there was a need for a further instrument to quantitatively assess the quality of decision aids developed. The IPDAS Instrument (IPDASi) was developed based upon the IPDAS checklist. Items are currently being finalized to improve inter-rater reliability prior to being released publically. The IPDASi is intended to also be used as a formative evaluation of decision aids under development (Elwyn & O'Connor, 2009).

The IPDAS checklist was applied to the decision support tool developed in this research, to confirm key content had been appropriately covered and presentation of the information was optimal for the user. The following table presents and discusses how the breast reconstruction decision support tool met the IPDAS checklist criteria (Table 4.7).

Table 4.7: Breast Reconstruction Decision Support Tool IPDAS Checklist

(http://decisionaid.ohri.ca/implement.html)

IPDAS criteria	Yes No Not applicable N/A	Discussion where criteria are not met or not applicable
CONTENT: Does the decision aid…		
…provide information about options in sufficient detail for decision making?		
Describe the health condition	Yes	Additional items in this section of the checklist relate to screening tests. These items were not applicable to the breast reconstruction decision support tool as the focus of this tool is surgery options, not screening tests.
List the options	Yes	
List the option of doing nothing	Yes	
Describe the natural course without options	Yes	Other additional items in this section of the checklist relate to presenting probabilities of outcomes in an unbiased and understandable way. Outcomes of breast reconstruction may relate to clinical outcomes of complication, psychosocial outcomes, aesthetic outcomes and satisfaction with breast reconstruction. Insufficient Australian data exists presenting complication rates of breast reconstruction procedures; therefore, this information could not be included. The subjective and personal nature of psychosocial, aesthetic and satisfaction outcomes makes probability outcomes difficult and of limited value. Rather the variable nature of aesthetic outcomes, satisfaction with breast reconstruction and psychosocial impacts of breast reconstruction are discussed in the decision support tool.
Describe procedures	Yes	
Describe positive features (benefits)	Yes	
Describe negative features (harms/side effects/disadvantages)	Yes	
Include chances of positive and negative outcomes	Yes	
…include methods for clarifying and expressing patients' values?		
Describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional and social effects	Yes	
Ask patients to consider which positive and negative features matter most	Yes	
Suggest ways for patients to share what matters most with others	Yes	

IPDAS criteria	Yes No Not applicable N/A	Discussion where criteria are not met or not applicable
CONTENT: Does the decision aid…		
…include structured guidance in deliberation and communication?		
Provide steps to making a decision	Yes	A question list to discuss with healthcare professionals was included in the decision support tool.
Suggest ways to talk about the decision with a healthcare professional	Yes	
Include tools (worksheet, question list) to discuss options with others	Yes	A values clarification worksheet was not included in the decision support tool. The research team concluded it may not be appropriate to include a values clarification exercise within the decision support tool, given the importance of shared decision making and the input and guidance required from healthcare professionals. Facilitating or encouraging women to make a decision at the time they are using the decision support tool independently may be counterproductive to quality decision making. The importance of values clarification is discussed and encouraged within the decision support tool, without inclusion of a structured exercise.
DEVELOPMENT PROCESS: Does the decision aid…		
…present information in a balanced manner?		
Able to compare positive/negative features of options	Yes	
Show negative/positive features with equal detail (fonts, order)	Yes	
…have a systematic development process?		
Includes developers' credentials/qualifications	Yes	The doctoral student's name and qualifications, along with her supervisors' were identified on the information sheet provided to participants prior to consenting to participate. The doctoral students name was noted on the website and within the booklet. Participants were aware that a Project Advisory Committee had been convened to contribute to the
Finds out what users need to discuss options	Yes	
Has peer review by patients/professional experts not involved in development and field testing	No	

IPDAS criteria	Yes No Not applicable N/A	Discussion where criteria are not met or not applicable
Is field tested with users	Yes	development of the resource. While particulars of the members were not listed, this information was available to participants upon request.
The field test shows the decision aid is acceptable, balanced for undecided patients and understood by those with limited reading skills	Yes	Patients/professional experts were members of the PAC involved in development and evaluation of the resource. Following completion of Phase Three of this research, management of the website was taken over by Cancer Australia, who subsequently undertook their own review including patients/professional experts who were not involved in the development or initial evaluation of the resource. This independent review undertaken by Cancer Australia did not form part of this research.
DEVELOPMENT PROCESS: Does the decision aid…		
…use up-to-date scientific evidence that is cited in a reference section or technical document?		
Provides references to evidence used	No	In order to keep the resources succinct and costs of production manageable, references and literature appraisal details were not included in the decision support tool developed. References could be provided to participants upon request. Details related to the evidence available and their appraisals are discussed in Chapters 1 and 3.
Reports steps to find, appraise and summarise the evidence	No	
Report date of last update	N/A	
Report how often the decision aid is updated	No	Culver and colleagues (2011) developed a decision aid for BRCA mutation carriers, conducting focus groups with patients and various healthcare professionals. All four groups of participants agreed users presume the level of evidence included in the decision aid to be appropriate and of a satisfactory standard, highlighting identifying levels of evidence may be unnecessary (Culver et al., 2011).
Describe quality of scientific evidence (including lack of evidence)	No	
Uses evidence from studies of patients similar to those of target audience	Yes	
		Participants were aware that the decision support tool had been newly developed and was the first version. The website identifies on each webpage the date information was posted. Updating the decision support tool content was now the responsibility of Cancer Australia, who managed the website.

IPDAS criteria	Yes No Not applicable N/A	Discussion where criteria are not met or not applicable
DEVELOPMENT PROCESS: Does the decision aid…		
…disclose conflicts of interest?		
Report source of funding to develop and distribute the patient decision aid	Yes	There were no conflicts of interest reported or identified relating to the research team or members of the PAC. Being a retrospective evaluation, women participating had already undertaken breast reconstruction; therefore, no benefit or loss to any participants was applicable.
Report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid	No	
…use plain language?		
Is written at a level that can be understood by the majority of patients in the target group	Yes	
Is written at a grade 8 equivalent or less	Yes	
Provides ways for patient to understand information other than reading	Yes	
Additional criteria for internet-based decision aids		
Provide a step-by-step way to move through the web pages	Yes	Personal health information is not entered into the decision support tool. It is designed as a resource to inform and assist women with decision making about breast reconstruction through the provision of comprehensive information. It is not a tool to be solely used to make decisions. The nature of breast reconstruction decision making requires healthcare professional input regarding clinical considerations women must take into account when weighing up their breast reconstruction options. Women are encouraged to access the information both independently and alongside their healthcare professionals.
Allow patients to search for key words	Yes	
Provide feedback on personal health information that is entered into the patient decision aid	No	
Provides security for personal health information entered into the decision aid	No	
Make it easy for patients to return to the decision aid after linking to other web pages	Yes	Website format aims to limit the duplication of paper-based information becoming out-dated. The cost effectiveness of a paper-based resource is being considered.
Permit printing as a single document	No	

IPDAS criteria	Yes No Not applicable N/A	Discussion where criteria are not met or not applicable
Additional criteria for stories used in patient decision aids		
Use stories that present a range of positive and negative experiences	Yes	There was no financial remuneration for use of patient stories and written consent was obtained; however this was not reported in the resources evaluated. Any publication of a paper-based decision support tool in the future would clearly state informed consent and no remuneration provided. It was stated in the decision support tool that women had consented to use of their photos.
Report if there was a financial or other reason why patients decided to share their story	No	
State in an accessible document that the patient gave informed consent to use their stories	No	
EFFECTIVENESS: Does the decision aid ensure decision making is informed and values based?		
Recognise a decision needs to be made	N/A	The effectiveness of the breast reconstruction decision support tool was not assessed as part of this research. The purpose of the research was to undertake initial development of a decision support tool and preliminary evaluation of the whether the decision support tool would meet women's information needs and be a useful resource for decision making. The evaluation was retrospective, undertaken by women who had already undertaken breast reconstruction. Now that the content and format of the decision support tool have been confirmed through evaluation by those who have experienced breast reconstruction information seeking and decision making, future research should prospectively evaluate the effectiveness of the decision support tool.
Know options and their features	N/A	
Understand that values affect decisions	N/A	
Be clear about option features that matter most	N/A	
Discuss values with their practitioner	N/A	
Become involved in preferred ways	N/A	
Improves the match between the chosen option and features that matter most to the informed patient	N/A	

Completing the IPDAS checklist for users provided a structured way for the researcher to undertake a form of internal summative evaluation of the decision support tool that had been developed, prior to the formal summative evaluation undertaken in Phase Three. It confirmed that rigorous and ethical research processes had been followed, comprehensive information had been included and identified potential modifications to future versions of the decision support tool for dissemination to the wider public.

4.5 Conclusion

The evaluation framework guiding the implementation of Phase Two of this research was a useful tool to lead input and process evaluation components of the CIPP model, particularly given the lengthy and intricate nature of collaborative decision support tool development. Input and process evaluations were successfully completed with a robust audit trail maintained, demonstrating accountability to the stakeholder group and rigour of the research processes. The engagement and contribution of stakeholders was invaluable to the content and design of an appropriate decision support tool to meet the aims of this research.

Challenges of the collaborative process included the time demands on a single researcher to maintain stakeholder engagement and facilitate collaboration over a long period, including the repeated review, collation and actioning of feedback from 13 individuals. Two members of the PAC did not consistently contribute to the review process. Individual attempts were made to re-engage these members, with minimal effect. Despite this, the collaboration of stakeholders was effective in producing two formats of a breast reconstruction decision support tool—booklet and website—and planning evaluation of the decision support tool.

Aspects of the collaboration that were particularly effective were: the varied composition of the stakeholder group, the use of teleconferencing and questionnaire feedback as strategies for stakeholder engagement, and providing multiple options for stakeholders to have input into the review process. Bringing a group of stakeholders with different perspectives and expertise together facilitated thorough

review of all aspects of decision support tool development. The PAC was able to discuss opinions and perspectives openly and agree on responsive actions to achieve the research aims. Specific expertise could be sought from individual PAC members or subgroups where required, prior to tabling items for discussion at the PAC meetings. This allowed for a considered approach to issues that needed to be addressed and assisted in minimising the demand on PAC members' time. Teleconferencing worked well, permitting input from stakeholders residing interstate; therefore, facilitating maintenance of stakeholder engagement. Providing multiple options for PAC member input maximised the amount of input and feedback received from PAC members, and allowed for accommodation of individual member preferences.

The PAC met their terms of reference by working collaboratively to produce a comprehensive, user friendly and contextually Australian source of information for women considering breast reconstruction following mastectomy. Phase Three seeks to evaluate if women who had previously considered, or may be considering, breast reconstruction believe the decision support tool meets their breast reconstruction information needs and would assist them to make decisions about breast reconstruction.

Chapter 5: Phase Three—Evaluation of a Decision Support Tool for Women Considering Breast Reconstruction Following Mastectomy

5.1 Introduction

Product evaluation was performed in Phase Three of the research. An integrated multiple method design was adopted, using surveys to evaluate the breast reconstruction decision support tool and semi-structured focus group, along with telephone interviews to clarify preliminary survey data analysis and further explore issues raised in the survey evaluation (Figure 5.1). Women who had undertaken breast reconstruction were asked to retrospectively evaluate if the decision support tool would have met their breast reconstruction information needs and assisted them in their decision-making process. Women who had not undertaken breast reconstruction were asked to prospectively evaluate whether the decision support tool met their information needs. The methods and results of the evaluation of the decision support tool will be presented and discussed.

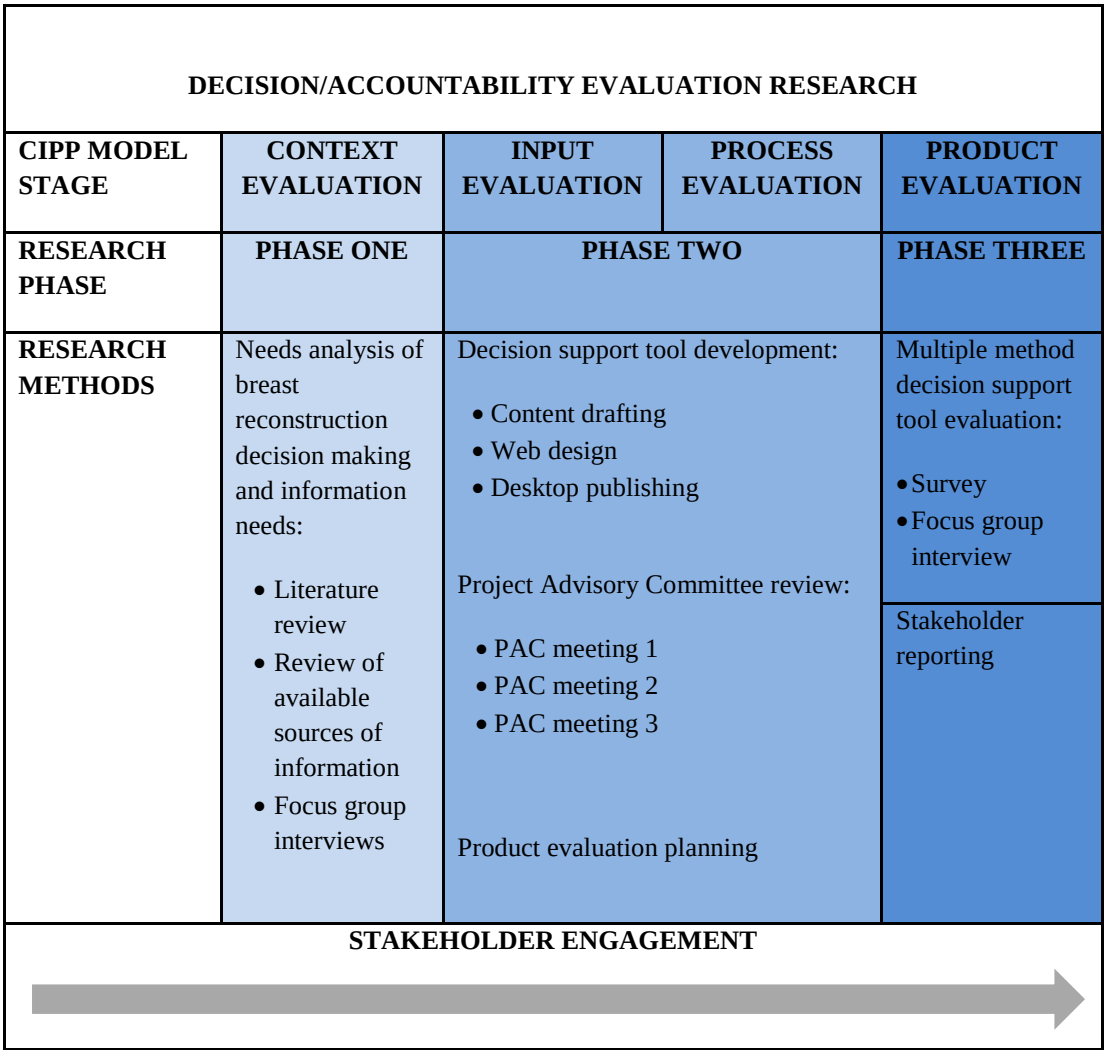

Figure 5.1: Evaluation Framework (Phases One, Two & Three)

5.1.1 Objectives

The aim of Phase Three of the research was the continued implementation of the evaluation framework for the breast reconstruction decision support tool; specifically, to conduct a summative evaluation of the decision support tool developed. The specific objectives of this phase of the research were to:

- undertake a summative evaluation to determine if the decision support tool developed would:
    - meet the information needs of women who may be considering breast reconstruction following mastectomy

- be useful for women to refer back to throughout their breast reconstruction experience
- be acceptable and useful for women to assist breast reconstruction decision making.

5.2 Methods

Phase Three of the research adopted an integrated multiple methods to evaluate the decision support tool that had been developed. Decision/accountability evaluation research often uses various methods to facilitate comprehensive appraisal to facilitate analysis of the merits of the product, service or programme being evaluated, and also to corroborate findings (Stufflebeam, 2001). Survey data enabled the researcher to obtain the perspective of a larger number of women. This was subsequently complemented by semi-structured focus group and telephone interviews, to clarify survey data analysis and further explore issues raised in the survey evaluation.

5.2.1 Participants

Three participant groups were invited to participate in the evaluation of the decision support tool:

1. women who had undergone mastectomy to treat breast cancer and had chosen to have breast reconstruction
2. women who had undergone mastectomy to treat breast cancer and had NOT had breast reconstruction
3. women who had no history of breast cancer diagnosis and had chosen to undergo bilateral prophylactic mastectomy and breast reconstruction.

The three participant groups represented women who: required, or chose, mastectomy to treat their breast cancer; those who may have opted for contralateral prophylactic mastectomy; may have undertaken other surgeries to treat their breast cancer that had later required progression to mastectomy; had undertaken immediate

or delayed breast reconstruction; were actively considering breast reconstruction; and had previously decided breast reconstruction was not for them.

Inclusion criteria for the participant groups were: 1) women who had been diagnosed with breast cancer, undergone mastectomy and had not had breast reconstruction; 2) women who had been diagnosed with breast cancer, undergone mastectomy and had breast reconstruction; and 3) women who did not have a breast cancer diagnosis, and had undergone bilateral prophylactic mastectomy and breast reconstruction. All participants were required to be over the age of 18 years and English speaking to provide informed consent, and complete the survey.

5.2.2 Recruitment

Participants of the first two groups were recruited through Breast Cancer Network Australia's Review and Survey Group. The Review and Survey Group is a database of women who have registered their interest to be involved in research projects in the areas of breast cancer and related issues. The Review and Survey Group is based on the Breast Cancer Network Australia philosophy of 'a seat at the table'; empowering women to become actively involved in decisions made about breast cancer treatment, care and services. The Review and Survey Group had approximately 942 registered members at the time of recruitment. Breast Cancer Network Australia policy officers manage the process of recruitment of the Review and Survey Group members, generally approaching double the number of desired participants, with further recruitment undertaken if the anticipated sample size is not achieved. Once inclusion criteria have been accounted for, based on registered members details, women are randomly contacted by Breast Cancer Network Australia on behalf of the researcher.

A Breast Cancer Network Australia Review and Survey Group request form was completed and submitted to Breast Cancer Network Australia policy officers identifying the inclusion criteria and participant commitment required. The researcher liaised with the policy officer to discuss details of the recruitment and the anticipated total sample size of 100. An e-mail inviting women to participate in the research was circulated to 150 women who met the inclusion criteria. The e-mail

included an information statement and an expression of interest/consent form (Appendix Six). Interested women were invited to contact the researcher directly. On the expression of interest/consent form, respondents identified their contact details, whether or not they had undertaken breast reconstruction and their preferred form of participation, either online survey completion or paper-based survey to be mailed to their nominated address. Expression of interest/consent forms were either e-mailed or mailed to the researcher. The researcher replied to the expression of interest via e-mail, thanking the woman for her interest, advising that further instructions for decision support tool review would be communicated in the coming weeks, and requesting the woman make contact if she had any further queries about the research or her participation.

The bilateral prophylactic mastectomy and breast reconstruction participant group were recruited through a breast reconstruction surgeon's consulting room in Perth, WA. Recruitment of this group was limited to Perth, as an existing well-established collaboration and recruitment process was in place following Phase One recruitment. This would allow timely recruitment for evaluation. Women meeting the inclusion criteria were mailed an information pack containing: a cover letter from the breast reconstruction surgeon introducing the research and clearly identifying no obligation to participate, along with an information statement and expression of interest/consent form (Appendix Six). These were sent from the breast reconstruction surgeon's consulting room, ensuring the researcher had no access to participants' personal details. Again, women were asked to make contact with the researcher. The participant expression of interest/consent form required respondents to identify their contact details, confirm they had undertaken mastectomy and breast reconstruction in the absence of a breast cancer diagnosis and nominate their preferred participation method. The researcher replied to women's expression of interest/consent in line with the previously detailed procedure undertaken for the other participant groups.

A total of 168 women were invited to participate; 150 women who had been diagnosed with breast cancer and 18 women who had chosen bilateral prophylactic mastectomy and breast reconstruction. Of the 150 women from the Breast Cancer Network Australia Review and Survey Group who were invited to participate, 109

responded with interest to participate in the research. Surveys were completed by 96 of these women, indicating a recruitment rate of 88 per cent. Twelve of the 18 women who had undertaken bilateral prophylactic mastectomy and breast reconstruction expressed their interest to participate, with 11 of those returning surveys (a recruitment rate of 92%). In total, 107 women were recruited to evaluate the decision support tool, achieving an overall recruitment rate of 64 per cent.

The information sheets also introduced the researcher's intent to recruit interested participants to attend focus group interviews at a later stage of the research. The information sheet emphasised that women would be contacted via e-mail at a later date and were in no way obliged to participate in the focus group interviews.

5.2.3 Survey Design

A survey is a tool used to collect data from a sample of participants, with the aim of gaining specific information about the population being studied (Griffin, M., Australian Development Agency for Statistics and Information Systems, personal communication, 26 September 2012). Survey was chosen as an appropriate data collection method, as it: would allow for consistent evaluation data to be collected from a large population sample; was a method that could be administered in multiple ways (paper-based or online) to accommodate participant preferences; and would provide quantitative data evaluating the decision support tool developed. Focus group interviews were an additional data collection method used to complement survey method, aimed at confirming data analysis, clarification of evaluation results. It also provided participants with the opportunity to further expand on their evaluation, within the context of their personal experiences of breast cancer and breast reconstruction.

Four sequential steps were followed when designing the survey: 1) identification of the study population; 2) design of the survey questions; 3) collection of the data; and 4) analysis of the data collected (Griffin, M., Australian Development Agency for Statistics and Information Systems, personal communication, 26 September 2012). In designing survey questions, the following key components were considered:

- construct (what it was to be measured)

- measurement (what questions could be ask to measure the construct)
- response (what answers would be obtained from these measurements). (Griffin, M., Australian Development Agency for Statistics and Information Systems, personal communication, 26 September 2012)

Members of the PAC first identified the topic areas to be studied, aligned with the research aims. A significant portion of the survey would focus on evaluating the decision support tool reviewed by participants. Additional information to be obtained included: demographic participant information to describe the participant sample; information on women's experiences of breast cancer and breast reconstruction (where applicable), to provide context to the discussion of survey results; information about women's breast reconstruction information seeking to contribute to, and compare against, existing knowledge about women's breast reconstruction information seeking trends; and women's information technology use and skill, to explore the feasibility and utility of paper-based and website decision support tool applications.

Collecting data about women's breast cancer and breast reconstruction experiences may provide valuable information on the factors affecting breast reconstruction decision making. While causal inferences cannot be made from this data, it affords some context to women's evaluation of how the decision support tool may have met their breast reconstruction information needs. Participants' computer and internet use patterns and enjoyment were measured. Several examples of existing surveys evaluating information technology use were reviewed to identify key survey items as appropriate measures.

When designing the survey questions, it became clear that different questioning was required for the three participant groups, due to their varying breast reconstruction contexts, resulting in three variations of the survey (Appendix Six). For example, those who had undertaken breast reconstruction (whether prophylactically or because of a breast cancer diagnosis) were asked about the information they had accessed when making their decisions about breast reconstruction. However, women who had been diagnosed with breast cancer without having had breast reconstruction

were asked to hypothesise where they might source breast reconstruction information. This group were also asked if they were currently actively considering breast reconstruction, to identify those who may not be hypothesising but were actually considering or accessing breast reconstruction information.

The survey items evaluating the decision support tool focused on women's appraisal of the format, visual appeal, information content and perceived usefulness of the decision support tool to those stakeholders involved in women's breast reconstruction decision making; namely, the women themselves, family and healthcare professionals. These questions appraised the decision support tool against its intended aims of providing appropriate, comprehensive, clear and useful information to women about breast reconstruction. In addition, a specific set of questions were included to measure women's responses to the images of breast reconstruction contained within the decision support tool. Available images are lacking and provide limited information to women; yet these were a significant component of the information women felt they needed about breast reconstruction. Evaluating how the images sourced were received provided valuable information in expanding this source of information to women in the future.

Finally, two open-ended measures sought women's thoughts regarding any particular information that was unclear or confusing, or if there was any information women felt had been omitted from the decision support tool. Women were also invited to document any other comments about their review of the decision support tool.

The surveys developed were reviewed by the researchers and deemed suitable measures to facilitate appraisal of the construct. Upon reviewing the surveys developed Tourangeau, Rips and Rasinski's (2000) seven types of misinterpretation of questions were considered:

1. grammatical ambiguity
2. excessive complexity
3. faulty presupposition
4. vague concepts
5. vague quantifiers

6. unfamiliar terms
7. false inferences.

Survey questions were written succinctly, to ensure they were clear and not complex in their request of the participant. False inferences would be avoided by survey questions being clear, not requiring the respondent to determine between a literal and assumed meaning (Tourangeau et al., 2000). Medical terminology was avoided in the questions; however, where such terminology was used (e.g., adjuvant therapy or specific types of breast reconstruction surgery), definition or explanations were provided as part of the question. In addition, women's review of the decision support tool would provide definitions for all related medical terminology.

Where questions related to timing were asked, participants were asked for a date (month/year), or timing options were provided as categorical responses; thus avoiding vague quantifiers. A simplistic, common 5-point likert scale of responses asked participants to what degree they agreed with each survey item. Survey items were checked to ensure they did not lead participant responses; they simply provided a statement, against which criteria the decision support tool was being appraised.

The evaluation framework for the decision support tool was integral to survey design. Decision/accountability evaluation research stipulates the questions be derived from stakeholders (Stufflebeam, 2001). The survey measures were developed based upon determined stakeholders' needs of what a breast reconstruction decision support tool should provide. In addition, the survey questions answer some main questions that Stufflebeam (2001) articulates should be answered by an evaluation:

- What is the assessed need of the target population?
- Is the product/service able to meet the target populations' needs?
- Is the product/service better than its alternatives?
- Is the product/service accessible and sustainable?

The survey design process and finalised surveys were presented to the PAC, who endorsed the surveys for implementation in Phase Three of the research.

5.2.4 Data Collection

Each woman who agreed to participate in the research was mailed a hard copy of the relevant booklet to their nominated address and a link to the website resource. The booklets were marked 'Not for dissemination' and a stamped self-addressed envelope was enclosed for women to return the booklet to the researcher once their review was complete. All women were sent instructions (Appendix Six) for review of the decision support tool, either via e-mail or mail as preferred. The instructions reiterated the aim of the research and clarified the developed formats of the decision support tool for review. The relevant online survey link and log in details for the specific participant group were sent. For those who nominated paper-based survey completion, the relevant paper-based survey was posted, along with the instructions and hard copy booklet. The completed survey was returned to the researcher in the stamped self-addressed envelope provided, along with the booklet. A survey completion closing date was provided.

Following preliminary analysis of the survey results, women were contacted via e-mail (Appendix Six) to express their interest in participating in focus group interviews. The purpose of the focus group interviews was to clarify preliminary survey data analysis and further explore prominent issues identified from the survey evaluation of the decision support tool. Focus group interviews were offered in Perth, Sydney and Melbourne, where the majority of participating women resided. Those not residing in these states were advised of the plan for focus group interviews in the event they were able to attend in a nearby state and were alternatively offered a telephone interview at a time suitable to them.

Two focus group interview times were offered in each state, providing one day and one evening interview. Several women replied to the e-mail invitation identifying they were not able to attend the scheduled times; however, were still very keen to participate. Telephone interviews were scheduled with these women at a time suitable to them. Women were e-mailed reminders one or two days prior to their scheduled focus group or telephone interview. A semi-structured interview schedule (Appendix Six) was followed for all interviews.

Two focus group interviews were held: one in Melbourne (n=9) and one in Sydney (n=4). Light refreshments were provided. The FGIs were audio recorded and lasted one hour and 16 minutes and one hour and 25 minutes respectively. Twenty-three telephone interviews were conducted, lasting between 25 minutes and 50 minutes. Field notes and verbatim comments were documented on the interview schedule by the researcher during the telephone interviews.

5.2.5 Data Analysis

Paper-based survey responses were manually entered into the online survey program by the researcher. Data was extracted from the online survey program into Excel spreadsheets, where data were checked, cleaned and coded. Checking of the data ensured there was only one entry per participant. There were two examples of double survey completion from participants, where the initial survey was incomplete due to the participant having trouble with the survey program. The incomplete surveys were deleted and the most recent survey completion retained. Cleaning of the data involved reviewing survey questions and identifying those to be manually analysed from those to be statistically analysed. Those items being manually analysed included descriptive open-ended responses. The manual analysis items were separated out into a separate Excel spreadsheet. Coding of the data being statistically analysed required each response option to be coded. The spreadsheets from each of the three differing surveys were then compiled into a single spreadsheet, differentiating participant group as a variable. A master coding key was compiled throughout this process.

Statistical analysis was undertaken using R software. R is a statistical computing and graphics program that facilitates data manipulation, calculation and graphical display. Calculations provided a mean, a range of responses and frequency of responses for the nominal data. The frequencies of responses of each group were compared using non-parametric tests to identify any statistically significant difference between responses of the three participant groups. The R software program identifies the appropriate and optimal statistical test to be applied to the data entered. Fisher’s exact test was used to compare survey responses between

participant groups. The Wilcoxon signed ranks test was used to compare differences in time (Polit & Tatano Beck, 2012).

Content analysis was undertaken for the open-ended survey responses. Content analysis allows the researcher to identify themes and patterns throughout the data (Polit & Tatano Beck, 2012). NVivo software (version 9) was used for data management. Open-ended responses were collated for each of the three participant groups and transcribed verbatim into NVivo. Responses were then grouped under the topic headings: unclear or confusing information in the decision support tool, information missing from the decision support tool and any other comments. A summary of responses under each heading was analysed, categorising the responses, identifying the number of responses per category, and exploring similarities and differences in responses between participant groups. Collective analysis of responses from the three participant groups identified shared concepts. This process facilitated the organisation and integration of open-ended responses to complement the survey evaluation data.

Audio-recorded focus group interviews were listened to twice by the researcher, with additional field notes made. The field notes and verbatim comments from both the focus group and telephone interviews were entered into NVivo (version 9) for data management purposes. Content analysis was undertaken on the interview data, coding data into common topics of discussion. Varying views were coded together within the topic discussed. The common topics were aligned with the semi-structured interview schedule. The content of each coded topic was analysed to identify differing views, the frequency of each point of view, and suggestions for related improvements to the decision support tool. Qualitative data coding and analysis was confirmed by the doctoral research supervisor.

5.3 Decision Support Tool Evaluation Results

One hundred and seven surveys were returned, indicating a participation response rate of 88 per cent. Eleven surveys were from women who had undertaken bilateral prophylactic mastectomy and breast reconstruction, 19 surveys were from women

who had undergone mastectomy without breast reconstruction and 77 surveys were from women who had undertaken mastectomy and breast reconstruction following a breast cancer diagnosis. The following results presented describe frequency statistics. While some statistical analysis has been undertaken to compare responses between the three groups of participants, the purpose of this data analysis is not to generalise statistically significant results to a wider population. The participant population is not representative of the breast cancer demographic of Australia with regard to age distribution or residence.

5.3.1 Participant Demographics

The majority of women participating in this phase of the research lived in metropolitan areas (92.5%), with only five living in rural Australia (4.7%), and three women living in remote Australia (2.8%). Women ranged in age from less than 35 years old to more than 70 years old, with the greatest number of women aged 51 to 55 years (Final column of Table 5.1). The 51 to 55 year age group also represented the average age of women participating. There was some variation in the dispersion of age frequencies between the three participant groups. The majority of women who had undertaken mastectomy and breast reconstruction were in the 51 to 55 age group; women who had not undertaken breast reconstruction were dispersed across the age categories 46 to 50, 51 to 55 and 56 to 60; the majority of women who had bilateral prophylactic mastectomy and breast reconstruction were aged 56 to 60, closely followed by women in each of the 35 to 40, 41 to 45 and 46 to 50 year age groups (Table 5.1). These difference in age across the three participant groups did not reach statistical significance ($p=0.052$).

Table 5.1: Age—Comparison Between the Three Participant Groups

Age (years)	Bilateral prophylactic mastectomy and breast reconstruction N (%)	Mastectomy with no breast reconstruction N (%)	Breast reconstruction N (%)	All N (%)
<35	1 (9.1)	0 (0)	0 (0)	1 (0.9)
35–40	**2 (18.2)**	1 (5.3)	2 (2.6)	5 (4.7)
41–45	**2 (18.2)**	1 (5.3)	5 (6.5)	8 (7.5)
46–50	**2 (18.2)**	**4 (21.1)**	10 (13)	16 (15)
51–55	1 (9.1)	**5 (26.3)**	**37 (48.1)**	**43 (40.2)**
56–60	**3 (27.3)**	**4 (21.1)**	14 (18.2)	21 (19.6)
61–65	0 (0)	2 (10.5)	6 (7.8)	8 (7.5)
66–70	0 (0)	2 (10.5)	2 (2.6)	4 (3.7)
>70	0 (0)	0 (0)	1 (1.3)	1 (0.9)
Total	11	19	77	107

Percentages rounded to one decimal place

Data referred to in text bolded

The majority of women held Diploma and Bachelor Degree qualifications (Table 5.2). There was no statistically significant difference between rural/remote and metropolitan women (p=0.771). The highest level of education attained for women in rural or remote areas was a Bachelor's degree held by one woman. Of the women residing in metropolitan areas, 33 held a Bachelor Degree (33.3%), 14 held a Master's qualification (14.1%) and one woman held a Doctorate qualification (1%).

Table 5.2: Level of Education—Comparison by residence

Level of Education	Rural/Remote N (%)	Metropolitan N (%)	All N (%)
Less than secondary	1 (1)	0 (0)	1 (1)
Secondary	2 (2)	22 (21)	24 (22)
Diploma	4 (4)	29 (27)	**33 (31)**
Bachelor's Degree	**1 (1)**	**33 (31)**	**34 (32)**
Master's Degree	0 (0)	**14 (13)**	14 (13)
Doctorate	0 (0)	**1 (1)**	0 (0)
Total	8	99	107

Percentages rounded to one decimal place

Data referred to in text bolded

Women were asked to identify their current occupation. The responses were then categorised according to the Australian Standard Classification of Occupations second edition sub major groups. The majority of women were either retired (N=15, 14%) or employed in the health (N=16, 15%) or education sectors (N=14, 13%) (Table 5.3).

Table 5.3: Occupation

Occupation	**All N (%)**
Health	**16 (15)**
Retired	**15 (14)**
Education	**14 (13)**
Home duties	10 (10)
Administration	9 (9)
Service	8 (8)
Management	6 (6)
Retail	6 (6)
Self employed	6 (6)
Arts	4 (4)
Sciences	3 (3)
Farmer	2 (2)
Unemployed	2 (2)
Student	1 (1)
Disability pension	1 (1)
Finance	1 (1)
Information technology	1 (1)
Total	105

Percentages rounded to one decimal place

Data referred to in text bolded

While the average household income of women was $70,000 to $84,999 per annum, the majority of households earned $100,000 to $149,000 per annum. While there was no statistically significant difference between participant groups (p=0.739), the majority of women who had not undertaken breast reconstruction either earned less than $40,000 per year or $70,000 to $84,999 per year, while the majority of women who had undertaken breast reconstruction (including the bilateral prophylactic

mastectomy and breast reconstruction participant group) earned $100,000 to $149,999 per year or greater than $150,000 per year (Table 5.4).

Table 5.4: Household Income—Comparison Between Three Participant Groups

Household income	Bilateral prophylactic mastectomy and breast reconstruction N (%)	Mastectomy with no breast reconstruction N (%)	Breast reconstruction N (%)	All N (%)
<$40,000	1 (10)	**4 (21.1)**	9 (12.2)	14 (13.6)
$40,000–$54,999	1 (10)	3 (15.8)	10 (13.5)	14 (13.6)
$55,000–$69,999	1 (10)	1 (5.3)	3 (4.1)	5 (4.9)
$70,000–$84,999	0 (0)	**4 (21.1)**	8 (10.8)	12 (11.7)
$85,000–$99,999	1 (10)	3 (15.8)	10 (13.5)	14 (13.6)
$100,000–$149,999	**4 (40)**	2 (10.5)	**19 (25.7)**	25 (24.3)
>$150,000	2 (20)	2 (10.5)	**15 (20.3)**	19 (18.4)
Total	10	19	74	103

Percentages rounded to one decimal place

Data referred to in text bolded

The vast majority of women were married (79.2%). Eight percent of women were divorced, 7% identified as defacto and 6% single. There was no statistically significant difference in relationship status between participant groups (p=0.703).

5.3.2 Use of Information Technology

Women were asked questions about their use of information technology to provide background information to the preferred formats of the decision support tool. The vast majority of women had been using computers for more than ten years (78.5%) (Table 5.5).

Table 5.5: Length of Time Participants Have Been Using Computers—Comparison Between Age Groups

Years	Participant age group (years)									
	<35	**35–40**	**41–45**	**46–50**	**51–55**	**56–60**	**61–65**	**66–70**	**> 70**	**Total**
1–3	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.9)
3–5	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.9)
5–10	1 (100)	0 (0)	0 (0)	3 (18.8)	5 (11.6)	4 (19)	6 (75)	2 (50)	0 (0)	21 (19.6)
> 10	0 (0)	5 (100)	8 (100)	13 (81.2)	36 (83.7)	17 (81)	2 (25)	2 (50)	1 (100)	84 (78.5)
Total	**1**	**5**	**8**	**16**	**43**	**21**	**8**	**4**	**1**	

Percentages rounded to one decimal place

The average number of hours women had spent using a computer over the last year was between 10 and 20 hours per week; however, frequencies were fairly evenly spread (Final column of Table 5.6). While there was no statistically significant difference in hours per week spent using computers by age or residence (p=0.53 and p=0.841 respectively), there was a statistically significant difference between participant groups (p=0.018). While the breast reconstruction group were more evenly dispersed among categories, the majority of women in the bilateral prophylactic mastectomy and breast reconstruction group spent one to five hours per week on the computer (N=4, 44.4%), and the group who did not have breast reconstruction mostly spent six to ten hours per week on their computers (N=9, 47.4%) (Table 5.6).

Table 5.6: Hours Per Week Spent Using Computers—Comparison Between Participant Groups

Computer use per week (hours)	Bilateral prophylactic mastectomy and breast reconstruction N (%)	Mastectomy with no breast reconstruction N (%)	Breast reconstruction N (%)	All N (%)
1–5	**4 (44.4)**	0 (0)	7 (9.1)	11 (10.5)
6–10	1 (11.1)	**9 (47.4)**	**17 (22.1)**	27 (25.7)
10–20	2 (22.2)	2 (10.5)	**21 (27.3)**	25 (23.8)
20–30	0 (0)	5 (26.3)	**14 (18.2)**	19 (18.1)
>30	2 (22.2)	3 (15.8)	**18 (23.4)**	23 (21.9)
Total	9	19	77	105

Percentages rounded to one decimal place

Data referred to in text bolded

Over the preceding 12-month period, the majority of women had used their computers at home only (46.7%), with 38.3 per cent using computers at home and work, and 15 per cent at work only. While it was not statistically significant, there was some variation in location of computer use between residences (p=0.055). Women residing in rural areas primarily used computers at work (N=3, 60%), followed by home (N=2, 40%), but not both (N=0). Remote dwelling women primarily used computers at home (N=2, 66.7%), followed by work and home (N=1, 33.3%), but not at work only (N=0). The majority of women agreed they enjoyed using computers (77.4%). There was no statistically significant difference between participant groups (p=0.457), ages (p=0.202) or residences (p=0.161).

Women had most frequently spent one to five hours per week accessing the internet in the past 12 months (25.5%), with the average internet use time being six to ten hours per week. Women were asked identify how frequently they had accessed specific information on the internet in the last 12 months (Table 5.7). The internet was most frequently used by women for e-mail. Banking and general information were most frequently sought weekly. The majority of women accessed health information monthly (40.2%).

Table 5.7: Information Accessed on the Internet

	Never N(%)	Rarely N(%)	Monthly N(%)	Weekly N(%)	Daily N(%)
E-mail	0 (0)	0 (0)	1 (0.9)	12 (11.2)	**94 (87.8)**
Social networking	30 (28)	23 (21.5)	4 (3.7)	25 (23.4)	25 (23.4)
Banking	14 (13.3)	10 (9.5)	17 (16.2)	**55 (52.4)**	9 (8.6)
Entertainment	11 (10.3)	34 (31.8)	29 (27.1)	27 (25.2)	6 (5.6)
News	9 (8.4)	39 (36.4)	13 (12.1)	17 (15.9)	29 (27.1)
General information	1 (0.9)	8 (7.5)	19 (17.8)	**49 (45.8)**	30 (28)
Health information	1 (0.9)	32 (29.9)	**43 (40.2)**	27 (25.2)	4 (3.7)
Shopping	18 (16.8)	44 (41.1)	23 (21.5)	21 (19.6)	1 (0.9)
Gaming	94 (87.8)	6 (5.6)	2 (1.9)	2 (1.9)	3 (2.8)

Percentages rounded to one decimal place

Highest frequency in bold font

Women mostly enjoyed using the internet (83.1%). There was no statistically significant difference in internet enjoyment between participant groups (p=0.397), age groups (p=0.286) or residences (p=0.669).

5.3.3 Breast Reconstruction Information Seeking

The two participant groups who had undertaken breast reconstruction, either following bilateral prophylactic mastectomy or because of breast cancer, were asked about the sources and value of information they received when deciding about breast reconstruction. These women accessed between one and nine different sources of information (mean, N=5). The majority of women accessed six sources of information. Those in the breast cancer and breast reconstruction group more frequently sought a greater number of information sources; namely six sources (N=18, 23.7%), compared with the bilateral prophylactic mastectomy and breast reconstruction group, who mostly sought two sources of information (N=3, 27.3%); however, this difference was not statistically significant (p=0.064).

The greatest amount of information was primarily received from the women's breast reconstruction surgeon (64.6%). One hundred per cent of the bilateral prophylactic mastectomy and breast reconstruction group identified that this source providing the

most information, compared with 57.5 per cent of the breast cancer and breast reconstruction group. Other sources of information accessed by both participant groups include books or pamphlets, other women who had breast reconstruction, breast surgeon or general surgeon, breast cancer support organisations, general practitioner, internet, breast care nurses, DVDs, breast clinics and friends or family. Some women diagnosed with breast cancer also received information from their medical oncologist, and some women choosing bilateral prophylactic mastectomy and breast reconstruction received information from genetic counselling clinics.

The majority of women identified the most valuable information to be received from their breast reconstruction surgeon (63.3%). Others identified the most valuable source of information to be books or pamphlets (N=6, 12.2%), other women who had breast reconstruction (N=5, 10.2%), breast surgeon or general surgeon (N=3, 6.1%), breast cancer support organisation (N=2, 4.1%), the internet (N=1, 2%) and a breast care nurse (N=1, 2%). There was no statistically significant difference regarding the most valuable source of information between the two breast reconstruction participant groups (p=0.889). There appears to be some correlation between the source from which the women received greatest volume of information and the source from which the women received most valuable information (Chart 5A).

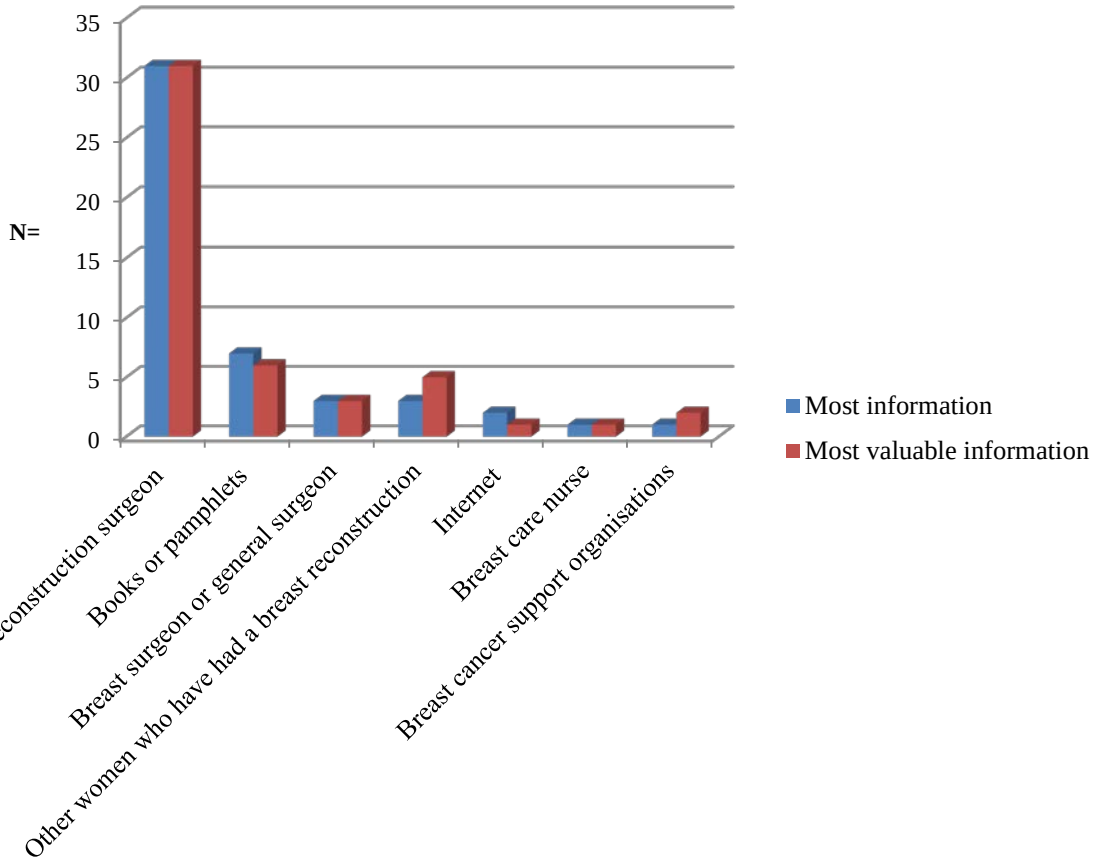

Chart 5A: Greatest Volume of Information and Most Valuable Information

Women who had not undertaken breast reconstruction were asked to rank where they would most likely source information from if they were seeking information about breast reconstruction (using a scale of '1' being most likely and '10' being least likely). The majority of women most frequently ranked either their breast reconstruction surgeon (N=5, 33%), breast cancer support organisation (N=4, 23.5%) or the internet (N=4, 23.5%) as the most likely source of information they would seek. The majority of women (61%) were highly likely to use the internet as a source of information, ranking it as number one or two. Books or pamphlets as a source of information were most frequently ranked at number four on the scale. Family or friends were most frequently ranked as the least likely source of information for women (N=6, 37.5%). Sixty-three per cent of women (N=12) in this participant group were actively considering breast reconstruction at the time of completing this survey.

5.3.4 Breast Reconstruction Experience

Women reported great variation in their breast reconstruction experience trajectory. Eighty-eight women had undertaken breast reconstruction; of whom 11 had bilateral prophylactic mastectomy and immediate breast reconstructions and 77 had breast reconstruction following a diagnosis of breast cancer. Of those 77 women 41 (53%) had delayed breast reconstruction and 36 (47%) had immediate breast reconstruction. Twenty-nine (38%) of the 77 women who had their cancerous breast removed and reconstructed also had their contralateral breast prophylactically removed and reconstructed (Table 5.8).

The survey asked women if they had undertaken more than one breast reconstruction at different times. The purpose of this question was to direct women to answer the subsequent questions about their breast reconstruction experience in relation to their most recent breast reconstruction. Eight women had undertaken two breast reconstructions at different times. One woman from the bilateral prophylactic mastectomy and breast reconstruction group reported the complication of symmastia (where connective tissue joins two breasts at the sternal midline) and required a second breast reconstruction. Another woman reported her implant tore away from the chest wall, requiring a second breast reconstruction. Another woman reported she had a second breast reconstruction as ‘the first reconstruction was not that good’. The remaining five women reported a second contralateral prophylactic mastectomy and breast reconstruction, indicating the 22 other women in this participant group also having contralateral prophylactic mastectomy and breast reconstruction did so at the same time they had their cancerous breast removed.

Table 5.8: Breast Reconstruction Trajectory

Breast reconstruction experience	Number of women	Percentage of women
Bilateral prophylactic mastectomy and bilateral immediate breast reconstruction	11	12.5%
Breast cancer, mastectomy and immediate breast reconstruction	11	12.5%
Breast cancer, mastectomy and delayed breast reconstruction	39	44.3%
Breast cancer, mastectomy, contralateral prophylactic mastectomy and bilateral immediate breast reconstruction	22	25%
Breast cancer, mastectomy and delayed breast reconstruction with subsequent contralateral prophylactic mastectomy and immediate breast reconstruction	2	2.3%
Breast cancer, mastectomy and immediate breast reconstruction with subsequent contralateral prophylactic mastectomy and immediate breast reconstruction	3	3.4%

For women choosing bilateral prophylactic mastectomy and breast reconstruction, the average time between when they were advised by their health care professional that they had a high risk of breast cancer and undergoing breast reconstruction was 3.533 years (minimum= 0.4 years, maximum= 13.75 years). The average time between women being diagnosed with breast cancer and undergoing breast reconstruction (immediate or delayed) was 1.995 years (minimum= 0 years, maximum= 10.83 years). For women having delayed breast reconstruction, the average time between diagnosis and breast reconstruction was 2.738 years (maximum= 10.83 years).

The majority of women underwent implant breast reconstruction (40.2%), with 26.4 per cent of women undertaking LD flap breast reconstruction and 20.7 per cent undertaking TRAM flap breast reconstruction (Final column of Table 5.10). There was a statistically significant difference in the type of breast reconstruction undertaken between the bilateral prophylactic mastectomy and breast reconstruction and breast cancer and breast reconstruction groups ($p=<0.004$). Women choosing bilateral prophylactic mastectomy and breast reconstruction most commonly opted for LD flap breast reconstruction (80%), followed by implant breast reconstruction (20%), while the breast cancer and breast reconstruction group exhibited more of a spread between breast reconstruction types (Table 5.9).

Table 5.9: Type of Breast Reconstruction (Comparison Between Two Participant Groups)

Type of breast reconstruction	Bilateral prophylactic mastectomy and breast reconstruction N (%)	Breast cancer and breast reconstruction N (%)	All N (%)
Implant	**2 (20)**	**33 (42.9)**	35 (40.2)
LD	**8 (80)**	**15 (19.5)**	23 (26.4)
TRAM	0 (0)	**18 (23.4)**	18 (20.7)
DIEP	0 (0)	**10 (13)**	10 (11.5)
Exterior oblique turnover flap with implant	0 (0)	1 (1.3)	1 (1.1)
Total	10	77	87

Percentages rounded to one decimal place

Data referred to in text bolded

Forty-one women reported experiencing complications following breast reconstruction surgery (46%). Twenty of those women had undertaken delayed breast reconstruction and 21 had undertaken immediate breast reconstruction. The majority of women experienced one complication (65.9%), while 22 per cent reported two complications, and 12.2 per cent reported three complications. The reported complications were categorised into minor, moderate or severe, depending on the reported treatment required (Table 5.10). This categorisation of reported complications was reviewed and confirmed by the breast surgeon and breast reconstruction surgeons of the PAC.

Table 5.10: Degree of Complication Severity

Complication	Treatment	Degree of severity
Infection	None or antibiotics	Minor
Infection	Including surgical procedure requiring hospitalisation	Moderate
Seroma/haematoma	None or surgical procedure not requiring hospitalisation	Minor
Seroma/haematoma	Including surgical procedure requiring hospitalisation	Moderate
Seroma/haematoma	Daily dressings	Minor
Faulty implant	Including surgical procedure requiring hospitalisation	Major
Implant capsular contractures	None	Moderate
Implant capsular contractures	Including surgical procedure requiring hospitalisation	Major
Stroke		Major
Pulmonary embolus		Major
Deformity	Including surgical procedure requiring hospitalisation	Moderate
Turning of the implant	Including surgical procedure requiring hospitalisation	Moderate
Frozen shoulder	Physio/pain management	Minor
Partial or full flap loss	Including surgical procedure requiring hospitalisation	Major
Partial nipple necrosis	Including surgical procedure not requiring hospitalisation	Minor
Abdominal weakness/hernia	Including surgical procedure requiring hospitalisation	Major
'dog ear'		Minor
Implant tore away from chest wall	Including surgical procedure requiring hospitalisation	Major
Donor site necrosis	Including surgical procedure not requiring hospitalisation	Moderate
Nerve damage	No treatment	Minor

There was a consistent spread in the degree of complications experienced by women, with 34.3 per cent categorised as minor, 34.3 per cent categorised as moderate and 31.4 per cent categorised as severe. There was no statistically significant difference in either the number or degree of complications reported depending on timing of breast reconstruction, type of breast reconstruction or participant group.

5.3.5 Breast Cancer Treatments

Women who had been diagnosed with breast cancer were asked about their breast cancer treatments. Eighty-one women had received adjuvant therapies to treat their breast cancer (85.3%); 18 of those women did not undertake breast reconstruction and 63 women did undertake breast reconstruction. On average, women received two types of adjuvant therapy (minimum=1, maximum=4). The average duration of adjuvant therapy was 3.3 years (minimum= 1 month, maximum=10 years). The majority of women (27.2%) underwent a combination of chemotherapy, radiotherapy and hormone therapy (Chart 5B). There was no statistically significant difference in time lapsed from diagnosis to commencement of adjuvant therapy between those who underwent breast reconstruction and those who did not (p=0.83).

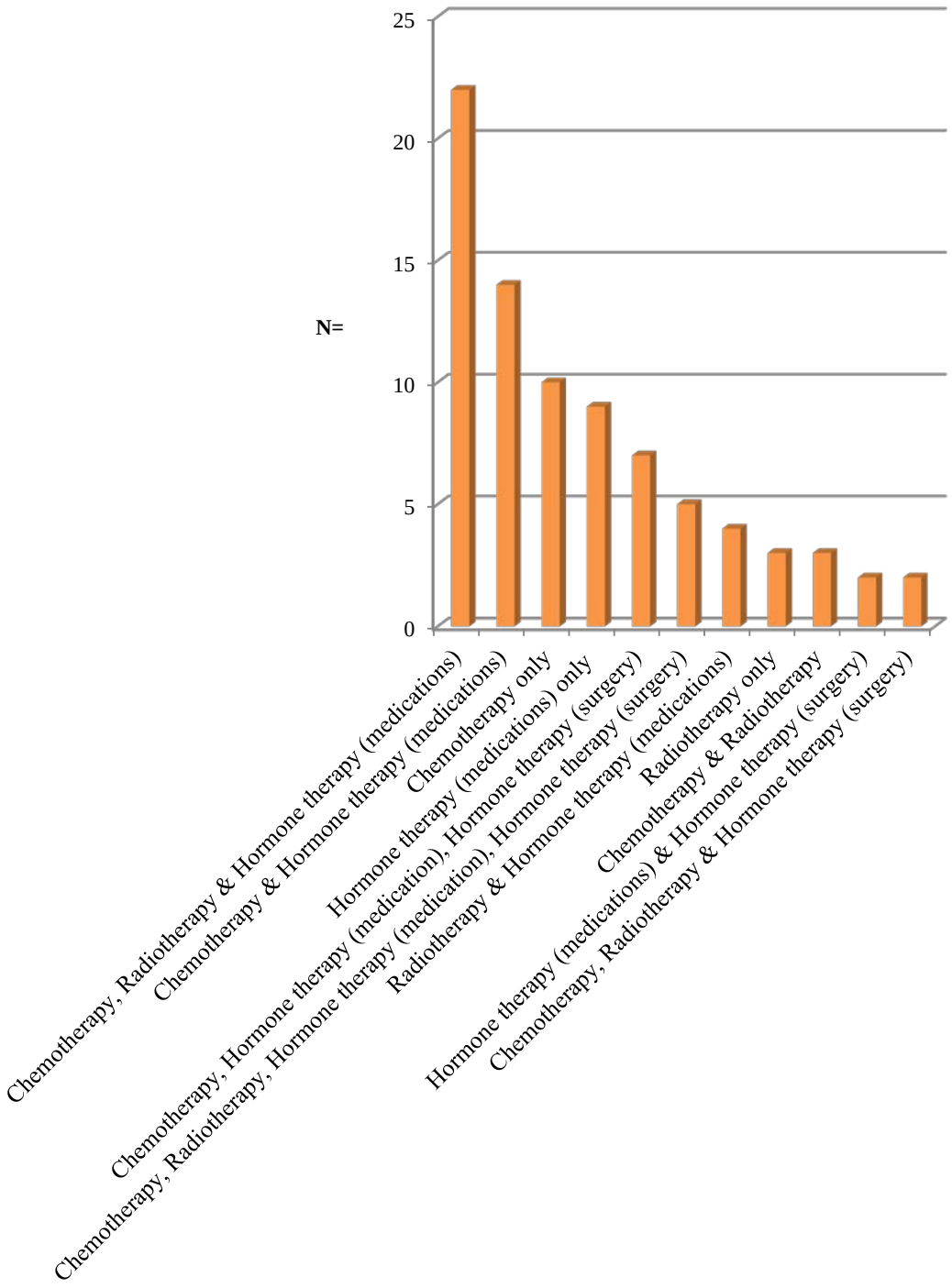

Chart 5B: Combinations of Adjuvant Therapy Undertaken

5.3.6 Decision Support Tool Evaluation

The collective responses of the survey evaluation of the decision support tool are presented in Table 5.11. In addition to the collective response analysis and

comparing the frequency of responses between the three participants groups, each survey item was also analysed to identify differences in response frequencies between those who did not undertake breast reconstruction and those who had undertaken breast reconstruction (bilateral prophylactic mastectomy and breast reconstruction participants, combined with breast cancer diagnosis and breast reconstruction participants). The purpose of these comparisons was to identify if there were any statistically significant differences between how women in these groups perceive the information presented and its usefulness.

Table 5.11: Collective Breast Reconstruction Decision Support Tool Evaluation Results

SURVEY ITEM		RESPONSES				
		SA	**A**	**N**	**D**	**SD**
The website is visually appealing	**N=**	33	52	16	3	0
	%	31.7	50	15.4	2.9	0
The booklet is visually appealing	**N=**	43	41	13	6	0
	%	41.7	39.8	12.6	5.8	0
The website is easy to navigate to find the desired information	**N=**	46	50	7	4	0
	%	43	46.7	6.5	3.7	0
The booklet is easy to navigate to find the desired information	**N=**	53	47	5	2	0
	%	49.5	43.9	4.7	1.9	0
The volume of information is appropriate	**N=**	49	53	1	4	0
	%	45.8	49.5	0.9	3.7	0
The information meets my information needs	**N=**	43	57	2	5	0
	%	40.2	53.3	1.9	4.7	0
The information is appropriately sequenced (ordered)	**N=**	42	59	1	4	1
	%	39.3	55.1	0.9	3.7	0.9
The information is easy to understand	**N=**	50	56	1	0	0
	%	46.7	52.3	0.9	0	0
The information resources would be useful to women to refer back to throughout their physical and emotional recovery from breast reconstruction surgery	**N=**	45	57	5	0	0
	%	42.1	53.3	4.7	0	0
The information resources would be useful for discussing breast reconstruction with health care professionals	**N=**	55	51	1	0	0
	%	51.4	47.7	0.9	0	0
The information resources would be useful to help family and friends understand the support I might need throughout my breast reconstruction experience	**N=**	39	51	14	3	0
	%	36.4	47.7	13.1	2.8	0
	N=	72	34	1	0	0

SURVEY ITEM		RESPONSES				
		SA	A	N	D	SD
Overall, the information resources would be a useful source of information for women considering breast reconstruction	%	67.3	31.8	0.9	0	0
The pictures of breast reconstruction are confronting	N=	17	31	20	29	10
	%	15.9	29.0	18.7	27.1	9.3
The pictures of breast reconstruction provide useful information for me	N=	56	49	2	0	0
	%	52.3	45.8	1.9	0	0
The description accompanying each picture enhances my understanding of the woman's breast reconstruction outcome	N=	43	57	5	2	0
	%	40.2	53.3	4.7	1.9	0
The pictures would discourage me from choosing to have a breast reconstruction	N=	1	3	14	59	30
	%	0.9	2.8	13.1	55.1	28.0
The pictures of breast reconstruction provide helpful information about surgical recovery and aesthetic outcomes (appearance) of breast reconstruction	N=	54	48	3	0	2
	%	50.5	44.9	2.8	0	1.9

SA=strongly agree, A=agree, N=neutral, D=disagree, SD=strongly disagree

Percentages rounded to one decimal place

The majority of women agreed the website was visually appealing (81.7%), with 15.4 per cent of responses being neutral. Similarly, 81.5 per cent agreed the booklet was visually appealing, with 12.6 per cent responding neutrally, and 5.8 per cent disagreeing. The website was easy to navigate for 89.7 per cent of women, while a greater proportion of women found the booklet easy to navigate (93.4%).

All except five women agreed that the volume of information within the resources was appropriate (95.3%). Ninety-four per cent of women agreed the information presented was appropriately sequenced. Although not reaching statistical significance (p=0.052), there were differences in responses between the three participant groups. The group who had not undertaken breast reconstruction most strongly agreed, with the breast reconstruction group agreeing to a lesser extent and women having undertaken bilateral prophylactic mastectomy and breast reconstruction agreed to an even lesser extent than the other two participant groups (Table 5.12).

Table 5.12: The Information Is Appropriately Sequenced—Comparison Between Three Participant Groups

	Bilateral prophylactic mastectomy and breast reconstruction N (%)	Mastectomy with no breast reconstruction N (%)	Breast reconstruction N (%)	Total N (%)
Strongly agree	**1 (9.1)**	**13 (68.4)**	**28 (36.4)**	42 (39.3)
Agree	**10 (90.9)**	**6 (31.6)**	**43 (55.8)**	59 (55.1)
Neutral	0 (0)	0 (0)	1 (1.3)	1 (0.9)
Disagree	0 (0)	0 (0)	4 (5.2)	4 (3.7)
Strongly disagree	0 (0)	0 (0)	1 (1.3)	1 (0.9)
Total	11	19	77	107

Percentages rounded to one decimal place

Data referred to in text bolded

The information was easy to understand for 99 per cent of women. While not reaching statistical significance (p=0.091), analysis of participant group responses identified a greater proportion of women who had not undertaken breast reconstruction strongly agreed that the information was easy to understand (Table 5.13).

Table 5.13: The Information is Easy to Understand—Comparison Between Two Participant Groups

	Breast reconstruction N (%)	No breast reconstruction N (%)	Total N (%)
Strongly agree	**37 (42)**	**13 (68.4)**	50 (46.7)
Agree	50 (56.8)	6 (31.6)	56 (52.3)
Neutral	1 (1.1)	0 (0)	1 (0.9)
Disagree	0 (0)	0 (0)	0 (0)
Strongly disagree	0 (0)	0 (0)	0 (0)
Total	88	19	107

Percentages rounded to one decimal place

Data referred to in text bolded

The decision support tool met the information needs of 93.5 per cent of women. There was a statistically significant difference in responses between the three

participant groups (p=0.011), with the group who had not undertaken breast reconstruction most strongly agreeing and the bilateral prophylactic mastectomy and breast reconstruction group least strongly agreeing (Table 5.14).

Table 5.14: The Information Met My Information Needs—Comparison Between Three Participant Groups

	Bilateral prophylactic mastectomy and breast reconstruction N (%)	**Mastectomy with no breast reconstruction N (%)**	**Breast reconstruction N (%)**	**Total N (%)**
Strongly agree	1 (9.1)	**13 (68.4)**	29 (37.7)	43 (40.2)
Agree	**10 (90.9)**	5 (26.3)	**42 (54.5)**	57 (53.3)
Neutral	0 (0)	1 (5.3)	1 (1.3)	2 (1.9)
Disagree	0 (0)	0 (0)	5 (6.5)	5 (4.7)
Strongly disagree	0 (0)	0 (0)	0 (0)	0 (0)
Total	11	19	77	107

Percentages rounded to one decimal place

Data referred to in text bolded

The decision support tool was evaluated to be useful for women considering breast reconstruction following mastectomy (99.1%). The majority of women (94.4%) agreed that the decision support tool would also be useful for women to refer back to throughout their physical and emotional recovery from breast reconstruction. Those who had not undertaken breast reconstruction more frequently strongly agreed with this survey item than other participant groups. Those women who had undertaken bilateral prophylactic mastectomy and breast reconstruction more frequently agreed to a lesser extent, compared with the other two participant groups (Table 5.15). However, these differences were not statistically significant (p=0.059).

Table 5.15: The Information Would Be Useful for Women to Refer Back to Throughout Their Physical and Emotional Recovery From Breast Reconstruction Surgery—Comparison Between Three Participant Groups

	Bilateral prophylactic mastectomy and breast reconstruction N (%)	Mastectomy with no breast reconstruction N (%)	Breast reconstruction N (%)	Total N (%)
Strongly agree	**4 (36.4)**	**10 (52.6)**	**31 (40.3)**	45 (42)
Agree	7 (63.6)	8 (42.1)	42 (54.5)	57 (53)
Neutral	0 (0)	1 (5.3)	4 (5.2)	5 (4.7)
Disagree	0 (0)	0 (0)	0 (0)	0 (0)
Strongly disagree	0 (0)	0 (0)	0 (0)	0 (0)
Total	11	19	77	107

Percentages rounded to one decimal place

Data referred to in text bolded

Ninety-nine per cent of women agreed the decision support tool would be useful for discussing breast reconstruction treatment options with healthcare professionals. Again, the group who had not undertaken breast reconstruction more frequently strongly agreed than others, and those who had undertaken bilateral prophylactic mastectomy and breast reconstruction more frequently agreed to a lesser extent (Table 5.16). These differences were statistically significant (p=0.002).

Table 5.16: The Information Would be Useful for Discussing Breast Reconstruction with Health Care Professionals—Comparison Between Three Participant Groups

	Bilateral prophylactic mastectomy and breast reconstruction N (%)	**Mastectomy with no breast reconstruction N (%)**	**Breast reconstruction N (%)**	**Total N (%)**
Strongly agree	**2 (18.2)**	**16 (84.2)**	**37 (48.1)**	55 (51.4)
Agree	9 (81.8)	3 (15.8)	39 (50.6)	51 (47.7)
Neutral	0 (0)	0 (0)	1 (1.3)	1 (0.9)
Disagree	0 (0)	0 (0)	0 (0)	0 (0)
Strongly disagree	0 (0)	0 (0)	0 (0)	0 (0)
Total	11	19	77	107

Percentages rounded to one decimal place

Data referred to in text bolded

Eighty-four per cent of women agreed the decision support tool would be useful for friends and family members, to gain an understanding of the support women may need throughout their breast reconstruction experience. There was a statistically significant difference in responses between those who had undertaken breast reconstruction and those who had not (p=0.036). While a greater proportion of women who had undertaken breast reconstruction agreed overall with this survey item (85.2% breast reconstruction, 79% no breast reconstruction), those who had not undertaken breast reconstruction more frequently strongly agreed (Table 5.17).

Table 5.17: The Information Would to be Useful to Help Family and Friends Understand the Support I Might Need Throughout my Breast Reconstruction Experience—Comparison Between Two Participant Groups

	Breast reconstruction N (%)	No breast reconstruction N (%)	Total N (%)
Strongly agree	**28 (31.8)**	**11 (57.9)**	39 (36.4)
Agree	47 (53.4)	4 (21.1)	51 (47.7)
Neutral	10 (11.4)	4 (21.1)	14 (13.1)
Disagree	3 (3.4)	0 (0)	3 (2.8)
Strongly disagree	0 (0)	0 (0)	0 (0)
Total	88	19	107

Percentages rounded to one decimal place

Data referred to in text bolded

There was variation in responses regarding whether the pictures of breast reconstruction within the decision support tool were confronting (Table 5.18).

Table 5.18: The Pictures of Breast Reconstruction are Confronting—Comparison Between Three Participant Groups

	Bilateral prophylactic mastectomy and breast reconstruction N (%)	Mastectomy with no breast reconstruction N (%)	Breast reconstruction N (%)	Total N (%)
Strongly agree	3 (27.3)	2 (10.5)	12 (15.6)	**17 (15.9)**
Agree	1 (9.1)	3 (15.8)	27 (35.1)	**31 (29)**
Neutral	3 (27.3)	3 (15.8)	14 (18.2)	**20 (18.7)**
Disagree	3 (27.3)	8 (42.1)	18 (23.4)	**29 (27.1)**
Strongly disagree	1 (9.1)	3 (15.8)	6 (7.8)	**10 (9.3)**
Total	**11**	**19**	**77**	**107**

Percentages rounded to one decimal place

Regardless of whether the pictures were perceived as confronting, 98.1 per cent of women agreed they provided useful information. There was a consistent dispersion of responses between strongly agree and agree for those who had been diagnosed with breast cancer and undertaken breast reconstruction. The bilateral prophylactic mastectomy and breast reconstruction group more frequently agreed to a lesser

extent than the other two groups. Women who had not undertaken breast reconstruction more frequently strongly agreed than the other two groups (Table 5.19).

Table 5.19: The Pictures of Breast Reconstruction Provided Useful Information for me—Comparison Between Three Participant Groups

	Bilateral prophylactic mastectomy and breast reconstruction N (%)	**Mastectomy with no breast reconstruction N (%)**	**Breast reconstruction N (%)**	**Total N (%)**
Strongly agree	**3 (27.3)**	**16 (84.2)**	**37 (48.1)**	56 (52.3)
Agree	8 (72.7)	3 (15.8)	38 (49.4)	49 (45.8)
Neutral	0 (0)	0 (0)	2 (2.6)	2 (1.9)
Disagree	0 (0)	0 (0)	0 (0)	0 (0)
Strongly disagree	0 (0)	0 (0)	0 (0)	0 (0)
Total	11	19	77	107

Percentages rounded to one decimal place

Data referred to in text bolded

The majority of women responded that pictures of breast reconstruction would not discourage them from choosing breast reconstruction (83.1%); 13.1 per cent of women responded neutral to this survey item and 3.7 per cent (N=4) would be discouraged from choosing breast reconstruction after viewing the pictures within the decision support tool. There was a greater spread across response options for those who had undertaken breast reconstruction compared to those who had not undertaken breast reconstruction, with a greater frequency of women who had not undertaken breast reconstruction responding that the pictures were not discouraging to them (Table 5.20).

Table 5.20: The Pictures Would Discourage Me from Choosing to Have a Breast Reconstruction—Comparison Between Two Participant Groups

	Breast reconstruction N (%)	No breast reconstruction N (%)	Total N (%)
Strongly agree	1 (1.1)	0 (0)	1 (0.9)
Agree	3 (3.4)	0 (0)	3 (2.8)
Neutral	13 (14.8)	1 (5.3)	14 (13.1)
Disagree	**45 (51.1)**	**14 (73.7)**	59 (55.1)
Strongly disagree	**26 (29.5)**	**4 (21.1)**	30 (28)
Total	88	19	107

Percentages rounded to one decimal place

Data referred to in text bolded

Most women agreed the pictures provided useful information about the surgical recovery from breast reconstruction surgery and aesthetic outcomes (95.4%). Women who had undertaken bilateral prophylactic mastectomy and breast reconstruction less frequently strongly agreed than the other two groups (Table 5.21). The descriptions accompanying each image within a series of images enhanced women's understanding of the aesthetic outcome that had been achieved (93.5%).

Table 5.21: The Pictures of Breast Reconstruction Provide Helpful Information About Surgical Recovery and Aesthetic Outcomes of Breast Reconstruction—Comparison Between Three Participant Groups

	Bilateral prophylactic mastectomy and breast reconstruction N (%)	Mastectomy with no breast reconstruction N (%)	Breast reconstruction N (%)	Total N (%)
Strongly agree	**2 (18.2)**	**12 (63.2)**	**40 (51.9)**	54 (50.)
Agree	8 (72.7)	7 (36.8)	33 (42.9)	48 (44.9)
Neutral	1 (9.1)	0 (0)	2 (2.6)	3 (2.8)
Disagree	0 (0)	0 (0)	0 (0)	0 (0)
Strongly disagree	0 (0)	0 (0)	2 (2.6)	2 (1.9)
Total	11	19	77	107

Percentages rounded to one decimal place

Data referred to in text bolded

When asked in what format women they preferred the decision support tool (website or booklet), 59.8 per cent of women preferred to have both the website and the booklet to review, 29 per cent preferred the booklet, 6.5 per cent had no preference, and 4.7 per cent preferred the website. One hundred per cent of women would recommend the decision support tool to women who may be considering breast reconstruction following mastectomy.

5.3.7 Open-Ended Survey Responses

The surveys contained three open-ended questions, asking women if there was any unclear or confusing information within the decision support tool, if there was any information they felt was missing, and if they had any other comments. Due to the anonymous nature of survey completion and amalgamated data of consistent survey items from three different surveys, source identification of open-ended responses was not possible. Analysis resulted in the open-ended responses being categorised into six main topics:

1. compliments of the decision support tool
2. missing information
3. information for family and friends
4. information about bilateral prophylactic mastectomy and breast reconstruction
5. breast reconstruction pictures
6. website versus booklet format.

5.3.7.1 Compliments of the Decision Support Tool

The open-ended response questions provided 52 comments complimenting the decision support tool. Twenty-one comments praised the resources as clear and informative. Six women commented they were well structured. Fourteen women commented they wished this information had been available when they were navigating their breast reconstruction experience:

> I think all the things I would like to have known at the time have been covered quite well.

> Even now the information is useful. I understand more about my surgery and the options I rejected.
>
> Thanks for your research. The information provided will be used as a reliable source for women approaching reconstruction.
>
> I am just about to undergo further surgery. The information in your booklet/website was very useful in assessing my choices.
>
> These are great resources. The information is very relevant; easy to access and read; and covers all aspects of the decision making process. Both the website and booklet are wonderful.
>
> Loved it. Loved it. Thank you!

5.3.7.2 Missing Information

Several women's comments requested further detailed information about nipple and areola reconstruction. Practical details such as nipples always staying erect, where stick on nipples may be purchased and the need to have areola tattooing repeated, were examples of the detail women desired. Some women commented that more detailed information about the breast reconstruction procedures and their complications would be useful, including the process of tissue expander inflation, how a belly button is repositioned following TRAM or DIEP flap breast reconstruction, and the period of time over which seroma drainage may be required. Exercise after breast reconstruction was another topic women identified as lacking in the decision support tool. While physical limitations are discussed, women wanted more information about when they could resume usual exercise activities and how they might be able to prepare their bodies for this through 'stretching' or 'rehabilitation'.

One woman commented that the reference in the decision support tool about shared decision making may be misleading and further clarification may be required:

> The impression is given that the breast cancer team is available for discussion as a collective, but in my experience this is not the case, with each member of the team needing to be consulted separately.

Five women commented that greater variability in women's quotations be included, with some women requesting more negative experiences and others requesting more positive experiences:

> At the time of my diagnosis, and even now, I want to hear personal and positive experiences from other women.

> I would like to read of two women's differing views. A view like mine of a disastrous reconstruction, immediately followed by a very good reconstruction outcome.

One woman commented she believed a balanced view was not portrayed:

> You say that the booklet is not designed to encourage women to have a reconstruction, but there does not seem to be a fair and reasonable weight of information about why not to choose reconstruction.

One woman commented on advising women about using counselling, not only in response to difficulty coping with breast cancer or breast reconstruction, but as a pre-emptive means to assist women to cope throughout the process of breast reconstruction decision making and recovery:

> On the recommendation of my breast care nurse I accessed psychological counselling- not to help me make my treatment/surgery decisions, but to help me cope with it all. Time spent in counselling was fundamental to successful surgery and recovery for me. Counselling before, during and after surgery was a big part of the whole surgery experience. This will not be the case for all, I just thought it was worth mentioning as it worked well for me.

5.3.7.3 Information for Family and Friends

Specific information for family and friends of women undergoing breast reconstruction was commented on by three women. Less detailed information was thought to be required for family and friends, and pictures of breast reconstruction were thought to be too confronting for family and friends. Specific information thought appropriate included: explaining the reasons why women chose to have breast reconstruction, the need to be supportive of that decision, and aspects of the surgical recovery including physical limitations. One woman commented that including information specific to same sex partners would also be useful:

> Perhaps more information for family/friends to help them understand a person's decision to have reconstruction—to be encouraging and not negative. The pain and commitment could be emphasised more.

5.3.7.4 Information about Bilateral Prophylactic Mastectomy and Breast Reconstruction

Women who had chosen to undergo bilateral prophylactic mastectomy and breast reconstruction commented that the information could be better tailored to this group of women by including more focused information about genetic counselling, explaining that skin sparing mastectomy is not necessarily the automatic option for bilateral prophylactic mastectomy, and presenting images of women who have undertaken bilateral prophylactic mastectomy and breast reconstruction.

5.3.7.5 Breast Reconstruction Pictures

The most frequent comments overall were compliments about the decision support tool. Next, the breast reconstruction images in the resource generated the greatest volume of comments. Women noted that representing a variety of aesthetic outcomes was important to encourage realistic expectations of women choosing breast reconstruction:

> It is good to show the negative and positive pictures. There is nothing misleading and then you know exactly what to expect and go into surgery with an open mind.

Six women commented that the images within the resource portrayed poor aesthetic outcomes in their view, and felt that better outcomes should be portrayed so women were not discouraged from having breast reconstruction:

> I found the reconstruction pictures confronting. I did not see photos like this from my surgeon ... it would have been discouraging. I have seen much better outcomes.

Women commented that they wanted more pictures, with a greater variation of breast sizes and more pictures of younger women who had undergone breast reconstruction. A longer trajectory of images was also proposed to enable the final result, suggested as two years down the track, be displayed:

> I think you should include photos of breasts two years or more after surgery. Although it is helpful to see how reconstruction evolves, I think it is also important to see the finished product, after the nipples have been reconstructed and after the scars have healed, to see what a good outcome you can have.

Two women suggested the images might be better placed after each type of breast reconstruction is discussed, rather than at the end of the decision support tool. One of these women felt placing them towards the back of the resource seemed to be hiding them in shame:

> I feel that the pictures seemed to be sort of ashamed and apologetic, like our breasts are something we shouldn't show so we will share them at the end as an afterthought and have as few as possible.

5.3.7.6 Website versus Booklet Format

One of the survey questions, which asked women to nominate their preferred format of information, web-based or booklet, generated several comments. While some comments favoured the website, the majority of comments found the booklet easier to navigate and more useful to refer back to. Several women commented there were too many pictures (stock photos) and too little text on each web page, meaning frequent clicking to subsequent pages was required to gain the information desired:

> It is difficult to take in all the information on the website. Printed booklet is far more useful as one can refer back to it at leisure and when the need arises without too much hassle.

> There was so much information on the website, sometimes I was drawn in some areas and had to navigate back to find the other thing that I found really interesting.

> I prefer the booklet as I can carry it with me, sit with a cup of tea and consider the options. I can read it anywhere and highlight/underline relevant parts. I can take it to my doctors/specialist and refer to it at any time, any place. The website is fantastic and I would refer my husband or close family to it to help them understand what I had ahead of me- it could answer some questions that I could not.

Some women did not like the layout of the booklet, commenting it was rather long and could be a little more spaced out. There were also comments that the design was not eye catching and could be brighter. One woman commented she was glad it was not pink like most other breast cancer resources.

5.3.8 Focus Group and Telephone Interviews

Based upon the collective survey responses and open-ended question analysis, a semi-structured interview schedule was developed to guide focus group and telephone interviews (Appendix Six). The purpose of these subsequent interviews was to clarify preliminary analysis and to further explore specific feedback or issues collated from the survey evaluation of the decision support tool. Additional questions were added to the interview schedule for those residing in rural or remote areas, to explore their experiences of accessing breast reconstruction services.

The areas where further feedback was sought included the appropriateness of the language level used in the resources, the clarity of information, how newly diagnosed women may find the decision support tool confronting, website navigation, comments on the suggested additions to the decision support tool, the information needs of family and friends regarding breast reconstruction, and further exploration about the breast reconstruction pictures. Thirteen women attended a focus group interview and 23 women participated in telephone interviews.

All women participating in the focus group and individual interviews expressed the level of language was appropriate, easy to understand and not too medicalised. Several women commented the terminology was sufficiently explained and found the glossary useful. Several women acknowledged they may have found the language appropriate as they had been through the experience, so were familiar with many of the terms, while others acknowledged their health care background may skew their opinion of the level of language:

> Language was non-judgemental, not patronising. It was obviously written by a woman for women.
>
> (Helen)

Three women commented that further modifying the level of language to facilitate ease of understanding would be ‘dumbing it down’, which they would find ‘insulting’. Women commented they had accessed other resources that were ‘frustratingly simplified’. One women identified the level of language may be problematic for women from a non-English speaking background.

The majority of women acknowledged the volume and depth of information contained in the decision support tool might be confronting for women who had been newly diagnosed with breast cancer. However, the general consensus was that little could be done to make the information less confronting and that having access to the information was better than not having access. Two women suggested recommending newly diagnosed women have someone with them as they go through the decision support tool. Several others suggested perhaps a simplified summary be created for newly diagnosed women, referring them to the more detailed information when they felt ready to access such information:

> While it might be confronting, it is all there. You can go back to it as it is needed.
>
> (Frances)

> It's all very confusing anyway for newly diagnosed women. Don't think you can do anything to make it easier.
>
> (Paula)

All, apart from three, women commented they did not have any difficulties navigating the website. One woman commented she found it easier to navigate than other websites she had visited and expressed that she thought women would get used to the structure of the website the more they explored it. Of those who did experience difficulties or frustrations with navigating information on the website, several made suggestions to minimise navigation problems, including a drop down menu or expansion of the navigation pane, a site map, and opening information in a new window so the initial information was not lost. One woman acknowledged that difficulties navigating the website could be related to the generation of users of this particular website:

> Depends on age/IT use. Have to have both the booklet and the web. This may change in the next 30 years.
>
> (Vicki)

Women in one focus group strongly responded to the suggestion of more personal comments, while those attending the second focus group interview thought there were enough personal comments throughout the resource; however, both groups of

women agreed stories accompanying the breast reconstruction pictures would be helpful. Eleven women who participated in telephone interviews thought it was a good idea to have more personal comments, with nine of those 11 women specifying differing views would be helpful. Four women were opposed to more personal comments. One stated that too many differing personal comments might confuse women:

> Too much information on others' experiences is not always helpful. (Laura)

> No more personal comments. I am accessing the resource for information, not others' experiences. There are plenty of other sources for that. (Theresa)

> I think personal comments are good, inspirational and uplifting. I would avoid really negative comments. Not sure it would be very helpful. (Jo)

Most women agreed more information on living with mastectomy and prosthesis may be useful, specifically how to care for a prosthesis, prosthesis bras and climate considerations. Six women commented that more detail about nipple and areola reconstruction should be included, explaining differing techniques and the costs of nipple and areola reconstruction. Those women who had undertaken bilateral prophylactic mastectomy requested more information about high breast cancer risk and genetic counselling.

Women requested more information related to the financial aspects of breast reconstruction and post-operative recovery. Several women commented they had underestimated the financial costs of breast reconstruction and requested more detail about specific costs over time, such as the advantages of timing costs over one financial year to claim possible taxation benefits, refinement surgeries not covered by Medicare, and health insurance coverage implications for women who chose bilateral prophylactic mastectomy and breast reconstruction.

The practical aspects of managing the post-operative period in hospital were of paramount importance to women, requiring such information as taking slippery pyjamas into hospital to facilitate movement in bed, having pyjamas that open at the front to facilitate regular observation of the reconstructed breast and being unable to

wear deodorant on the side of the reconstructed breast. Women commented it was not until you experienced breast reconstruction surgery that you realised how important such simple information can be in both preparing the woman for what lay ahead and facilitating comfort during recovery.

Women felt the medium to long-term aspects of post-operative care were important to cover, including such information as: difficulty washing hair for those who had undertaken LD flap breast reconstruction, discomfort wearing underwire bras, differences at the donor site post-operatively, managing pain upon return home from hospital, strategies to minimise scarring, returning to usual exercise and physical activity and the importance of physiotherapy to aid recovery.

When asked about the information needs of family and friends, women discussed two aspects of information: firstly information about the women's decision making, and secondly post-operative recovery from surgery. Women felt others did not understand why they had made the decision to undergo breast reconstruction, and as a result some women felt less than supported with regard to their decision:

> It's a really individual decision. They (family and friends) just don't get it. (Jacqueline)

> 'Why would you bother?' Because every day it would remind me of breast cancer. It's about how you feel about it, not what others think about it. (Elaine)

Women suggested that explaining to family and friends the importance breasts have to women, and providing insight into the psychological impact of mastectomy on women, may facilitate understanding about breast reconstruction decision making. One woman who had undergone bilateral prophylactic mastectomy and breast reconstruction also commented that others did not understand her decision to preventatively remove her breasts, perceiving this as unnecessary.

Women identified that having an understanding of the significance and complexity of post-operative recovery was important for family and friends, so that they understand the physical limitations of the post-operative recovery period and what

they can do to help the woman recovering. Women commented that family and friends did not understand that breast reconstruction could be major surgery, often requiring multiple operations and leaving women with significant physical and functional limitations for weeks following the surgery. Details of surgical techniques were not deemed necessary and several women thought pictures of breast reconstruction were too confronting for family and friends.

Women also felt family and friends needed to have an understanding of the emotional aspects of recovery from breast reconstruction surgery. Information suggested included: how the woman may be adjusting to her new breast, what emotions the woman might be experiencing; and the importance of being able to share how you are feeling. While some women suggested a separate summary pamphlet of basic information for family and friends, others commented they thought the decision support tool would be appropriate and valuable to inform family or friends.

As the majority of women completing the survey acknowledged the images of women who had undertaken breast reconstruction were confronting, this was further explored in the interviews. When asked what specifically was confronting about the images, women identified the scarring, shape, absence of a nipple, absence of a breast in some pictures, redness, asymmetry and the overall outcome of the images were confronting. Regardless of the confronting nature of the images, all women agreed the images were imperative in providing valuable information to women considering breast reconstruction:

> You need to have that perspective. It's not going to be the same. It shows when you are fully clothed you look normal.
> (Rose)

> It's a bit confronting, but needs to be there. It is information you need and want to see. Whatever you do, it will be confronting.
> (Suzanne)

> They were confronting, however I wish they had been available when making my decision. Not having the information could be more dangerous for women. Sugar coating it would be a disservice.
> (Lynn)

It is confronting, but these are real women living with this.
(Denise)

Women's comments varied regarding the quality of the pictures. While some women thought the pictures were 'good' outcomes and found them 'empowering' to view, several women commented that the pictures looked medicalised, were inconsistent, and demonstrated 'poor' aesthetic outcomes. Suggestions to improve the quality of the pictures included a consistent photographic approach and using the same style of bra or camisole to allow greater consistency and comparison between women. Women also commented that there should be more pictures demonstrating 'better' aesthetic outcomes, images of breast reconstruction after radiotherapy, images of women in clothes, including bathers and evening wear, more images of nipple reconstruction, more images of younger women and more images of slimmer women.

A little too pretty compared to my outcome.
(Eileen)

I thought they were extremely accurate. They weren't hiding anything.
(Irene)

I found them empowering—they showed you can have a good outcome.
(Roberta)

Women found the sequencing of pictures useful in demonstrating the physical recovery from breast reconstruction. While women found the explanations of surgical recovery to be helpful, they suggested vignettes from the women in the pictures explaining their experiences and how they felt about their surgical recovery and final outcomes of their breast reconstruction:

Seeing a few can be daunting ... seeing many gives you a general idea.
(Anne)

The trajectory of women's surgery outcomes was useful—it took you through a process.
(Sarah)

> It's important to know what happens in the middle, not just at the beginning and the end. That is fairy tale stuff.
> (Maureen)

Two women participating in telephone interviews and several women within the focus group interviews commented they would be happy to have their own pictures included in such a resource. One woman commented that women's faces should be included in the pictures making them a 'celebration' of breast reconstruction.

Four women residing in rural or remote areas of Australia participated in telephone interviews. In addition to the standard interview schedule, these women were asked what impact their rural or remote residence had on their decision to undergo breast reconstruction, their access to breast reconstruction and their recovery from breast reconstruction. All women reported that their residence did not affect their decision to have breast reconstruction; neither did they perceive it affected their access to breast reconstruction services. Two women commented the travel to and from the city centre for appointments, breast reconstruction surgery, follow-up appointments and subsequent procedures were 'costly', 'tiring' and 'draining'. When asked what effect their rural or remote residence had on their breast reconstruction experience women stated:

> None. It was something I decided to do. It's just a mentality—that's what you have to do. Travel time is draining. You just accept it and get on with it.
>
> (Jeanne)

> None. If you want to have it done, you have it done. I just got on with it. Travel is tiring and costly. Where we live, we have to travel for everything, so I am used to it.
>
> (Kathy)

Five women commented that the questions to ask breast reconstruction surgeons were very useful. One woman suggested that compiling a register of women who would be happy to talk with women considering breast reconstruction would be a useful initiative. Several women noted they would be happy to share their experiences of breast reconstruction in such a resource. Another suggestion for the

booklet was to have a column down the side for women to make notes on as they read the resource. Other comments women provided in the interviews were primarily compliments of the decision support tool (Table 5.22).

Table 5.22: Complimentary Comments about the Decision Support Tool

'I thought it was a fabulous resource'.	(Sylvia)
'I think you've done a great job at meeting varying information needs of different women'.	(Anita)
'Your information gave me the clearest information and questions to ask that I have ever had'.	(Rebecca)
'Had I had this information back then I may have felt more confident about decisions regarding breast reconstruction'.	(Joan)
'Lots of people surf the net. It's good to have something reliable and in one place'.	(Alice)
'The resources were great. I was glad to see them. There was not that much information other than from surgeons. I really felt like this was missing'.	(Sheila)
'The amount of information given was great. Previously, information given was limited'.	(Marcia)
'I thought it was really good. When I was diagnosed I could not get enough information. Hopefully it will help women make their decisions'.	(Sally)
'I wish it was around years ago. The whole thing was put together really well. I thought it was fantastic'.	(Charlotte)
'It was a lovely little booklet. I wouldn't change a thing. I believe you can't have too much knowledge. Knowledge is empowering'.	(Evelyn)

5.4 Conclusion

The great variation in breast cancer and breast reconstruction trajectory of women participating in this research allowed for comprehensive evaluation of how the breast reconstruction decision support tool met the needs of women in multiple and variable situations. Evaluation of the decision support tool was overwhelmingly positive. The women found the website and booklets visually appealing and easy to navigate. The volume of information contained within the decision support tool was deemed appropriate and clearly sequenced. The vast majority of women felt the decision support tool was easy to understand. The evaluation undertaken clearly identifies that the decision support tool met women's information needs, was perceived as useful to refer back to throughout a woman's breast reconstruction

experience, and would be an acceptable and useful tool to assist women making decisions about breast reconstruction.

While all three participants groups—women who had breast reconstruction, women who had not had breast reconstruction, and women who had bilateral prophylactic mastectomy and breast reconstruction—evaluated the decision support tool positively, some differences were noted in the evaluation between these groups. Women who had not undertaken breast reconstruction more positively responded to survey items than the other participant groups. This may be the most indicative appraisal of the value and quality of the decision support tool developed, as it is designed for women who have not yet made the decision to reconstruct their breast. Of this group of women, 63 per cent were actively considering breast reconstruction at the time they evaluated the decision support tool. Another common difference between participant groups was that women who had undertaken bilateral prophylactic mastectomy and breast reconstruction tended to agree to a lesser extent than the other participant groups. This finding suggests information should be tailored to this group of women's specific situation, which is distinct from those experiencing a breast cancer diagnosis and mastectomy.

The results of this evaluation of the breast reconstruction decision support tool are not intended to be generalisable. The majority of participants were purposely selected from a sample of women registered to proactively review and assist with breast cancer policy development and research, and are not statistically representative of the breast cancer population in terms of age or residence. The results of this phase of the research are intended to inform the revision and finalisation of a decision support tool, to assist women seeking information and making decisions about breast reconstruction. The resultant useful, informative and user-friendly decision support tool has been made available to the Australian public via Cancer Australia's website.

Limitations to this phase of the research may include: the majority of women were undertaking a retrospective evaluation of the decision support tool, rather than evaluating it from the prospective information-seeking trajectory for which it is intended. However, perhaps the previous experiences of breast cancer and breast reconstruction best place this group of women to critique how the information

presented may or may not meet women's information and decision-making needs. Additionally, there was no inclusion criterion specifying time since diagnosis, with the maximum time since breast cancer diagnosis of 13.75 years. In this time, breast reconstruction trends and sources of information available have been developed. In addition, women's experiences of their own aesthetic outcome, information seeking experiences, breast cancer treatments and surgical complications may affect their evaluation of the decision support tool presented. To build on this phase of the research, future research should undertake prospective evaluation of the usefulness of the decision support tool in meeting the information needs, and assisting the decision making, of women considering breast reconstruction following mastectomy.

Further discussion of the findings of this phase of the research, recommendations for decision support tool revision and future research opportunities will be detailed in Chapter Six.

Chapter 6: Discussion and Conclusion

6.1 Introduction

This research has made a significant contribution to the care of women with breast cancer, and those acting to prevent breast cancer, by developing an evidence-based information resource to aid decision making about breast reconstruction. The research has provided insight into the complexity women face when considering breast reconstruction, and has identified women's information needs regarding breast reconstruction.

This thesis adds to the body of knowledge on the benefit and processes to support collaborative research with consumers. Both in terms of the research question and processes being driven by key stakeholders and, in particular, undertaking research with consumers. Evaluation research facilitated the stakeholder group to work collaboratively, continuously improving the decision support tool being developed and planning a robust appraisal of its quality and value to women who may be considering breast reconstruction following mastectomy. Alignment of the research process with the CIPP model provided structure and direction to the stakeholder group, and the Ottawa Decision Support Framework led the rigorous steps of developing a decision support tool. Figure 6.1 represents the culmination of key findings and outcomes resulting from implementing the evaluation framework.

Figure 6.1: Key Findings and Outcomes from Implementation of the Evaluation Framework

DECISION/ACCOUNTABILITY EVALUATION RESEARCH			
CIPP MODEL STAGE	**CONTEXT EVALUATION**	**INPUT & PROCESS EVALUATION**	**PRODUCT EVALUATION**
RESEARCH PHASE	**PHASE ONE** Needs analysis	**PHASE TWO** Decision support tool development	**PHASE THREE** Decision support tool evaluation
OTTAWA DECISION SUPPORT FRAMEWORK ELEMENT	**DECISIONAL NEEDS**	**DECISION QUALITY**	**DECISION SUPPORT**
KEY FINDINGS/ OUTCOMES	**BREAST RECONSTRUCTION DECISION MAKING…** ▪ Is complex ▪ Requires multiple decisions ▪ Occurs over an extended period of time ▪ Is often made within the context of a breast cancer diagnosis ▪ Is influenced by multiple personal, clinical and situational factors **INFORMATION NEEDS…** ▪ Do not come to an once end the decision to have a breast reconstruction has been made, but evolve as women experience breast reconstruction ▪ Differ between those who have been diagnosed with breast cancer and women who choose to prophylactically remove and reconstruct their breasts	**PROJECT ADVISORY COMMITTEE ACHIEVMENTS:** ▪ Decision support tool conceptualisation informed by Phase One findings ▪ Decision support tool content drafting ▪ Web design ▪ Desktop publishing ▪ IPDAS Collaboration checklist completion ▪ Decision support tool summative evaluation plan	**DECISION SUPPORT TOOL EVALUATION RESULTS:** ▪ Met women's breast reconstruction information needs (93.5%) ▪ Easy to use (89.7% web & 93.4% booklet) ▪ Clear source of information (99%) ▪ Useful to refer back to throughout breast reconstruction experience (94.4%) ▪ Useful to facilitate discussion with breast reconstruction with healthcare professionals (99.1%) **Stakeholder reporting**

	▪ Are currently not comprehensively met. Information available to women undergoing mastectomy is limited. All-inclusive information about breast reconstruction is required to better inform and prepare women faced with decisions about breast reconstruction ▪ Include practical, physical, visual and emotional information regarding breast reconstruction surgery and recovery		
	STAKEHOLDER ENGAGEMENT 		

The research developed and successfully evaluated a decision support tool for women considering breast reconstruction following mastectomy. The decision support tool (website and booklet) was overwhelmingly positively evaluated as an informative and useful source of information, both by women who had already experienced breast reconstruction decision making and those who were considering breast reconstruction. Since completion of the research, a report of the evaluation findings and the online resource has been passed to Cancer Australia. Following their own internal review processes, inclusive of independent expert review and minor amendments to the structure of the website, it was publically launched on the Cancer Australia website on the 8 October 2013 (www.canceraustralia.gov.au/breastreconstruction). The media release can be viewed at http://sydney.edu.au/news/84.html?newsstoryid=13019.

This chapter will further discuss the application of the research methodology and the findings of the decision support tool evaluation. The conclusion will summarise the impact of this research and suggest areas of future research.

6.2 The Complexity of Breast Reconstruction Decision Making

Phase one of this research reinforced the complexity that undermines women's ease of making decisions regarding reconstruction of the breast(s). The women described the challenge of making a decision regarding their core cancer treatment, and having to consider the implications of these decisions in relation to, not only survival, but also options for breast reconstruction either immediately or later on. Both previous research and the findings from Phase One highlighted the lack of preparation for the practical aspects of having breast reconstruction surgery. Perhaps most evident was the lack of preparation for the multitude of decisions needed, once the decision to reconstruct the breast was made. These included decisions regarding the type and timing of breast reconstruction, surgical refinement of both the reconstructed or other breast, and nipple or areola reconstruction options.

As described by the women in this research; personal, medical and situational factors needed to be considered beyond choosing to have a breast reconstruction, or a

specific type of breast reconstruction. For women with breast cancer, the impact of adjuvant therapies on breast reconstruction recovery, and vice versa, needed to be considered. Medical factors such as the breast size to be recreated, the woman's body size and shape, available tissue to transfer, and comorbidities should be measured when identifying the suitability of different types of breast reconstruction. Several authors have highlighted that differing breast reconstruction types and timings will have financial implications that may influence an individual woman's options (Heller & Miller, 2004; Potter et al., 2013; Rainsbury & Straker, 2008; Steligo, 2005). Situational factors, including geographical location to breast reconstruction specialist services, may affect the type and timing of breast reconstruction procedure and the refinement surgeries offered to women. Travel requirements to access these services will have flow-on effects to finances and family life. All these factors need to be considered against the individual woman's personal values and goals.

The medical and health aspects of breast reconstruction decision making noted earlier confirms the importance of shared decision making with healthcare professionals. Women require specialist guidance when considering the medical factors affecting breast reconstruction treatment options following mastectomy. This guidance should come from healthcare professionals with knowledge of the technical aspects of breast and breast reconstruction surgery and cancer treatments. Access to comprehensive, relevant information about breast reconstruction treatment options to aid women in making decisions about breast reconstruction needs to acknowledge and inform women of the various factors affecting breast reconstruction decision making (Edwards & Elwyn, 2009; Heller & Miller, 2004; O'Connor & Edwards, 2009; Wolf, 2004a).

The review of research into decision support tools and the specific information resources on breast reconstruction was incorporated into the findings from Phase One. Tools to aid decision making in health care (or cancer care) have been developed, including question prompt lists, values clarification exercises and decision trees. Each of these formats were considered for this project. The premise behind decision support tools is to meet the decisional needs of the individual to facilitate quality decision making (https://decisionaid.ohri.ca/ odsf.html). Decision support tools ideally take into account the complexity of decision making,

incorporating existing knowledge base, individual values, decision type and timing, and personal characteristics impacting options. Decision support is provided through information, encouraging individuals to clarify the decisions to be made and their values relating to these decisions; therefore, supporting the individual's decision-making process (https://decisionaid.ohri.ca/odsf.html). Implementation of decision support tools in varying formats have been shown to improve knowledge, reduce decisional conflict and modify expectations (Stacey et al., 2014).

A decision tree may be both be complex and confusing, rather than assisting women considering the information required for each informed decision. A limitation of the decision tree approach is that it does not emphasise the importance of shared decision making and may foster unrealistic expectations. The researcher had initially envisaged developing a decision tree; however, it became rapidly apparent that a decision tree would not have the flexibility, breadth, or detail of information required. The inclusion of values clarification exercises may not be appropriate given the importance of shared decision making and the input and guidance required from healthcare professionals about the suitability of specific breast reconstruction options. Facilitating or encouraging women to make a decision at the time they were using the decision support tool independently may be counterproductive to quality decision making. In consultation with stakeholders, it was determined more relevant and appropriate for women to have access to information and be informed, rather directing the decision-making process itself. The decision support tool developed in this research achieves this by acknowledging the complexity of breast reconstruction decision making, emphasising the importance of shared decision making with healthcare professionals, encouraging values clarification without inclusion of a structured exercise, and providing comprehensive information to inform women as active participants in their decisions about breast reconstruction.

6.3 Application of the Research Methodology

Adoption of an evaluation research methodology achieved the aims of this research. The logical course of evaluation research follows a process of development, evolution and improvement to determine quality and value; this aligns with the

intended aim to develop a decision support tool for women considering breast reconstruction following mastectomy. Decision/accountability evaluation research was identified as the frame within which to conduct evaluation research of a decision support tool to assist women making complex decisions about breast reconstruction treatment options. This approach had been evaluated strongly against the Joint Committee Program Evaluation Standards, demonstrating a robust, reliable method of evaluation (Stufflebeam, 2001).

The strong focus within decision/accountability evaluation research on stakeholder engagement was a significant factor in selecting this approach. Further to the application of this type of evaluation methodology, the CIPP model developed by the founder of decision/accountability evaluation research, Daniel Stufflebeam, was implemented to provide structure, transparency and accountability for the evaluation research processes when developing the decision support tool. Critical to this research was collaboration and consultation with end users of the decision support tool. Decision/accountability evaluation research requires key stakeholders to play an active role throughout the development and research process. The conceptual framework of the Ottawa Decision Support Framework, as a well-developed model of decision support tool development, complemented the decision/accountability evaluation research approach. It provided a useful tool to guide the stakeholder group in decision support tool development, given that most members had no experience in the development of such resources.

The evaluation research approach and conceptual framework adopted were aligned in an evaluation framework for this research. Implementation of the evaluation framework ensured a comprehensive and rigorous approach to decision support tool development, inclusive of stakeholder input, was carried out to meet the needs of its intended users. The breast reconstruction decision support tool development process outlined in Chapters Three and Four included expert opinion, focus group interviews and review of the evidence. No other breast reconstruction information resource adopts all of these methods. Only one other resource reported using expert opinion and focus groups in their resource development process (Heller et al., 2008), and only one other reported incorporation of a review of the literature (Lee, Chen et al., 2010).

6.3.1 The Importance of Collaboration and Working with Consumers

The valuable contribution consumers can make to health services research has been increasingly recognised over the past two decades (National Health and Medical Research Council & Consumers' Health Forum of Australia, 2002). The National Health and Medical Research Council and Consumers' Health Forum of Australia's 'Statement on Consumer and Community Participation in Health and Medical Research' (2002) formalises this recognition with a vision for consumers and researchers to work as partners undertaking respectful collaboration on research projects aimed at improving population health outcomes. To support consumer involvement, Cancer Australia and Cancer Voices Australia has developed a National Framework for Consumer Involvement in Cancer Control (2011), offering principles to guide consumer engagement. The premise of consumer involvement is that it provides a real and practical depth of knowledge to a research or other project, by acting with, rather than upon, those receiving care and services (Cancer Australia & Cancer Voices Australia, 2011). Further, it is acknowledged not only to provide a benefit to research, but is also a right of health service consumers to be involved in health services research (National Health and Medical Research Council & Consumers' Health Forum of Australia, 2002). Consumer involvement in health service products and initiative development can improve health and wellbeing and promote sustainability (Popay et al., 2007).

Consumers are defined as persons who have been affected by the circumstances, products or services being investigated, or consumer organisations representing the views of consumers (Cancer Australia & Cancer Voices Australia, 2011; National Health and Medical Research Council & Consumers' Health Forum of Australia, 2002). The consumers engaged in this research were women who had undertaken breast reconstruction, those who were in a position of considering breast reconstruction as an option, and consumer organisations representing, and serving to inform and support, women affected by breast cancer and breast reconstruction.

The National Framework for Consumer Involvement in Cancer Control (2011) identifies progressive levels of participation, based upon Popay's community

engagement pathways: namely informing, consulting, involving, partnership and consumer-led participation (Cancer Australia & Cancer Voices Australia, 2011). This research represents consumer-led participation, whereby consumers partnered equally with healthcare professionals and researchers to set research objectives, contributed to the development of a decision support tool product, and guided and monitored evaluation research processes. The stakeholder group not only contributed to development of the decision support tool, but assumed ownership and direction of the decision support tool development and evaluation, including determining specific content of the decision support tool. The key elements of the National Framework for Consumer Involvement in Cancer Control (2011) are committed organisations, capable consumers, inclusive groups and shared focus (Cancer Australia & Cancer Voices Australia, 2011). These criteria were met by the research team's commitment to: valued consumer engagement; consumer nomination as capable representatives by industry/community leaders; establishing a shared focus of mutually agreed objectives of the research; and supporting consumers to participate in research by educating them about the research methodology and decision support tool development process guided by a structured framework.

Chapters Two and Four detail the governance processes implemented to initiate and maintain consumer engagement throughout the research. Clear objectives were established in the PAC terms of reference (Appendix Five). Ongoing communication strategies adopted were crucial to directing the shared focus of the research and encouraging the contribution of consumers over the extended period of research. The researcher monitored consumer involvement activities to ensure consumers were supported and facilitated to contribute to the research. The consumers nominated were motivated, capably experienced to contribute and demonstrated understanding of their role as partners in this research. The consumers were successfully supported by the governance processes initiated and managed by the researcher, to actively participate in development and implementation of an evaluation framework for a breast reconstruction decision support tool for women considering breast reconstruction following mastectomy.

6.4 Discussion of Decision Support Tool Evaluation Results

The timeframe and circumstances of decision making about breast reconstruction vary significantly for women. Women may be considering immediate breast reconstruction within a restricted time frame; others may have lived with mastectomy for a period and were now contemplating delayed breast reconstruction. Some women may be considering preventative measures to reduce the risk of breast cancer in their non-diseased breast. Another group of women may be considering bilateral mastectomy to prevent breast cancer, due to a high familial risk and/or genetic testing results. Each of these groups of women will have differing information needs at different times of their breast reconstruction experience trajectory. Findings from evaluation of the decision support tool were overwhelmingly positive. The decision support tool met the different information needs and was able to be used effectively at variable time points during a woman's decision making, as required. The decision support tool was identified to be clear and easy to understand. Women reported the decision support tool would also be useful to guide discussion with their breast reconstruction surgeon, and was useful for women to refer back to throughout their physical and emotional recovery from breast reconstruction.

Women expressed that the information within the decision support tool was comprehensive and provided much needed information about the practical aspects of breast reconstruction surgery and recovery. A review of breast reconstruction educational material revealed no other resource covered the clinical, physical and psychosocial aspects of breast reconstruction (Preminger et al., 2011). Most materials are focused on the types of breast reconstruction available (Heller et al., 2008; Lee, Chen et al., 2010) and the complications and risks of breast reconstruction (Lee, Chen et al., 2010). Only one resource discusses satisfaction with breast reconstruction and social functioning following breast reconstruction (Heller et al., 2008). Only one of the evaluated materials reported including pictures (Heller et al., 2008), and few report the inclusion of patient interviews (Dravet et al., 2010; Heller et al., 2008). The breast reconstruction decision support tool discusses all of these topics, along with information about the complexities of decision making, the

possible effects of cancer treatments, post-operative recovery, psychosocial recovery including body image and sexuality, and long-term practical and physical implications of breast reconstruction.

While the intent was not to conduct comparative analysis between participant groups—rather it was to confirm that the decision support tool met the needs of women in different situations—the comparison of evaluation results between the three groups of women revealed trends of difference. Women who had not undertaken breast reconstruction most strongly agreed with evaluation survey items. The bilateral prophylactic mastectomy and breast reconstruction group agreed to a lesser extent, with the extent to which the breast cancer and breast reconstruction group agreed with the evaluation survey items somewhere in between the other two groups.

Women who had not had their breast reconstructed were more likely to strongly agree with survey items than women who had undertaken breast reconstruction. This may indicate this group of women's desire for information to inform their decisions about breast reconstruction. Women who had not undertaken breast reconstruction were the target audience for this resource, perhaps making their evaluation most valid. Women who had not experienced breast reconstruction may have previously sought breast reconstruction information identifying the lack of detailed, relevant information, or may never have accessed any information about breast reconstruction. In either case, this group of women may have been impressed by a single, comprehensive source of information they felt was applicable to them.

However, it is beneficial to consider the worth of the decision support tool evaluation provided by the groups of women who had experienced breast reconstruction. These women have the benefit of reflecting on their information seeking and decision making, the impact of breast cancer on their experience (where applicable), and their long term recovery from breast reconstruction. This is valuable, as this group of women were able to highlight gaps in the information content of the decision support tool from a longitudinal perspective, most accurately evaluating whether the decision support tool would be beneficial for women to refer back to throughout their breast reconstruction experience. However, their own personal experiences and

resulting satisfaction with breast reconstruction decision making, recovery and breast reconstruction outcomes was likely to influence their evaluation of the decision support tool. This was evident from this group of women's variable comments provided in the evaluation. For example, some women identified a need for more quotations reflecting others' experiences and pictures of breast reconstruction, while others preferred less quotations and images. While it is important that a balanced view is presented, women's experiences as depicted in quotations and pictures should be generally representative of a variety of usual outcomes, and should not depict the unusual or extreme experiences of very few.

That the bilateral prophylactic mastectomy and breast reconstruction group agreed with evaluation items to a lesser extent than the other two groups may reflect their differing information needs to those who had a concurrent breast cancer diagnosis. While this group had a dedicated written booklet, the website contained information for all groups, directing access to relevant information through explanation and a navigation pane. Perhaps the significant volume of information related to those who had experienced a breast cancer diagnosis was distracting for women to whom this information was not applicable. Women who had chosen to undergo bilateral prophylactic mastectomy and breast reconstruction commented the information could be better tailored to them. An existing gap in this resource is the lack of pictures of women who have had bilateral prophylactic mastectomy. Such images should be sourced for inclusion in the resource, as surgical techniques of mastectomy may vary, subsequently affecting aesthetic outcomes compared to those receiving mastectomy to treat breast cancer.

The evaluation of the decision support tool identified areas for improvement. These included website navigation, breast reconstruction pictures, targeted information for women considering bilateral prophylactic breast reconstruction and ensuring balanced information about breast reconstruction experiences and outcomes. As the website was constructed and hosted by Cancer Australia, content was restricted to only three levels of headings in the navigation pane. Given the volume of information to be presented, this proved problematic during the development phase of the decision support tool, and much discussion occurred regarding how to optimise navigation within this constraint. While evaluation revealed the vast

majority of women found the website easy to navigate (89.7%), others commented they found navigation challenging. This feedback was reported to Cancer Australia for consideration in their review process prior to launching the website, including a recommendation to open links in a new browser and consider increasing the amount of heading levels.

Access to an appropriate and broad range of images of breast reconstruction for use in the decision support tool was limited. The purpose of including images was to provide information depicting women's breast reconstruction surgery progression and aesthetic outcome. The stakeholder group agreed that a variety of experiences and outcomes should be presented. Different types of breast reconstruction, different timing, unilateral, bilateral, older women, younger women, Caucasian women, non-Caucasian women, 'good' aesthetic outcomes, 'not-so-good' aesthetic outcomes, common minor complications and donor sites of where tissue had been transferred from were represented in the images. A longitudinal series of images was necessary to provide realistic expectations of healing time and final aesthetic outcomes. Observer subjectivity meant agreement on what were 'good' aesthetic outcomes differed among the stakeholder group. Clinical stakeholders held differing views of the quality and representation of the images to other stakeholders. The challenge of providing images acceptable to the entire stakeholder group required consultation and discussion with surgical members of the stakeholder group, resulting in consensus.

Very few sources of breast reconstruction images exist. The small gallery accessed for inclusion in the decisions support tool provided limited options. While a range of representatively appropriate images were sourced for inclusion in the decision support tool, a gap in high quality, consistent images, depicting variable clinical circumstances remains. No images of bilateral prophylactic mastectomy and breast reconstruction could be sourced. Women considering this procedure were referred to view the bilateral immediate breast reconstruction images. Despite evaluation of the images providing useful information (98.1%), it is clear a gap remains in sourcing pictures of women with a greater variation of breast sizes, younger women, and a longer trajectory of images to depict completed outcomes.

The aim of the decision support tool development was to provide unbiased information about breast reconstruction options, including not having a breast reconstruction. The key to avoiding bias towards breast reconstruction was to maintain balance in the presented information. Several strategies were adopted to achieve this end. One aspect of this was to ensure balance within the stakeholder group. Two consumer representatives were recruited to take part in the stakeholder group: one who had chosen not to have a breast reconstruction. The beginning of the decision support tool clearly stated breast reconstruction was not for everyone; and options included no breast reconstruction, with or without use of external breast prosthesis. To ensure balance, images of external breast prosthesis use were taken and included. While inclusion of women's quotations were important in providing another source of valuable information about breast reconstruction experiences, representing a balanced view was necessary. Quotations were reviewed repeatedly by the stakeholder group to ensure this balance was achieved.

The format of information materials is important in engaging the user to access and understand the information presented. Much consideration was given to what format of information would be optimal to reach the intended target audience. The decision support tool was created in both a booklet and a website format, to ensure it would capture differing preferences and enable comparative evaluation of preferences. No other breast reconstruction educational material has been created in both internet and booklet formats (Preminger et al., 2011). Earlier resources have been written materials (Chapman et al., 1995; Finlayson et al., 2001), CD-Roms (Heller et al., 2008; Lee, Chen et al., 2010) or video format (Dravet et al., 2010).

The literature on both breast cancer (Lee et al., 2010; Walsh et al, 2010) and breast reconstruction identifies that women commonly seek health information on the internet (Losken et al., 2005; Macdonald et al., 2010; Sheehan et al., 2007; Wolf, 2004a); yet interestingly, the majority of women participating in this research (59.8%) preferred to use both the booklet and website; followed by the booklet only (29%), and the website only (4.7%). This finding demonstrates women want information readily accessible in multiple formats. A strong preference for the booklet, despite a very computer literate participant group, may indicate a preference for the women's location when they are accessing information or the desire to

annotate their thoughts/feelings and responses to the information presented. Such a practice may be useful to assist values clarification during decision making.

Several systematic reviews of the effectiveness of computerised decision aids (CD-Rom and internet) have revealed resulting knowledge improvements (Fox, 2009; Ryhanen, Siekkinen, Rankinen & Leino-Kilpi, 2010; Sheehan & Sherman, 2012), less decision conflict, and greater user satisfaction than other formats (Sheehan & Sherman, 2012). Sheehan and Sherman (2012) concluded that further exploration of how computerised decision aids tailor information, assist to clarify values and incorporate shared decision making was required. Given concerns about the reliability and quality of readily accessible web-based content, criteria for evaluating information available on the internet has been developed (Charnock & Shepperd, 2004). A study appraising web-based breast reconstruction information against these criteria identified no correlation existed between the Google ranking of websites most frequently accessed and the criteria ranking of websites (Macdonald et al., 2010).

Regardless of the research participants' preference for the booklet format, only the website format has been made available publically on Cancer Australia's website. Paper-based resources are expensive to produce and have the potential to leave out-of-date information circulating in the public domain. In a world of varying and evolving breast reconstruction techniques, the importance of maintaining current and relevant information to meet women's needs and facilitate realistic expectations of breast reconstruction options cannot be underestimated. The decision support tool developed in this research is now publically available from a national government cancer organisation that undertakes independent expert review and regularly reviews educational materials to ensure they are up-to-date with current evidence-based best practice.

The advantages of internet based decision support tools include unlimited restrictions on quantity of information, the ability to combine basic information and more complex detailed information to meet varying information needs, and use of multiple mediums including video, audio and graphics. The internet is accessible, easily updated, cost effective and the individual is able to control the amount and

type of information received (Murray, 2009). The author reviewed 17 systematic reviews of internet based information resources; summarising these studies identified improved user knowledge of the condition and treatments in question, improved self-efficacy of users and the provision of social support through personal stories of others or discussion groups. Improvements in an individual's belief in their ability to act may facilitate greater involvement in decision making (Murray, 2009).

In conclusion, effective use of an evaluation framework ensured a rigorous research process was maintained. Collaboration with various stakeholders—most critically consumer involvement—was key to producing a resource that met the needs of, and was accepted by, breast reconstruction stakeholders. The collaborations formed with peak national bodies Cancer Australia and Breast Cancer Network Australia not only added another perspective of input contributing to the development of the decision support tool, but facilitated consumer representation on the stakeholder group, recruitment of a participant sample for evaluation of the decision support tool and dissemination of the final product.

The achieved aims of this research culminated in a nationally endorsed and accessible source of breast reconstruction information, to assist Australian women with their decision making. Not only does this mean women have access to reliable, evidence-based, comprehensive information, but also their health care professionals can use this resource as a tool for directed discussion about women's breast reconstruction treatment options. Using the resource in this way will assist women to be involved in breast reconstruction decision making to the extent they desire, may improve retention of important health information and facilitate informed decision making.

Studies evaluating dedicated breast reconstruction information resources against which to compare and contrast the findings of this research are lacking. Only three studies evaluating educational material exclusively about breast reconstruction have been published (Dravet et al., 2010; Heller et al., 2008; Lee, Chen et al., 2010). These studies differ from this research in two main ways: 1) they are prospective, where this evaluation is retrospective; and 2) the outcomes being evaluated relate to knowledge, satisfaction and anxiety, where this research sought evaluation of the

construct, content and perceived usefulness of the resource itself. Further research should focus on prospective evaluation of the effect of the decision support tool use on knowledge and decision making outcomes.

6.5 Conclusion and Future Research

Increasing complexity in decision making is not an uncommon occurrence in healthcare. This research has shown that providing information which can be tailored to meet the needs of individuals can provide crucial support in complex and complicated health situations. In recent years, growing recognition of complexity of health decisions and increased treatment options has led to the development of decision support tools. Central to the different types of decision support tools is ensuring individuals have the information required, so they have the autonomy to make informed decisions about their healthcare. The decision support tool developed in this research adds to this body of work, and contributes to the ongoing care of women diagnosed with breast cancer. The value of consumer involvement in the development of these resources is reflected in this study, and is a reflection of changes in broader community attitudes and expectations regarding their involvement in decisions regarding their healthcare.

Implementing the evaluation framework for this research, in collaboration with stakeholders, has been an overwhelmingly positive experience. The decision support tool for women considering breast reconstruction following mastectomy has been adopted for national use. The information obtained within the decision support tools will be able to assist Australian women to navigate breast reconstruction decision making, and better prepare them for breast reconstruction surgery and recovery.

Further research is required to gain a better understanding of the barriers for women in accessing breast reconstruction, and the long-term psychosocial impact of breast reconstruction. Further evaluation of the different approaches to breast reconstruction is also required. Currently, no national statistics on breast reconstruction outcomes are collated, making it impossible to include reliable risk and benefit probabilities of breast reconstruction in the decision support tool to

inform women's decisions. It is a limitation of this study that a small number of women from rural, regional and remote Australia were able to be recruited. In addition, very little is known regarding the cultural barriers or needs of Aboriginal women, or of migrant Australian women.

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Appendix 1: Literature Review Search Strategy

The literature search aimed to identify literature pertinent to the topic areas being explored. The topics of focus evolved as the research was conducted. As a topic became pertinent, key search terms were established and the list of databases search. All abstracts were reviewed, and for those meeting inclusion criteria the full text was reviewed.

Data bases searched: CINAHL Plus, PubMed, Austhealth, Science Citation Index Expanded (Web of Science), Sciverse Science Direct (Elsevier) & One file (Gale).

Inclusion criteria determined search limitations. Literature included research papers, systematic reviews, government reports and clinical practice guidelines. Research studies were limited to the preceding 10 year period and were required to be published in English.

TOPIC AREA	SEARCH TERMS
Breast cancer	Breast cancer + decision making Mastectomy + decision making Mastectomy + psychosocial impact
Prophylactic mastectomy	Contralateral prophylactic mastectomy + decision making Bilateral prophylactic mastectomy + decision making Contralateral prophylactic mastectomy + breast reconstruction/restoration outcomes Bilateral prophylactic mastectomy + breast reconstruction/restoration outcomes
Breast reconstruction	Breast reconstruction/restoration + types Implant breast reconstruction Latissimus Dorsi flap breast reconstruction TRAM flap breast reconstruction DIEP flap breast reconstruction Breast reconstruction + immediate Breast reconstruction + delayed
Brest reconstruction decision making	Breast reconstruction/restoration + decision making Breast reconstruction/restoration + shared decision making Breast reconstruction/restoration + decision conflict/regret Breast reconstruction/restoration + decision support Breast reconstruction/restoration + decision aids
Breast reconstruction information needs	Breast reconstruction/restoration + information Breast reconstruction/restoration + education
Breast reconstruction outcomes	Breast reconstruction/restoration + outcomes Breast reconstruction/restoration + aesthetic Breast reconstruction/restoration + psychosocial Breast reconstruction/restoration + clinical Breast reconstruction/restoration + complications Breast reconstruction/restoration + quality of life Breast reconstruction/restoration + satisfaction

Appendix 2: Advantages and Disadvantages of the Differing Types of Breast Reconstruction Commonly Used in Australia

(Rainsbury & Straker, 2008; Steligo, 2005)

Type of breast reconstruction	Advantages	Disadvantages
Breast reconstruction using implants	Less surgery and shorter recovery time compared with tissue flap breast reconstructions	Less natural look, feel and movement than tissue flap breast reconstructions Reconstructed breast(s) sits higher on the chest than a natural breast Does not move like a natural breast (e.g., when lying down) Does not change in size with weight gain or loss Does not 'age' with other areas of the body High risk of side effects and complications May experience chest tightness which may affect movement
LD flap Latissimus dorsi flap	More natural look, feel and movement compared with implants only Some change in size with weight gain or loss 'Ages' more naturally than implants only	Longer surgery and recovery time compared with breast reconstruction using implants only More than one scar Not as much of a change in size with weight gain or loss, compared with TRAM flap or DIEP flap May affect movement of muscles in the back and arm
TRAM flap Transverse rectus abdominus myocutaneous flap	TRAM and DIEP flaps have the most natural look and feel Usually suitable for women with larger breasts Changes in size with weight gain or loss 'Ages' naturally with other areas of the body	Longer surgery and recovery time compared with breast reconstruction using implants More than one scar Possible weakness of abdominal muscles

Type of breast reconstruction	Advantages	Disadvantages
DIEP flap Deep inferior epigastric perforator flap	TRAM and DIEP flaps have the most natural look, feel and movement Usually suitable for women with larger breasts Changes in size with weight gain or loss 'Ages' naturally with other areas of the body Less effect on the abdominal muscles compared with TRAM flap	Longer surgery and recovery time compared with breast reconstruction using implants More complex surgery than TRAM flap More than one scar

Appendix 3: Ethics Approval

The University of Sydney

Faculty of Nursing & Midwifery

Phase One Ethics Approval

27 June 2007

Professor Kate White
Research Development and Support Unit
Faculty of Nursing and Midwifery—M02
The University of Sydney

Dear Professor White
I am pleased to inform you that the Human Research Ethics Committee (HREC) at its meeting on **5 June 2007** approved your protocol entitled ***'Development, Implementation and Evaluation of a Breast Reconstruction Decision Aid for Women Requiring Mastectomy for Breast Cancer'***.
Details of the approval are as follows:

Ref No.: ***06-2007/9864***
Approval Period: ***June 2007 to June 2008***

Authorised Personnel: **Professor K White**
Ms O Hill
Professosr P Butow
Professor C Saunders
Mr T Connell

The HREC is a fully constituted Ethics Committee in accordance with the *National Statement on Ethical Conduct in Research Involving Humans-June 1999* under *Section 2.6.*

The approval of this project is **conditional** upon your continuing compliance with the *National Statement on Ethical Conduct in Research Involving Humans.* We draw to your attention the requirement that a report on this research must be submitted every 12 months from the date of the approval or on completion of the project, whichever occurs first. Failure to submit reports will result in withdrawal of consent for the project to proceed.

Special Condition/s of Approval
This approval relates to Phase One (Focus Groups)

Chief Investigator / Supervisor's responsibilities to ensure that:

(1) All serious and unexpected adverse events are to be reported to the HREC as soon as possible.

(2) All unforeseen events that might affect continued ethical acceptability of the project are to be reported to the HREC as soon as possible.

(3) The HREC must be notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. These include:-

- If any of the investigators change or leave the University.
- Any changes to the Participant Information Statement and/or Consent Form.

(4) All research participants are to be provided with a Participant Information Statement and Consent Form, unless otherwise agreed by the Committee. The Participant Information Statement and Consent Form are to be on University of Sydney letterhead and include the full title of the research project and telephone contacts for the researchers, unless otherwise agreed by the Committee and the following statement must appear on the bottom of the Participant Information Statement. *Any person with concerns or complaints about the conduct of a research study can contact the Senior Ethics Officer, University of Sydney, on (02) 9351 4811 (Telephone); (02) 9351 6706 (Facsimile) or gbriody@usyd.edu.au (E-mail).*

(5) The HREC approval is valid for four (4) years from the Approval Period stated in this letter. Investigators are requested to submit a progress report annually.

(6) A report and a copy of any published material should be provided at the completion of the Project.

Yours sincerely

Professor D I Cook
Chairman
Human Research Ethics Committee

The University of Sydney

Faculty of Nursing & Midwifery

Phase Two & Three Ethics Approval

19 November 2009

Prof Kate White
Faculty of Nursing and Midwifery
Mallett St Campus - M02
The University of Sydney
E-mail: k.white@usyd.edu.au

Dear Professor White

Thank you for your correspondence dated 1 October 2009 addressing comments made to you by the Human Research Ethics Committee (HREC). After considering the additional information, the Executive Committee at its meeting held on **4 November 2009** approved your protocol entitled ***"Development, implementation and piloting of an evaluation framework for a breast reconstruction information resource for women considering breast reconstruction following mastectomy"***.

Details of the approval are as follows:

Ref No.:	***11-2009/11985***
Approval Period:	***November 2009 to November 2010***
Authorised Personnel:	Prof Kate White
Miss Olivia Hill	
Prof Phyllis Butow	
Prof Christobel Saunders	
Mr Tony Connell	

The HREC is a fully constituted Ethics Committee in accordance with the *National Statement on Ethical Conduct in Research Involving Humans-March 2007* under *Section 5.1.29*

The approval of this project is **conditional** upon your continuing compliance with the *National Statement on Ethical Conduct in Research Involving Humans.* We draw to your attention the requirement that a report on this research must be submitted every 12 months from the date of the approval or on completion of the project, whichever occurs first. Failure to submit reports will result in withdrawal of consent for the project to proceed.

Special Conditions of Approval

Please forward a copy of the survey and demographic questionnaire when finalised.

Chief Investigator / Supervisor's responsibilities to ensure that:

(1) All serious and unexpected adverse events should be reported to the HREC as soon as possible.

(2) All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.

(3) The HREC must be notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. These include:-
- If any of the investigators change or leave the University.
- Any changes to the Participant Information Statement and/or Consent Form.

(4) All research participants are to be provided with a Participant Information Statement and Consent Form, unless otherwise agreed by the Committee. The Participant Information Statement and Consent Form are to be on University of Sydney letterhead and include the full title of the research project and telephone contacts for the researchers, unless otherwise agreed by the Committee and the following statement must appear on the bottom of the Participant Information Statement. *Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Ethics Administration, University of Sydney, on (02) 8627 8176 (Telephone); (02) 8627 8177 (Facsimile) or human.ethics@usyd.edu.au (E-mail).*

(5) Copies of all signed Consent Forms must be retained and made available to the HREC on request.

(6) It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.

(7) The HREC approval is valid for four (4) years from the Approval Period stated in this letter. Investigators are requested to submit a progress report annually.

(8) A report and a copy of any published material should be provided at the completion of the Project.

Yours sincerely

Professor D I Cook
Chairman
Human Research Ethics Committee

Phase Two & Three Ethics Amendment Approval

THE UNIVERSITY OF SYDNEY NSW 2006

THE UNIVERSITY OF SYDNEY

HUMAN RESEARCH ETHICS COMMITTEE
REQUEST FOR MODIFICATION

APPROVED 28/4/10

1. **Principal Investigator:** Professor Kate White
   Department: Faculty Nursing and Midwifery
   Address: C/- Sydney Cancer Centre
2. **Project Title:**
3. **HREC Approval No.:** Ref no. 11-2009/11985
4. **Names of Students/Co-Investigators:** Olivia Hill
5. **Project Description:**
   Please provide a one paragraph lay summary of your original project

The aim of this project is to development and evaluate of an information resource for women considering breast reconstruction after diagnosis of breast cancer. Currently in Australia, only 8% of eligible women undergo breast reconstruction following mastectomy. Research has shown significant improvement in psychological outcomes for women who undergo reconstruction. Earlier research by the team has identified a lack of information about surgical options for breast cancer, timing of information and lack of support in reconstruction decision making as barriers to women accessing breast reconstruction. This project seeks the lack of evidence based information resources in this area.

6. **Any previously approved minor amendments?** ☐ Yes x☐ No
   If YES, please briefly outline

7. **Nature of and reasons for amendment(s)**
   Please provide details of the changes you propose to make to the project and explain why they are necessary. Please justify any increase In sample size.

This submission is not to amend or alter the research project.

In developing the information resource we have been provided with an opportunity to access sequential images taken of women who have undergone different types of surgical breast reconstruction. The images are pre, immediately , 3 and 6 months post surgery. They provide a realistic visual description of what recovery of re constructed breast using different surgical approaches is like. These images are stored at "the Breast Gallery" and accessible to all women in Western Australia. Women whose images are stored have consented to the images being used in "The Breast Gallery "resource by the RPA Specialist breast Nurses has a visual guide for women considering reconstruction. RPA has given permission for a small selection of the images to be used. They will make the initial approach to women

to obtain their consent or not for their images to be sued in the resource being developed In our project. We are now seeking review of the information sheet and consent form for the use of the images.

As this is a doctoral student of University of Sydney , we are seeking approval at this ethics committee as first point of contact.

Appendix 4: Phase One

Phase One Surgeon's Cover Letter

Dear _____,

I wish to take this opportunity to inform you of a research study being undertaken by a nursing colleague, Olivia Hill. The study being conducted is related to the decision making aspects of breast reconstruction following the need for mastectomy for breast cancer. Phase One of Miss Hill's study involves a series of group interviews with women who have undergone the different types of breast reconstruction, in order to gain information regarding this treatment decision. An information sheet that outlines the details of the study and the contact details for participation are enclosed. If you are interested in participating in this study or receiving further information please complete the forms attached and return in the enclosed envelope.

You are under NO OBLIGATION to agree to participate in this study. Your decision to participate or not, will in no way impact on any care you receive from myself or the Mount Hospital. None of your personal details have been provided to the researcher.

Kind Regards,

Mr _____

The University of Sydney

Faculty of Nursing & Midwifery

MOUNT HOSPITAL

Phase One Participant Information Statement

Title: Development, Implementation and Evaluation of a Breast Reconstruction Decision Aid for Women Requiring Mastectomy for Breast Cancer

Researcher: Olivia Hill RN(Hons) PhD Candidate

Supervisor: Professor Kate White

Associate Supervisors: Mr Tony Connell

Professor Christobel Saunders

Professor Phyllis Butow

Who is carrying out the study?

My name is Olivia Hill. I am a registered nurse, currently undertaking a research project on breast reconstruction decision making. This research will form the basis of a PhD Degree being undertaken at the University of Sydney, under the supervision of Professor Kate White. With Dr _____ permission I am writing to invite you to participate in my study regarding your experience of deciding whether or not to undergo breast reconstruction.

What is the study about?

The purpose of this study is to develop an information resource to assist women in making decisions regarding breast reconstruction. These information resources are often referred to as a 'decision aid'.

What does the study involve?

If you agree to participate, your participation would involve attending a group interview with the researcher and approximately five other women who have had breast reconstruction. This interview will take place at the Mount Hospital.

How much time will the study take?

The interview will include a series of open-ended questions about your experiences of deciding to undergo a breast reconstruction and what type, and will take around 60–90 minutes. If you choose to participate in the study, would you please indicate on the consent form which scheduled interview you would be able to attend; Wednesday October 17th at 7pm, Saturday October 20th at 10am, or Wednesday October 24th at 7pm.

Will anyone else know the results?

The interview will be tape-recorded and later transcribed by a qualified transcriber. Any personal details or identifying information will be removed from the transcript. Original tapes and transcripts will be secured in a locked filing cabinet, and stored at the University premises for a period of 7 years after publication of the research study, at which time they will be destroyed. The information gathered about you by the investigator or obtained during the group interview will be held by the investigator in strict confidence. The only people having access to the transcript will be the researcher, the Lead Supervisor and a professional transcriber. All the people who handle your information will adhere to traditional standards of confidentiality. If the results of the study are published in a medical journal, as is intended, no publication will be able to identify individual participants.

Will the study benefit me?

The perceived benefits to you in participating may include the opportunity to talk about your experiences within a supportive setting. In addition, information from this phase of the study will assist in developing a further information source for women considering breast reconstruction, to inform and guide them through this complex decision making process at this difficult time in their lives.

Can I withdraw from the study?

In the event that discussing your personal experiences causes emotional distress, the interview would be stopped immediately. You would be given the option of continuing or withdrawing from the study. <u>You may choose to withdraw your participation from this study at any time and this will have no impact on your relationship with your surgeon or any health service.</u>

What if I have a complaint or concerns?

Please note this study has been approved by both the University of Sydney and the Mount Hospital ethics committees. Further information may be obtained from the Researcher Olivia Hill on 0407770946. Any complaints should be addressed to Chairman of the Mount Hospital Ethics Committee on (08) 9483 2841, or University of Sydney Human Research Ethics Committee on (02) 93514811.

Please find enclosed a consent form and stamped self-addressed envelope. Submission of contact details and signed consent is required as soon as possible. The Researcher will then be in contact with you by telephone in the imminent future.

What if I require further information?

Your participation would be greatly appreciated. If something is unclear or you have any queries, please do not hesitate to contact me;

Mobile: 0407770946

E-mail: ohil3117@mail.usyd.edu.au

_____

Olivia Hill

PhD Candidate

The University of Sydney

MOUNT HOSPITAL

Faculty of Nursing & Midwifery

Phase One Consent Form

Title: Development, Implementation and Evaluation of a Breast Reconstruction Decision Aid for Women Requiring Mastectomy for Breast Cancer

Researcher: Olivia Hill RN(Hons) PhD Candidate

Supervisor: Professor Kate White

Associate Supervisors: Mr Tony Connell
Professor Christobel Saunders
Professor Phyllis Butow

- I have been given clear written information about this study and have been given the opportunity to ask questions about the study.
- I have been informed of the possible risks and benefits of participating in the study.
- I am aware my participation will be confidential and any personal, identifying details will be removed from the data.
- I understand ethical approval for this study has been given by both the University of Sydney and the Mount Hospital.
- I understand my participation is voluntary and I may withdraw from this study at any time without impact on my future medical treatment by any medical professional or organisation attached to the study.
- I am willing to participate in the study and permit the Researcher to contact me with further details of the scheduled group interview.

_____ _____

Participant's signature Date

_____ _____

Witness signature Date

Written explanation of this study has been given to the participant and I have sought her understanding for informed consent.

_____ _____

Researcher's signature Date

Phase One Participant Demographic Information

Name: _____

Telephone contacts: (Home)_____

(Mobile)_____

E-mail: _____

Postal address:

_____

_____

Please indicate which group interview date/s you are able to attend:

□Wednesday October 17th 7pm
□Saturday October 20th 10am
□Wednesday October 24th 7pm

Age:
□ 40–45
□ 46–50
□ 51–55
□ 56–60
□ 61–65

Highest level of education completed:
□ Less than secondary education
□ Secondary education
□ Diploma (TAFE/college)
□ University degree
□ Masters Degree
□ Doctoral degree
□ Professional Degree
Other _____

Occupation:
_____

Total household income:
□ 40,000–54,999
□ 55,000–69,999
□ 70,000–84,999
□ 85,000–999,999
□ 100,000–149,999
□ >150,000

Marital status:
□ Single
□ De Facto
□ Married
□ Separated
□ Divorced
□ Widowed

Residence:
□ Rural
□ Metropolitan

Date diagnosed with breast cancer: _____

Time lapse between breast cancer diagnosis and first surgery: _____

Date of breast reconstruction procedure: _____

Surgeon performing the surgery:
□ Tony Connell
□ Ed Van Beem
□ Sean Hamilton
□ Tim Cooper

Type of breast reconstructive procedure undertaken:
□ Implant breast reconstruction
□ Latissimus Dorsi breast reconstruction (back muscle)
□ TRAM flap breast reconstruction (abdominal muscle)

Timing of breast reconstructive procedure:
□ Immediate (same time as mastectomy surgery)
□ Delayed (separate operation to mastectomy surgery)

Breast reconstruction post-operative complications encountered:
□ Infection
□ Seroma/haematoma (collection of serous fluid or blood at the site of surgery)
□ Implant capsular contractures (scar tissue forming around the implant that tightens and squeezes the implant)
□ Partial flap loss (death of tissue)
□ Total flap loss (death of tissue requiring removal of the reconstructed breast)
□ Abdominal weakness/hernia (bulge in the abdominal wall muscle)
□ Skin necrosis (skin death requiring removal)
□ Donor site necrosis (tissue death at site the tissue was taken from- abdomen or back)
□ Pulmonary embolus

Other: _____

Treatment of post-operative complications:
□ None
□ Antibiotics (to fight infection)
□ Surgical procedure requiring hospitalisation
-length of hospitalisation: _____
□ Surgical procedure not requiring hospitalisation
Other: _____

Adjuvant therapy:
□ Chemotherapy
□ Radiotherapy
□ Chemotherapy and radiotherapy
□ Hormone treatment

Date adjuvant therapy commenced: _____

Duration of adjuvant therapy: _____

Phase One Focus Group Interview Schedule

1. Could you explain how the option of Breast Reconstruction introduced to you?
    a. Who introduced you to breast reconstruction as a treatment option
    b. When was breast reconstruction introduced to you as an option?

2. What were your initial views/thoughts on Breast Reconstruction at this time?
    a. What else was happening in your life at that time that affected how you made your decision?
    b. delayed breast reconstruction-living with mastectomy….
    c. immediate breast reconstruction-recent breast cancer diagnosis…..
    d. How did this context/life circumstances impact on your decision making?
    e. Explore second reconstruction decision
    f. Explore prophylactic reconstruction decision

3. What information did you receive from others?
    a. From whom?
    b. What form was this information take?
    c. In what ways was this information helpful or not helpful?

4. What information did you access yourself?
    a. What sources did you access?
    b. Why did you feel the need to access this information?
    c. In what ways was this information helpful or not helpful?

5. Did anyone help you come to your decision?
    a. Who?
    b. How?

6. Did anyone hinder your decision making?
    a. who?
    b. how?

7. What support, if any, did you receive during your decision making period?
    a. What support do you think is necessary during this decision making period?

8. What were the deciding factors for you? -Explore each of these
    a. Immediate
    b. delayed
    c. TRAM
    d. LD

9. Looking back, what information do you think is really important to have?
    a. What format would you like this information in?

10. How do you feel about the decision you have made?
    a. Explore positive aspects
    b. Explore decision regret

Appendix 5: Project Advisory Committee

The University of Sydney

Faculty of Nursing & Midwifery

Project Advisory Committee Terms of Reference

DEVELOPMENT AND IMPLEMENTATION OF AN EVALUATION FRAMEWORK FOR A BREAST RECONSTRUCTION DECISION SUPPORT TOOL FOR WOMEN CONSIDERING BREAST RECONSTRUCTION FOLLOWING MASTECTOMY

University of Sydney doctoral candidate- Olivia Hill
Supervisor- Professor Kate White
Associate supervisors- Professor Phyllis Butow, Professor Christobel Saunders, Mr Tony Connell

TERMS OF REFERENCE

To develop a breast reconstruction information resource for women considering breast reconstruction following mastectomy;

To develop an evaluation framework within which to pilot the breast reconstruction information resource;

To develop the resource in a collaborative manner by involving all stakeholders in the process and utilising the expertise of these persons to produce a contextually appropriate, accurate, relevant and useful resource for women;

To utilise national evidence-based best practice to guide the content development of the resource within an evaluation research framework;

Adoption of a collaborative approach by the nation's leading experts in the field to reach the outcome of comprehensive information provision that meets the needs of women considering breast reconstruction post mastectomy.

Composition & procedures:

The Project Advisory Committee will consist of members of the multidisciplinary health care team including breast surgeons, plastic/reconstructive surgeons, breast care nurses, and psychologists. Other integral members will include the consumer representative body (Breast Cancer Network of Australia) and consumers who

have and have not previously undertaken breast reconstruction, along with the members of the research team.

The members will be selected by the research team based upon their clinical expertise, research experience and willingness to contribute to the study. The consumer representatives will be recruited through the BCNA. Membership to the Project Advisory Committee will secured upon acceptance of the group's Terms of Reference, evidenced by signing of the consent form.

Members of the Project Advisory Committee will not be paid for their participation in, and contribution to, the research. The research will remain the intellectual property of the lead researcher Olivia Hill. Members of the Project Advisory Committee will be acknowledged in all publications of the research. Authorship on publications arising from this study will be in accordance with National Health and Medical Research Council (NHMRC) Guidelines.

The lead researcher Olivia Hill will be the primary point of contact between members of the group in relation to this study and will manage all communication regarding the tasks of the Project Advisory Committee. Communications will be undertaken via e-mail and telephone contact.

The Project Advisory Committee will meet regularly to review the resource development progress. These meeting will be held in person at differing locations across Australia (namely Perth, Melbourne and Sydney). A meeting agenda, review materials and a suggested review template will be circulated to each member of the Project Advisory Committee two weeks prior to the scheduled meeting date. Those unable to attend in person may participate through teleconference facilities or undertake independent review of resources utilising a structured feedback template. The review process will occur over a period of 6–9 months, with the Project Advisory Committee meeting a minimum of three times during this period. In addition the Project Advisory Committee will undertake a round table meeting with particular reference to the evaluative framework development and piloting of the information resource.

Minutes of each scheduled meeting will be produced and circulated to the members of the Project Advisory Committee by the lead researcher Olivia Hill. In addition, regular updates on the progress of agreed revisions and resource development will be provided to all members via e-mail.

The University of Sydney

Faculty of Nursing & Midwifery

Project Advisory Committee Member Consent Form

DEVELOPMENT, IMPLEMENTATION AND PILOTING OF AN EVALUATION FRAMEWORK FOR A BREAST RECONSTRUCTION INFORMATION RESOURCE FOR WOMEN CONSIDERING BREAST RECONSTRUCTION POST MASTECTOMY

University of Sydney doctoral candidate- Olivia Hill
Supervisor- Professor Kate White
Associate supervisors- Professor Phyllis Butow, Professor Christobel Saunders, Mr Tony Connell

I _____ have been provided with a copy of the research plan and Project Advisory Committee Terms of Reference. I have read and understand the Terms of Reference. Any questions I have about the research study and the Project Advisory Committee have been answered by the members of the research team to my satisfaction.

I hereby endorse the proposed Terms of Reference and agree to become a member of the Project Advisory Committee of the above-mentioned study.

Signature: _____

Date: _____

Appendix 6: Phase Three

Phase Three Participant Recruitment E-mail

Dear <first name>,

Many women speak to us about the limited information that is available to women considering a breast reconstruction following mastectomy.

As a member of BCNA's *Review and Survey Group*, you may be interested in an opportunity to review a website and a booklet which aim to provide information to women about breast reconstruction. The website and booklet include information about options following mastectomy, as well as the physical and emotional aspects of recovery following reconstruction.

Am I eligible to participate?
Any woman who has had a mastectomy, to treat breast cancer or to try and prevent it from developing, is eligible to participate. You do not need to have had a breast reconstruction.

What is involved?
This research involves:

- Reviewing an online information resource and a booklet
- Completing a survey which will evaluate each resource

You will also have the choice to participate in a focus group discussion, to allow the research team to further explore the survey results. Focus group discussions will be in person (locations to be determined by the research team) or on the phone for women who live in remote areas.

If you would like to find out more about this study, please refer to the <Participant Information Sheet>, or contact **Olivia Hill** at ohil3117@uni.sydney.edu.au, or by calling **0407 770 946**. If you are interested in participating, we ask that you please complete and return the <Participant Expression of Interest form> to Olivia either by e-mail or post to the mail address on the Participant Information Sheet.

Thank you for taking the time to consider this request.

Warmest regards,

Policy Officer
Breast Cancer Network Australia

The University of Sydney

Faculty of Nursing & Midwifery

Phase Three Surgeon's Cover Letter

Dear _____,

I wish to take this opportunity to inform you of a research study being undertaken by a nursing colleague, Olivia Hill. The study being conducted is related to the decision making aspects of breast reconstruction following mastectomy. You may be interested in an opportunity to review a website and a booklet which aim to provide information to women about breast reconstruction. The website and booklet include information about options following mastectomy, as well as the physical and emotional aspects of recovery following reconstruction.

An information sheet that outlines the details of the study is enclosed. If you are interested in participating in this study please complete the expression of interest/consent form attached and return directly to the researcher in the enclosed envelope.

You are under NO OBLIGATION to agree to participate in this study. Your decision to participate or not, will in no way impact on any care you receive from myself or the Mount Hospital. None of your personal details have been provided to the researcher.

Kind Regards,

Mr _____

The University of Sydney

Faculty of Nursing & Midwifery

Phase Three Participant Information Statement

Title: Development, implementation and piloting of an evaluation framework for a breast reconstruction information resource for women considering breast reconstruction following mastectomy.

Researcher: Olivia Hill RN(Hons) PhD Candidate

Supervisor: Professor Kate White

Associate Supervisors:

Mr Tony Connell
Professor Christobel Saunders
Professor Phyllis Butow

Who is carrying out the study?

My name is Olivia Hill. I am a registered nurse, currently undertaking a research project on breast reconstruction decision making and information needs. This research will form the basis of a Doctorate of Philosophy being undertaken at the University of Sydney, under the supervision of Professor Kate White, in collaboration with Breast Cancer Network Australia (BCNA) & National Breast & Ovarian Cancer Centre (NBOCC).

What is the study about?

The purpose of this study is to develop and evaluate an information resource to provide women with comprehensive information about breast reconstruction as a treatment option following mastectomy.

What does the study involve?

If you agree to participate, your participation would involve reviewing the developed resource in its two forms (web-based & written booklet) and completing a survey about the content, format and useability of the resource. The survey may be completed electronically or sent via postal mail. Return of the survey to the researcher will be recognised as your consent to participate in the research study. A follow-up focus group interview lasting approximately 1–2 hours will be held in your state; in order to discuss, clarify and elaborate on your survey evaluations. A participant may chose to complete the evaluation, but not attend the focus group interview.

How much time will the study take?

The breast reconstruction information resource is a comprehensive resource and is in two different forms in order to meet the learning needs of different women. A two week period will be provided to give you time to review the resources at your own pace. Once you have reviewed the resources it is estimated the survey will take approximately 30–40 minutes to complete.

Will anyone else know the results?

Any personal details or identifying information will be removed from the data. The information collected will be secured in a locked filing cabinet, and stored at the University premises for a period of 7 years after completion of the research study, at which time they will be destroyed. The information gathered about you by the investigator will be held by the investigator in strict confidence. The only people having access to the data will be the researcher and the Supervisor. All the people who handle your information will adhere to traditional standards of confidentiality. If the results of the study are published in a medical journal, as is intended, the publication will not identify individual participants.

Will the study benefit me?

The perceived benefits to you in participating may include your valued contribution to the development of the information resource. The information resource will provide access to further information for women considering breast reconstruction, to inform and guide them through their breast reconstruction experience.

Can I withdraw from the study?

Being in this study is completely voluntary and you are not under any obligation to consent to participate. Submitting a completed survey and attending the focus group interview is an indication of your consent to participate in the study. In the event that reviewing the information resource causes emotional distress at any time, you have the option to withdraw from the study by notifying the researcher. You may choose to withdraw your participation from this study at any time and this will have no impact on your relationship with any organisation or health care provider connected to this study.

What if I have a complaint or concerns?

This study has been granted ethical approval by the University of Sydney. Further information may be obtained from the researcher, Ms Olivia Hill. Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Ethics Administration, University of Sydney on (02) 8627 8176 (Telephone); (02) 8627 8180 (Facsimile) or ro.humanethics@sydney.edu.au (e-mail).

What if I require further information?

Your participation would be greatly appreciated. If something is unclear or you have any queries, please do not hesitate to contact me;

Mobile: 0407 770 946

E-mail: ohil3117@uni.sydney.edu.au

Postal address: PO Box 1533, Wangara DC, WA, 6947

If you are keen to participate in this study please complete the Participant Expression of Interest Form and return to the researcher (Olivia Hill) via e-mail or mail, who will be in contact with further details.

Kind Regards,

Olivia Hill

PhD Candidate

University of Sydney

Phase Three Participant Expression of Interest/Consent Form

Breast cancer +/- breast reconstruction

Name:

Contact telephone number:

Postal address:

E-mail address:

Please indicate the option that best describes your situation:

☐ I have had a breast reconstruction

☐ I am considering having a breast reconstruction in the future

☐ I have not had a breast reconstruction

I would prefer to complete the survey:

☐ Electronically

☐ On hard copy, returning by postal mail

I have been given clear written information about the study & have been given the opportunity to ask questions about the study.

I understand ethical approval for this study has been given by the University of Sydney.

I understand my participation is voluntary & I may withdraw from the study at any time without any impact on my future relations with any organisation attached to this study.

Signature:

Date:

The University of Sydney

Faculty of Nursing & Midwifery

Phase Three Participant Expression of Interest/Consent Form

Bilateral prophylactic mastectomy and breast reconstruction

Name:

Contact telephone number:

Postal address:

E-mail address:

Please confirm if you have had a preventative (prophylactic) breast reconstruction in the absence of a breast cancer diagnosis

☐ Yes

☐ No

I would prefer to complete the survey:

☐ Electronically

☐ On hard copy, returning by postal mail

I have been given clear written information about the study & have been given the opportunity to ask questions about the study.

I understand ethical approval for this study has been given by the University of Sydney.

I understand my participation is voluntary & I may withdraw from the study at any time without any impact on my future relations with any organisation attached to this study.

Signature:

Date:

The University of Sydney

Faculty of Nursing & Midwifery

Phase Three Survey Evaluation Instructions- Online

Thank you for agreeing to participate in the study; *'Development, implementation and piloting of an evaluation framework for a breast reconstruction information resource for women considering breast reconstruction following mastectomy'*.

The aim of this research is to develop and evaluate an information resource to provide women with information about breast reconstruction as a treatment option following mastectomy.

The information resource has been produced in two formats; a web site and also a booklet. Please provide your feedback on both the web site and booklet resources by completing the survey. Your perspective of the usefulness of these resources in providing relevant, appropriate and clear information about breast reconstruction as a treatment option following mastectomy is a critical aspect of this research.

It should be noted this research study does not aim to imply women should have breast reconstruction following mastectomy.

A copy of the information booklet has been mailed to your address and should be received in the next few days. If you have not received it in the mail after this time please contact me (phone; 0407 770 946 or e-mail ohil3117@uni.sydney.edu.au).

The website can be accessed by clicking on the link below:

http://canceraustralia.nbocc.org.au/breast-cancer/breast-reconstruction/breast-reconstruction

You will be requested to enter a case sensitive login and password:

- Login: stage
- Password: strut&fret7

The website provides information to women who are considering breast reconstruction after mastectomy as a result of breast cancer and also for women who are considering preventative (prophylactic) breast reconstruction following mastectomy in the absence of a breast cancer diagnosis. The web site has been designed to allow women to navigate through information that is applicable to their situation.

Once you have reviewed the information resources you can access the survey by clicking on the link below:

https://www.surveymonkey.com/s/brreconinforesource

The link can only be accessed once, therefore you will need to complete the survey in one sitting. The survey will collect information about your demographic situation, breast cancer experience, your use of information technology and your evaluation of the information resources. It contains 45 questions in total and is anticipated to take between 30–40 minutes to complete. A two week period is provided for you to review the resources. **Completion of the survey is required by November 18th.**

You have been provided with these resources for the purpose of participation in this research study. The web site and booklet are confidential and are not for distribution. Please do not pass on the website login and password or the booklet to anyone. **Once you have completed your review please return the booklet in the stamped self-addressed envelope enclosed in your mail package.**

As you were previously advised in the information sheet sent to you seeking your participation; several focus groups will be undertaken across Australia in early December. The purpose of these focus groups is to clarify the survey evaluation of the information resources and to gain more in-depth feedback from you about the information resources. Participation in these focus groups is optional. You will receive further information about these scheduled focus groups in the coming weeks.

If you have any queries or difficulties in completing the information resource review and survey please do not hesitate to contact me.

Kind regards,

Olivia Hill
PhD Candidate
University of Sydney
Ph; 0407770946
Fax; (08)92041334
E-mail; ohil3117@uni.sydney.edu.au

The University of Sydney

Faculty of Nursing & Midwifery

Phase Three Survey Evaluation Instructions- Mail

Thank you for agreeing to participate in the study; *'Development, implementation and piloting of an evaluation framework for a breast reconstruction information resource for women considering breast reconstruction following mastectomy'*.

The aim of this research is to develop and evaluate an information resource to provide women with information about breast reconstruction as a treatment option following mastectomy.

The information resource has been produced in two formats; a web site and also a booklet. Please provide your feedback on both the web site and booklet resources by completing the survey. Your perspective of the usefulness of these resources in providing relevant, appropriate and clear information about breast reconstruction as a treatment option following mastectomy is a critical aspect of this research.

It should be noted this research study does not aim to imply women should have breast reconstruction following mastectomy.

A copy of the information booklet has been mailed to your address and should be received in the next few days. If you have not received it in the mail after this time please contact me (phone; 0407 770 946 or e-mail ohil3117@uni.sydney.edu.au).

The website can be accessed by clicking on the link below:

http://canceraustralia.nbocc.org.au/breast-cancer/breast-reconstruction/breast-reconstruction

You will be requested to enter a case sensitive login and password:

- Login: stage
- Password: strut&fret7

The website provides information to women who are considering breast reconstruction after mastectomy as a result of breast cancer and also for women who are considering preventative (prophylactic) breast reconstruction following mastectomy in the absence of a breast cancer diagnosis. The website has been designed to allow women to navigate through information that is applicable to their situation.

Once you have reviewed the information resources you can complete the survey that has been mailed to your address as requested. Please return your completed survey in the stamped self-addressed envelope provided in your mail package.

The survey will collect information about your demographic situation, breast reconstruction experience, your use of information technology and your evaluation of the information resources. It contains 49 questions in total and is anticipated to take between 30–40 minutes to complete. A two week period is provided for you to review the resources. **Completion of the survey is required by November 18th.**

You have been provided with these resources for the purpose of participation in this research study. The web site and booklet are confidential and are not for distribution. Please do not pass on the website login and password or the booklet to anyone. **Once you have completed your review please return the booklet, along with your completed survey, in the stamped self-addressed envelope enclosed in your mail package.**

As you were previously advised in the information sheet sent to you seeking your participation; several focus groups will be undertaken across Australia in early December. The purpose of these focus groups is to clarify the survey evaluation of the information resources and to gain more in-depth feedback from you about the information resources. Participation in these focus groups is optional. You will receive further information about these scheduled focus groups in the coming weeks.

If you have any queries or difficulties in completing the information resource review and survey please do not hesitate to contact me.

Kind regards,

Olivia Hill
PhD Candidate
University of Sydney
Ph; 0407770946
Fax; (08)92041334
E-mail; ohil3117@uni.sydney.edu.au

The University of Sydney

Faculty of Nursing & Midwifery

Participant Survey

Women who have not had a breast reconstruction

DEMOGRAPHIC INFORMATION

1. What is your current age?

□<35
□ 35–40
□ 40–45
□ 46–50
□51–55
□ 56–60
□ 61–65
□ 65–70
□ >70

2. What is the highest level of education you have completed?

□ Less than secondary education
□ Secondary education
□ Diploma (TAFE/college)
□ Bachelor's degree
□ Masters
□ Professional doctorate
□ Doctorate of Philosophy

3. What is your current occupation?

_____

4. What is your total (combined) household income?

□ <$40,000
□ $40,000–$54,999
□ $55,000–$69,999
□ $70,000–$84,999
□ $85,000–$99,999
□ $100,000–$149,999
□ >$150,000

5. What is your current relationship status?

□ Single
□ De Facto
□ Married
□ Separated
□ Divorced
□ Widowed

6. What is your residential postcode? _____

USE OF INFORMATION TECHNOLOGY

The breast reconstruction information resource has been developed into a web-based format and a written booklet. As part of this evaluation we are seeking information about your use of computers and the internet.

7. How long have you been using computers for?

□ I do not use computers **(Go to question 15)**
□ less than 1 year
□ 1–3 years
□ 3–5 years
□ 5–10 years
□ more than 10 years

8. Considering your computer usage over the last 12 months; How many hours per week would you spend using a computer?

□ 0 hours
□ 1–5 hours
□ 6–10 hours
□ 10–20 hours
□ 20–30 hours
□ more than 30 hours

9. Considering your computer usage over the last 12 months; Where do you usually use a computer (<u>please select all that apply</u>)?

□ at work
□ at university, college or school
□ at home
□ Other (specify):
_____

10. I enjoy using computers

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

11. Considering your computer usage over the last 12 months; How many hours per week would you spend using the internet?

□0 hours
□ 1–5 hours
□ 6–10 hours
□ 10–20 hours
□ 20–30 hours
□ more than 30 hours

12. Have you ever accessed health information on the internet?

□ Yes
□ No

13. Considering your computer usage over the last 12 months; Indicate the frequency of your use of the web for following activities:

E-mail	□never □rarely □monthly □weekly □daily
Social networking	□never □rarely □monthly □weekly □daily
Banking	□never □rarely □monthly □weekly □daily
Entertainment	□never □rarely □monthly □weekly □daily
News	□never □rarely □monthly □weekly □daily
General information	□never □rarely □monthly □weekly □daily
Health information	□never □rarely □monthly □weekly □daily
Shopping	□never □rarely □monthly □weekly □daily
Gaming	□never □rarely □monthly □weekly □daily

14. I enjoy using the internet

□ strongly agree
□ agree
□ neutral
□ disagree
□□ strongly disagree

SEEKING INFORMATION ABOUT BREAST RECONSTRUCTION

15. If you were seeking information on breast reconstruction, please rank where you would be most likely to source information on breast reconstruction (1 being most likely – 10 being least likely)

□ Books or pamphlets
□ Breast care nurse
□ Breast surgeon or general surgeon
□ Breast reconstruction surgeon
□ Breast cancer support organisations
□ Friends or family
□ General Practitioner
□ Internet
□ Medical Oncologist
□ Other women who have had breast reconstruction

16. Are you currently considering whether to have a breast reconstruction?
□ Yes
□ No

BREAST CANCER
As part of this evaluation we are seeking information about your own breast cancer experience.

17. What date (month & year) were you diagnosed with breast cancer?

_____

18. Have you undergone surgery for breast cancer?
□Yes
□ No **(Go to question 20)**

19. Please indicate what surgeries you have had for breast cancer
□ Breast conserving surgery or lumpectomy
□ Mastectomy
□ Other (please specify)
_____

20. Have you undergone adjuvant therapy (chemotherapy, radiotherapy, hormone therapy) for breast cancer?
□ Yes
□ No **(Go to question 24)**

21. Please select all adjuvant therapies you have had:
□ Chemotherapy
□ Radiotherapy
□ Hormone therapy (medications)
□ Hormone therapy (surgery- removal of ovaries)

22. What date (month & year) did your adjuvant therapy commence?

_____

23. How long have you been having adjuvant therapy for?

_____

EVALUATION OF THE BREAST RECONSTRUCTION INFORMATION RESOURCES (WEBSITE & BOOKLET)

These questions relate to your evaluation of the website and booklet information resources.

All responses are answered on a 5 point scale (strongly agree, agree, neutral, disagree & strongly disagree).

24. The website is visually appealing

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

25. The booklet is visually appealing

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

26. The website is easy to navigate to find the desired information

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

27. The booklet is easy to navigate to find the desired information

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

28. The volume of information is appropriate

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

29. The information meets my information needs

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

30. The information is appropriately sequenced (ordered)

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

31. The information is easy to understand

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

32. The information resources would be useful to women to refer back to throughout their physical and emotional recovery from breast reconstruction surgery

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

33. The information resources would be useful for discussing breast reconstruction with health care professionals

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

34. The information resources would be useful to help family and friends understand the support I might need throughout my breast reconstruction experience

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

35. Overall, the information resources would be a useful source of information for women considering breast reconstruction

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

36. Would you recommend these information resources to other women who may be considering breast reconstruction?

□ Yes
□ No

37. Overall, in which format would you prefer to have information on breast reconstruction?

□ website
□ booklet
□ either
□ both

BREAST RECONSTRUCTION PICTURES

Please answer the following questions in relation to the pictures of breast reconstruction you have viewed within the information resources

38. The pictures of breast reconstruction are confronting

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

39. The pictures of breast reconstruction provide useful information for me

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

40. The description accompanying each picture enhances my understanding of the woman's breast reconstruction outcome

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

41. The pictures would discourage me from choosing to have a breast reconstruction

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

42. The pictures of breast reconstruction provide helpful information about surgical recovery and aesthetic outcomes (appearance) of breast reconstruction

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

OTHER COMMENTS
We welcome any further comments you have about the website information resource.

43. Are there any unclear or confusing parts if the information resources (please specify)?

_____
_____
_____
_____
_____
_____

44. Is there any information you would like to have that is not in the information resources (please specify)?

_____
_____
_____
_____
_____
_____

45. Do you have any other comments about the information resources?

_____
_____
_____
_____
_____
_____

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY

The University of Sydney

Faculty of Nursing & Midwifery

Participant Survey

Women who have had a breast reconstruction

DEMOGRAPHIC INFORMATION

1. What is your current age?

□ <35
□ 35–40
□ 40–45
□ 46–50
□51–55
□ 56–60
□ 61–65
□ 65–70
□ >70

2. What is the highest level of education you have completed?

□ Less than secondary education
□ Secondary education
□ Diploma (TAFE/college)
□ Bachelor's degree
□ Masters
□ Professional doctorate
□ Doctorate of Philosophy

3. What is your current occupation?

_____

4. What is your total (combined) household income?

□ <$40,000
□ $40,000–$54,999
□ $55,000–$69,999
□ $70,000– $84,999
□ $85,000–$99,999
□ $100,000–$149,999
□ >$150,000

5. What is your current relationship status?

□ Single
□ De Facto
□ Married
□ Separated
□ Divorced
□ Widowed

6. What is your residential postcode? _____

USE OF INFORMATION TECHNOLOGY

The breast reconstruction information resource has been developed into a web-based format and a written booklet. As part of this evaluation we are seeking information about your use of computers and the internet.

7. How long have you been using computers for?

□ I do not use computers **(Go to question 15)**
□ less than 1 year
□ 1–3 years
□ 3–5 years
□ 5–10 years
□ more than 10 years

8. Considering your computer usage over the last 12 months; How many hours per week would you spend using a computer?

□ 0 hours
□ 1–5 hours
□ 6–10 hours
□ 10–20 hours
□ 20–30 hours
□ more than 30 hours

9. Considering your computer usage over the last 12 months; Where do you usually use a computer (<u>please select all that apply</u>)?

□ at work
□ at university, college or school
□ at home
□ other (specify):
_____

10. I enjoy using computers

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

11. Considering your computer usage over the last 12 months, how many hours per week would you spend using the internet?

□0 hours
□ 1–5 hours
□ 6–10 hours
□ 10–20 hours
□ 2030 hours
□ more than 30 hours

12. Have you ever accessed health information on the internet?

□ Yes
□ No

13. Considering your computer usage over the last 12 months, indicate the frequency of your use of the web for following activities:

E-mail	□never □rarely □monthly □weekly □daily
Social networking	□never □rarely □monthly □weekly □daily
Banking	□never □rarely □monthly □weekly □daily
Entertainment	□never □rarely □monthly □weekly □daily
News	□never □rarely □monthly □weekly □daily
General information	□never □rarely □monthly □weekly □daily
Health information	□never □rarely □monthly □weekly □daily
Shopping	□never □rarely □monthly □weekly □daily
Gaming	□never □rarely □monthly □weekly □daily

14. I enjoy using the internet

□strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

SEEKING INFORMATION ABOUT BREAST RECONSTRUCTION

15. From where have you received information about breast reconstruction (<u>please select all that apply</u>)?

□ Books or pamphlets
□ Breast care nurse
□ Breast surgeon or general surgeon
□ Breast reconstruction surgeon
□ Breast cancer support organisations
□ Friends or family
□ General Practitioner
□ Internet
□ Medical Oncologist
□ Other women who have had a breast reconstruction
□ Other (specify):

_____

16. From where did you receive the largest amount of information about breast reconstruction?

□ Books or pamphlets
□ Breast care nurse
□ Breast surgeon or general surgeon
□ Breast reconstruction surgeon
□ Breast cancer support organisations
□ Friends or family
□ General Practitioner
□ Internet
□ Medical Oncologist
□ Other women who have had a breast reconstruction
□ Other (specify):

_____

17. From where did you receive the most valuable information about breast reconstruction?

□ Books or pamphlets
□ Breast care nurse
□ Breast surgeon or general surgeon
□ Breast reconstruction surgeon
□ Breast cancer support organisations
□ Friends or family
□ General Practitioner
□ Internet
□ Medical Oncologist
□ Other women who have had a breast reconstruction
□ Other (specify):

_____

BREAST RECONSTRUCTION

As part of this evaluation we are seeking information about your own breast cancer and breast reconstruction experience.

18. What date (month & year) were you diagnosed with breast cancer?

_____

19. Have you undergone adjuvant therapy (chemotherapy, radiotherapy, hormone therapy) for breast cancer?

□ Yes
□ No **(Go to question 23)**

20. Please select all adjuvant therapies you have had:

□ Chemotherapy
□ Radiotherapy
□ Hormone therapy (medications)
□ Hormone therapy (surgery- removal of ovaries)

21. What date (month & year) did your adjuvant therapy commence?

_____

22. How long have you been having adjuvant therapy for?

_____

23. Have you had more than one breast reconstruction <u>at different times</u>?

□ Yes (**<u>The remaining survey questions relate to your first breast reconstruction experience</u>)**
□ No

If yes, please specify why:

_____
_____
_____

24. What was the date (month & year) of your breast reconstruction surgery?

_____

25. Did you choose to have a preventative mastectomy of the other non-cancerous breast?

□ Yes
□ No

26. What was the timing of your breast reconstruction surgery?

□ Immediate breast reconstruction (at the same time as mastectomy surgery)
□ Delayed breast reconstruction (in a separate operation to mastectomy surgery)

27. What type of breast reconstruction did you have?

□ Implant breast reconstruction
□ Latissimus Dorsi breast reconstruction (back muscle)
□ TRAM flap breast reconstruction (abdominal muscle)
□ DIEP flap breast reconstruction (abdomen area)
Other (specify): _____

28. Did you experience any post-operative complications?
□ Yes
□ No **(Go to question 31)**

29. Please select all complications experienced:
□ Infection
□ Seroma/haematoma (collection of serous fluid or blood at the site of surgery)
□ Implant capsular contractures (scar tissue forming around the implant that tightens and squeezes the implant)
□ Partial flap loss (death of some tissue)
□ Total flap loss (death of tissue requiring removal of the reconstructed breast)
□ Abdominal weakness/hernia (bulge in the abdominal wall muscle)
□ Skin necrosis (skin death requiring removal)
□ Donor site necrosis (tissue death at site the tissue was taken from- e.g. abdomen or back)
□ Other (specify):
_____

30. Please select any treatment received for your post-operative complications:
□ None
□ Antibiotics (to fight infection)
□ Surgical procedure requiring hospitalisation
□ Surgical procedure not requiring hospitalisation
□ Other (specify):
_____

EVALUATION OF THE BREAST RECONSTRUCTION INFORMATION RESOURCES (WEBSITE & BOOKLET)

These questions relate to your evaluation of the website and booklet information resources.
All responses are answered on a 5 point scale (strongly agree, agree, neutral, disagree & strongly disagree).

31. The website is visually appealing
□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

32. The booklet is visually appealing
□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

33. The website is easy to navigate to find the desired information

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

34. The booklet is easy to navigate to find the desired information

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

35. The volume of information is appropriate

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

36. The information meets my information needs

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

37. The information is appropriately sequenced (ordered)

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

38. The information is easy to understand

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

39. The information resources would be useful to women to refer back to throughout their physical and emotional recovery from breast reconstruction surgery

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

40. The information resources would be useful for discussing breast reconstruction with health care professionals

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

41. The information resources would be useful to help family and friends understand the support I might need throughout my breast reconstruction experience

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

42. Overall, the information resources would be a useful source of information for women considering breast reconstruction

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

43. Would you recommend these information resources to other women who may be considering breast reconstruction?

□ Yes
□ No

44. Overall, in which format would you prefer to have information on breast reconstruction?

□ website
□ booklet
□ either
□ both

BREAST RECONSTRUCTION PICTURES
Please answer the following questions in relation to the pictures of breast reconstruction you have viewed within the information resources

45. The pictures of breast reconstruction are confronting
□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

46. The pictures of breast reconstruction provide useful information for me
□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

47. The description accompanying each picture enhances my understanding of the woman's breast reconstruction outcome
□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

48. The pictures would discourage me from choosing to have a breast reconstruction
□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

49. The pictures of breast reconstruction provide helpful information about surgical recovery and aesthetic outcomes (appearance) of breast reconstruction
□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

OTHER COMMENTS
We welcome any further comments you have about the website information resource.

50. Are there any unclear or confusing parts if the information resources (please specify)?

_____
_____
_____
_____
_____
_____

51. Is there any information you would like to have that is not in the information resources (please specify)?

_____
_____
_____
_____
_____
_____

52. Do you have any other comments about the information resources?

_____
_____
_____
_____
_____
_____

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY

The University of Sydney

Faculty of Nursing & Midwifery

Participant Survey

Women who have had a preventative (prophylactic) breast reconstruction

DEMOGRAPHIC INFORMATION

1. What is your current age?

□ <35
□ 35–40
□ 40–45
□ 46–50
□ 51–55
□ 56–60
□ 61–65
□ 65–70
□ >70

2. What is the highest level of education you have completed?

□ Less than secondary education
□ Secondary education
□ Diploma (TAFE/college)
□ Bachelors degree
□ Masters
□ Professional doctorate
□ Doctorate of Philosophy

3. What is your current occupation?

_____

4. What is your total (combined) household income?

□ <$40,000
□ $40,000–$54,999
□ $55,000–$69,999
□ $70,000–$84,999
□ $85,000–$99,999
□ $100,000–$149,999
□ >$150,000

5. What is your current relationship status?

□ Single
□ De Facto
□ Married
□ Separated
□ Divorced
□ Widowed

6. What is your residential postcode? _____

USE OF INFORMATION TECHNOLOGY

The breast reconstruction information resource has been developed into a web-based format and a written booklet. As part of this evaluation we are seeking information about your use of computers and the internet.

7. How long have you been using computers for?

□ I do not use computers **(Go to question 15)**
□ less than 1 year
□ 1–3 years
□ 3–5 years
□ 5–10 years
□ more than 10 years

8. Considering your computer usage over the last 12 months; How many hours per week would you spend using a computer?

□ 0 hours
□ 1–5 hours
□ 6–10 hours
□ 10–20 hours
□ 20–30 hours
□ more than 30 hours

9. Considering your computer usage over the last 12 months; Where do you usually use a computer (<u>please select all that apply</u>)?

□ at work
□ at university, college or school
□ at home
□ Other (specify):
_____

10. I enjoy using computers

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

11. Considering your computer usage over the last 12 months; How many hours per week would you spend using the internet?

□ 0 hours
□ 1–5 hours
□ 6–10 hours
□ 10–20 hours
□ 20–30 hours
□ more than 30 hours

12. Have you ever accessed health information on the internet?

□ Yes
□ No

13. Considering your computer usage over the last 12 months; Indicate the frequency of your use of the web for following activities:

E-mail	□never □rarely □monthly □weekly □daily
Social networking	□never □rarely □monthly □weekly □daily
Banking	□never □rarely □monthly □weekly □daily
Entertainment	□never □rarely □monthly □weekly □daily
News	□never □rarely □monthly □weekly □daily
General information	□never □rarely □monthly □weekly □daily
Health information	□never □rarely □monthly □weekly □daily
Shopping	□never □rarely □monthly □weekly □daily
Gaming	□never □rarely □monthly □weekly □daily

14. I enjoy using the internet

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

SEEKING INFORMATION ABOUT BREAST RECONSTRUCTION

15. From where have you received information about breast reconstruction (<u>please select all that apply</u>)?

□ Books or pamphlets
□ Breast care nurse
□ Breast surgeon or general surgeon
□ Breast reconstruction surgeon
□ Breast cancer support organisations
□ Friends or family
□ General Practitioner
□ Internet
□ Medical Oncologist
□ Other women who have had a breast reconstruction
□ Other (specify):

_____

16. From where did you receive the largest amount of information about breast reconstruction?

□ Books or pamphlets
□ Breast care nurse
□ Breast surgeon or general surgeon
□ Breast reconstruction surgeon
□ Breast cancer support organisations
□ Friends or family
□ General Practitioner
□ Internet
□ Medical Oncologist
□ Other women who have had a breast reconstruction
□ Other (specify):

_____

17. From where did you receive the most valuable information about breast reconstruction?

□ Books or pamphlets
□ Breast care nurse
□ Breast surgeon or general surgeon
□ Breast reconstruction surgeon
□ Breast cancer support organisations
□ Friends or family
□ General Practitioner
□ Internet
□ Medical Oncologist
□ Other women who have had a breast reconstruction
□ Other (specify):

_____

BREAST RECONSTRUCTION

As part of this evaluation we are seeking information about your own breast reconstruction experience.

18. What date (month & year) you were advised you had a high risk of developing breast cancer?

_____

19. How many of your first degree relatives (mother & sisters) had been diagnosed with breast cancer when you decided to have a preventative (prophylactic) mastectomy?

_____

20. How many of your second degree relatives on your mother's side (aunts & grandmothers) had been diagnosed with breast cancer when you decided to have a preventative (prophylactic) mastectomy?

_____

21. Have you had more than one breast reconstruction <u>at different times</u>?
□ Yes (**<u>The remaining survey questions relate to your first breast reconstruction experience</u>)**
□ No
If yes, please specify why:
_____
_____

22. What was the date (month & year) of breast reconstruction surgery?

_____

23. Timing of breast reconstructive procedure:
□ Immediate (same time as mastectomy surgery)
□ Delayed (separate operation to mastectomy surgery)

24. What type of breast reconstruction procedure did you have?
□ Implant breast reconstruction
□ Latissimus Dorsi breast reconstruction (back muscle)
□ TRAM flap breast reconstruction (abdominal muscle)
□ DIEP flap breast reconstruction (abdomen area)

Other (specify): _____

25. Did you experience any post-operative complications?
□ Yes
□ No **(Go to question 28)**

26. Please select all complications experienced:
□ Infection
□ Seroma/haematoma (collection of serous fluid or blood at the site of surgery)
□ Implant capsular contractures (scar tissue forming around the implant that tightens and squeezes the implant)
□ Partial flap loss (death of tissue)
□ Total flap loss (death of tissue requiring removal of the reconstructed breast)
□ Abdominal weakness/hernia (bulge in the abdominal wall muscle)
□ Skin necrosis (skin death requiring removal)
□ Donor site necrosis (tissue death at site the tissue was taken from- abdomen or back)
□ Other (specify):
_____

27. Please select any treatment received for your post-operative complications:

□ None
□ Antibiotics (to fight infection)
□ Surgical procedure requiring hospitalisation
Please specify length of hospitalisation:
_____
□ Surgical procedure not requiring hospitalisation
□ Other (specify):
_____

EVALUATION OF THE BREAST RECONSTRUCTION INFORMATION RESOURCES (WEBSITE & BOOKLET)

These questions relate to your evaluation of the website and booklet information resources.
All responses are answered on a 5 point scale (strongly agree, agree, neutral, disagree & strongly disagree).

28. The website is visually appealing

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

29. The booklet is visually appealing

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

30. The website is easy to navigate to find the desired information

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

31. The booklet is easy to navigate to find the desired information

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

32. The volume of information is appropriate

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

33. The information meets my information needs

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

34. The information is appropriately sequenced (ordered)

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

35. The information is easy to understand

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

36. The information resources would be useful to women to refer back to throughout their physical and emotional recovery from breast reconstruction surgery

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

37. The information resources would be useful for discussing breast reconstruction with health care professionals

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

38. The information resources would be useful to help family and friends understand the support I might need throughout my breast reconstruction experience

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

39. Overall, the information resources would be a useful source of information for women considering breast reconstruction

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

40. Would you recommend these information resources to other women who may be considering breast reconstruction?

□ Yes
□ No

41. Overall, in which format would you prefer to have information on breast reconstruction?

□ website
□ booklet
□ either
□ both

BREAST RECONSTRUCTION PICTURES

Please answer the following questions in relation to the pictures of breast reconstruction you have viewed within the information resources

42. The pictures of breast reconstruction are confronting

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

43. The pictures of breast reconstruction provide useful information for me

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

44. The description accompanying each picture enhances my understanding of the woman's breast reconstruction outcome

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

45. The pictures would discourage me from choosing to have a breast reconstruction

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

46. The pictures of breast reconstruction provide helpful information about surgical recovery and aesthetic outcomes (appearance) of breast reconstruction

□ strongly agree
□ agree
□ neutral
□ disagree
□ strongly disagree

OTHER COMMENTS

We welcome any further comments you have about the website information resource.

47. Are there any unclear or confusing parts if the information resources (please specify)?

_____
_____
_____
_____
_____
_____

48. Is there any information you would like to have that is not in the information resources (please specify)?

_____
_____
_____
_____
_____
_____

49. Do you have any other comments about the information resources?

_____
_____
_____
_____
_____
_____

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY

Phase Three Focus Group Interview Recruitment E-mail

Dear _____,

Many thanks to those of you who participated in the study by completing the survey evaluating the website & booklet. As previously mentioned, an additional component of this study is to run some focus group discussions with those who completed the review & survey, to discuss in-depth some aspects of your evaluation.

You are not obliged to attend a focus group- it is entirely up to you. If you do choose to attend, your verbal feedback & clarification will be very valuable to this study.

There are two focus groups being held in New South Wales:

- Thursday 8th December at 6pm
- Friday 9th December at 1pm

The venue is Sydney Nursing School, 88 Mallett Street, Camperdown, Sydney.

If you are interested in attending please reply to this e-mail and advise me of your preferred timeslot.

I will provide attendees with more detailed information closer to the date.

Many thanks

Olivia Hill
PhD Candidate
University of Sydney
Ph; 0407770946
Fax; (08)92041334

Phase Three Focus Group Interview Schedule

1. Welcome, introductions & thank you for participating in this study

2. Project background
    a. Doctoral project
    b. Resource development
    c. Project advisory committee
    d. Multiple resources developed
    e. Evaluation process
    f. Expected outcome of research

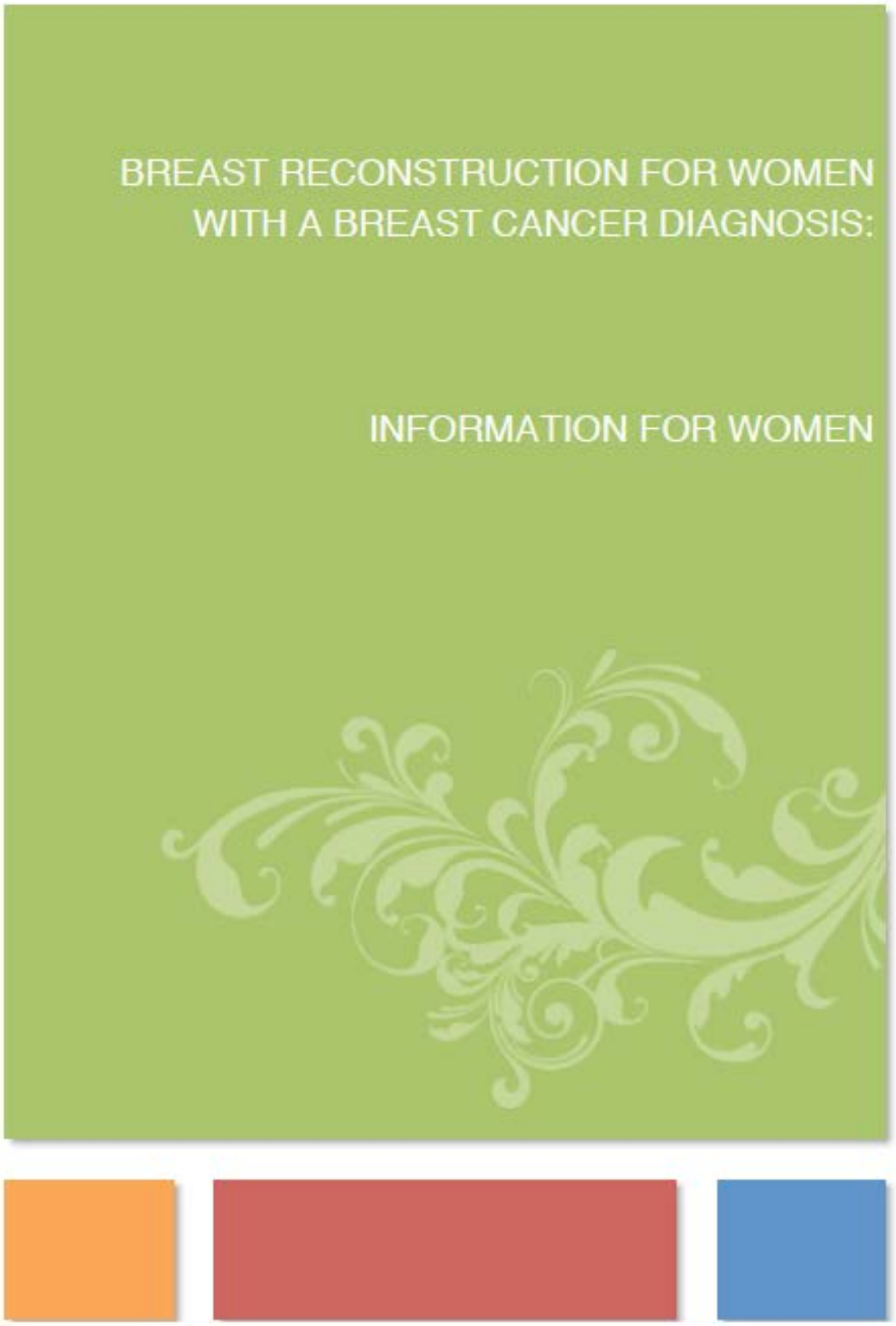
3. Participant summary (reconstruction group only)

4. General summary of the survey evaluation (includes prophylactic group)

5. Specific areas of focus for discussion
    a. Website navigation
    b. Booklet formatting
    c. Additional information for inclusion in the resources
    d. Pictures of breast reconstructions

6. Questions/comments & close

Appendix 7: Decision support tool content outline (booklet)



6. IMAGE GALLERY

BREAST RECONSTRUCTION USING IMPLANTS
LATISSIMUS DORSI (LD) FLAP BREAST RECONSTRUCTION
TRANSVERSE RECTUS ABDOMINUS MYOCUTANEOUS (TRAM) FLAP BREAST RECONSTRUCTION
DEEP INFERIOR EPIGASTRIC PERFORATOR (DIEP) FLAP
NIPPLE AND AREOLA RECONSTRUCTION

GLOSSARY

NOTES

BREAST RECONSTRUCTION FOR WOMEN CONSIDERING PREVENTATIVE (PROPHYLACTIC) MASTECTOMY:

INFORMATION FOR WOMEN