Development of an ovarian cancer symptom awareness tool with tailored content for women at increased genetic risk of developing ovarian cancer

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Summary

In the absence of a routine ovarian screening programme, ovarian cancer symptom awareness is a potential route to earlier symptomatic presentation and disease diagnosis. However, materials to support this strategy may need to be tailored according to risk. The work presented in this thesis identified the contributors to anticipated symptomatic presentation for women at increased genetic risk of ovarian cancer.

A mixed-method approach was used to identify determinants of anticipated symptomatic presentation, and included a systematic search of existing ovarian cancer symptom awareness tools, cross-sectional surveys with two risk populations and qualitative interviews with women at increased genetic risk. Additionally, a systematic search and a virtual reference group were used to identify symptom content. Cognitive interviews were undertaken to pilot the draft tool for acceptability and usability with a sample of potential users and providers.

Endorsing more benefits than barriers to presentation was associated with earlier anticipated presentation in both risk populations; however, differential effects of underlying health beliefs on anticipated presentation were also identified. In those at increased genetic risk, emotional (worry) rather than cognitive aspects of risk perception predominate in influencing earlier anticipated presentation. Interviews with women at increased genetic risk revealed that personal experience with ovarian cancer shaped beliefs about the disease. The identified health beliefs were incorporated into OvSTAT (ovarian cancer symptom awareness tool), with core content applicable for women from the general population and tailored content to address the specific needs of women at increased genetic risk. OvSTAT was well received in user testing.

Overall, the findings suggest that the emotional representation of risk distinguishes earlier anticipated presentation in women at increased genetic risk from that in the general population. OvSTAT could be a mechanism through which appropriate symptomatic presentation is improved, by helping women to manage worry associated with their increased genetic risk status.

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List of abbreviations in this thesis

BMI - Body mass index

EPPM - Extended Parallel Processing Model

GP - General Practitioner

HBM - Health Belief Model

IBS - Irritable bowel syndrome

IPA - Interpretative phenomenological analysis

MRC - Medical Research Council

NAEDI - National awareness and early diagnosis initiative

PMT - Protection Motivation Theory

PPV - Positive predictive value

PysFOCS - Psychological evaluation of familial ovarian cancer screening

RCT - Randomised controlled trial

RRSO - Risk-reducing bilateral salpingo-oophorectomy

SEM - Structural equation modelling

SCT - Social Cognitive Theory

TPB - Theory of Planned Behaviour

UKFOCSS – United Kingdom Familial Ovarian Cancer Screening Study

UKTOCS - United Kingdom Collaborative Trial of Ovarian Cancer Screening

1 Introduction and thesis overview

1.1 Chapter overview

This chapter will provide an overview of the clinical background for women at increased genetic risk of ovarian cancer and present some of the issues these women face in relation to ovarian cancer risk management. The psychological background to being at increased genetic risk will be explored, and symptom awareness will be introduced as a potential strategy to bring about earlier ovarian cancer symptomatic presentation. This will lead to the aims, objectives and rationale of the PhD.

1.2 Ovarian cancer clinical background

1.2.1 Ovarian cancer statistics

The fifth most common cancer and fourth most common cause of cancer death in women in the UK is ovarian cancer (Cancer Research UK 2011). Ovarian cancer is the second most common gynaecological cancer after uterus cancer, yet it accounts for the most deaths from gynaecological cancer. The approximate lifetime risk of a woman living in the UK developing ovarian cancer is 1 in 50 (Cancer Research UK 2011). Ovarian cancer is mainly seen in post-menopausal women, with 80% of cases presenting in women over the age of 50. Incidence rates vary worldwide, but it is estimated that 225,000 cases are diagnosed each year, and account for 4% of all cancers diagnosed in women (Cancer Research UK 2011). Developments in platinum based chemotherapy have led to increased survival rates, however such treatments are only possible in early stage disease. This is problematic as most (around 60%) of the 6,500 women who are diagnosed yearly in the UK are diagnosed at late stages (Cancer Research UK 2011).

1.2.2 Ovarian cancer risk factors

There are certain factors that increase a woman's susceptibility to developing ovarian cancer. Gene mutations that increase the risk of ovarian cancer mean that there is a

family history link. Gene mutations in BRCA1 and BRCA2 increase the risk of developing ovarian cancer, with 5-15% of ovarian cancer cases associated with an identified family history or inherited gene (Gayther and Pharoah 2010, Risch et al. 2001, Watson et al. 2008). The BRCA1/2 genes are also associated with hereditary breast cancer, and therefore women at increased genetic risk for ovarian cancer may also be at increased risk of breast cancer (Antoniou et al. 2003, Chen and Parmigiani 2007). BRCA1 is associated with a higher lifetime risk of ovarian cancer, at around 40-60%, whereas the lifetime risk is 10-30% for BRCA2 carriers (Andersen et al. 2003b, Howard et al. 2009, Tiller et al. 2005, Watson et al. 2008).

Lifetime risk of ovarian cancer is influenced by many factors, including age of relative at diagnosis, relationship to diagnosed family member and number of diagnosed relatives. A meta-analysis conducted by Stratton et al. (1998) reported an approximate lifetime risk of 4% for women with one first degree relative with an ovarian cancer diagnosis. The lifetime risk for women with mothers diagnosed with ovarian cancer was estimated at 7.5%, around 5% in those with a sister diagnosed and up to 14% when multiple relatives had been diagnosed (Stratton et al. 1998). Up to 2 in 5 women who are at increased genetic risk will develop ovarian cancer in their lifetime (Antoniou et al. 2003, Chen and Parmigiani 2007). These risk estimates are particularly high when compared to the general population lifetime risk of 2% (Cancer Research UK 2011). Lifetime risk of ovarian cancer is also increased (at 7%) in families with hereditary nonpolyposis colorectal cancer, also referred to as Lynch Syndrome (Watson et al. 2008). Being of Ashkenazi Jewish decent also increases lifetime risk due to high frequencies of the BRCA1/2 genes in this population, with these gene mutations found to be present in between 8%-36% of Ashkenazi Jewish women (Gayther and Pharoah 2010).

In addition to a positive family history and gene mutations that increase susceptibility to ovarian cancer, other risk factors include older age, high body mass index, nulliparity, infertility, not breastfeeding and not having taken contraceptives (Andersen et al. 2002). Taking oral contraceptives is reported to potentially reduce

ovarian cancer risk by 20% with every five years of use (Lockwood-Rayermann et al. 2009b, Tiller et al. 2005). Most of these non-genetic risk factors relate to childbearing or the disruption of the menstrual cycle, with ovarian cancer risk being reduced by factors that interrupt ovulation (Cancer Research UK 2011).

1.2.3 Ovarian cancer staging

Stage of disease at diagnosis is one of the largest determinants of survival rates for ovarian cancer. Staging is conducted during laparotomy and follows the International Federation of Gynecology and Obstetrics (FIGO) guidelines. There is an inverse relationship between stage and survival (Prat 2014). Five year survival rates for early stage ovarian cancer (FIGO stages 1 and 2) have been reported to be as high as 90%, whereas for late stage disease (FIGO stages 3-5) this falls dramatically to around 10% (Cancer Research UK 2011, Hensley et al. 2003, Menon et al. 2009). These statistics are concerning when the numbers of women diagnosed at each stage are considered. Around 30% of women are diagnosed with early stage disease, whereas around 60% are diagnosed with late stage (Cancer Research UK 2011, Gilbert et al. 2012). This suggests that much is to be gained by detecting ovarian cancer earlier.

1.3 Ovarian cancer risk management options for women at increased risk

Women at increased genetic risk of ovarian cancer may use risk management strategies including risk reducing surgery, screening and symptom awareness to help reduce their susceptibility to the disease, or increase the chances that it will be detected at an early stage.

1.3.1 Ovarian cancer screening

Screening allows people to undergo tests or medical examinations which aim to detect disease presence. The clinical effectiveness of ovarian cancer screening is currently being investigated in a large scale UK population screening trial (Jacobs et al. 1999, Menon et al. 2009, Quaye et al. 2008), and the partner, UK Familial Ovarian Cancer Screening Study (Rosenthal and Jacobs 2006). Until policy recommendations are made based on the findings of these studies, ovarian screening should not be offered outside

of clinical trials (Brain et al. 2012, Rosenthal and Jacobs 2006). Screening involves a combination of blood tests to detect the tumour biomarker CA 125, and transvaginal ultrasounds. The results of the UK ovarian cancer screening studies are due out in 2015 and until then, women at increased genetic risk who had previously been involved in the familial screening study may have to pay for private tests and scans if they wish to pursue screening, or consider other risk management options.

1.3.2 Risk-reducing salpingo-oophorectomy

Risk-reducing salpingo-oophorectomy (RRSO) is currently the most reliable method for reducing ovarian cancer risk (Hensley et al. 2003). For women who have mutations in BRCA1 or BRCA2, this surgery reduces the risk of developing ovarian cancer by up to 80% (Rebbeck et al. 2009). The procedure involves the pre-emptive removal of healthy ovaries and fallopian tubes; however, this may not be a favourable option to all women due to the loss of fertility, the earlier onset of menopause and associated quality of life issues (Howard et al. 2009, Miller et al. 5094). Consequently, women who decide not to have RRSO may have to rely on symptom awareness and presenting to primary care until a policy decision has been made regarding the routine implementation of ovarian cancer screening.

1.3.3 Symptom awareness and presentation

There is evidence that cancer survival can be improved by encouraging individuals to present earlier for medical advice regarding potential symptoms (Evans et al. 2014, Neal 2009). However, in order for symptom awareness to be utilised, an understanding of symptom awareness and presentation behaviour in women at increased genetic risk is needed. Symptom awareness is defined as knowledge about symptoms for a particular disease, and can be assessed through recognition (‘is X a symptom of Y?’), or recall (‘can you name any symptoms of Y?) (Simon et al. 2012a). Presentation behaviour is often harder to study, due to the associated resources, cost and time associated with collecting prospective data on behaviour, or with issues surrounding accurate recall of symptoms in retrospective research (Robb et al. 2009). Due to these

difficulties, anticipated presentation is commonly studied, which refers to how long people think it will take them to seek medical advice if they experience symptoms. Anticipated presentation is often measured by asking individuals 'if you had a symptom you thought might be a sign of X, how long would it take you to go to the doctors from the time you first noticed the symptom?' (Simon et al. 2012b). In ovarian cancer, there is currently no agreed presentation interval that is considered appropriate. However, it is known that earlier stage diagnosis is associated with better treatment outcomes and ultimately survival (Cancer Research UK 2011, Prat 2014)**.** Therefore, earlier symptomatic presentation is deemed advantageous (Richards 2009b).

Tools to promote cancer symptom awareness and encourage earlier anticipated presentation include educational materials which can take the form of leaflets, factsheets, pamphlets, videos and posters (Chung et al. 2007). For a symptom awareness approach to be used, an understanding of the symptoms is also needed. Ovarian cancer was once referred to as the silent killer, with this phrase frequently used to describe what was believed to be an asymptomatic disease (Gajjar et al. 2012, Goff et al. 2007, Twombly 2007). However, this has been discounted over recent years, with numerous studies highlighting that ovarian cancer does indeed have symptoms which are present in various stages of the disease, and are not just limited to advanced disease (Bankhead et al. 2005, Goff et al. 2007, Hamilton et al. 2009, Lockwood-Rayermann et al. 2009b, Rufford et al. 2007). This transition from a silent killer to a symptomatic disease has been reflected in policy and medical guidelines. These guidelines provide information to health professionals about what they should know about ovarian cancer, what symptoms to look for and what to do if ovarian cancer is suspected (Department of Health 2009, National Institute for Health and Clinical Excellence 2011).

1.3.4 Ovarian cancer symptoms

The key symptoms of ovarian cancer are persistent abdominal distension (often referred to by women as 'bloating'), feeling full (early satiety) and/or loss of appetite, pelvic or abdominal pain, and increased urinary urgency and/or frequency (Department of Health 2009, National Institute for Health and Clinical Excellence 2011). Although symptoms are now advocated for ovarian cancer, debate still surrounds them due to their low positive predictive value (PPV). The symptoms have a PPV of less than 1%, except for persistent abdominal distension, which has a PPV of 2.5 (Goff et al. 2007). The low PPVs associated with ovarian cancer symptoms could reflect the common every day nature of the symptoms, which may involve bodily sensations that women frequently experience as part of everyday life, and are therefore hard to attribute or identify as possible symptoms (Austoker 2009, Hamilton et al. 2009, Kirwan et al. 2002). Women tend to misattribute ovarian cancer symptoms to other causes such as ageing, the menopause and stress (Goff et al. 2000, Lockwood-Rayermann et al. 2009b, Yawn et al. 2004). In order to help women and healthcare professionals discriminate between what may be general feelings and sensations and those which may be a possible symptom of ovarian cancer, the frequency, severity and persistency of symptoms are being emphasised (Austoker 2009, Department of Health 2009). However, the messages regarding frequency and duration of symptoms are mixed, with clear clinical consensus on symptom frequency and duration that is indicative of ovarian cancer currently lacking. For example the National Institute for Health and Clinical Excellence (2011) guidelines state that if symptoms are "experienced more than 12 times per month" medical advice should be sought, while the Department of Health (2009) states that advice should be sought "if symptoms occur on most days".

A recurring theme in the literature is the lack of awareness that women have of the non-gynaecological symptoms of ovarian cancer (Bankhead et al. 2008, Goff et al. 2000, Lockwood-Rayermann et al. 2009b). Women often report that they would expect symptoms of ovarian cancer to be gynaecological in nature (Cooper et al. 2011), possibly reflecting expectations of a disease of the ovaries to have symptoms in that

part of the body (Lockwood-Rayermann et al. 2009b). A challenge to ovarian cancer symptom awareness could therefore be to educate women about the non-gynaecological nature of symptoms and to disentangle these symptoms from those associated with other conditions, such as irritable bowel syndrome (IBS) or the menopause (Goff et al. 2000, Lockwood-Rayermann et al. 2009b, Yawn et al. 2004).

1.4 Early diagnosis in ovarian cancer: the NAEDI pathway

The importance and potential benefits of earlier cancer diagnosis has been highlighted by the National Awareness and Early Diagnosis Initiative (NAEDI) which outlines how better cancer survival rates in the UK could be achieved through early diagnosis (Richards 2009a). The NAEDI model in Figure 1.1 conceptualises the diagnostic pathway and allows for different areas of the pathway to be identified and then targeted in order to ultimately bring about earlier cancer diagnosis and better prognostic outcomes.

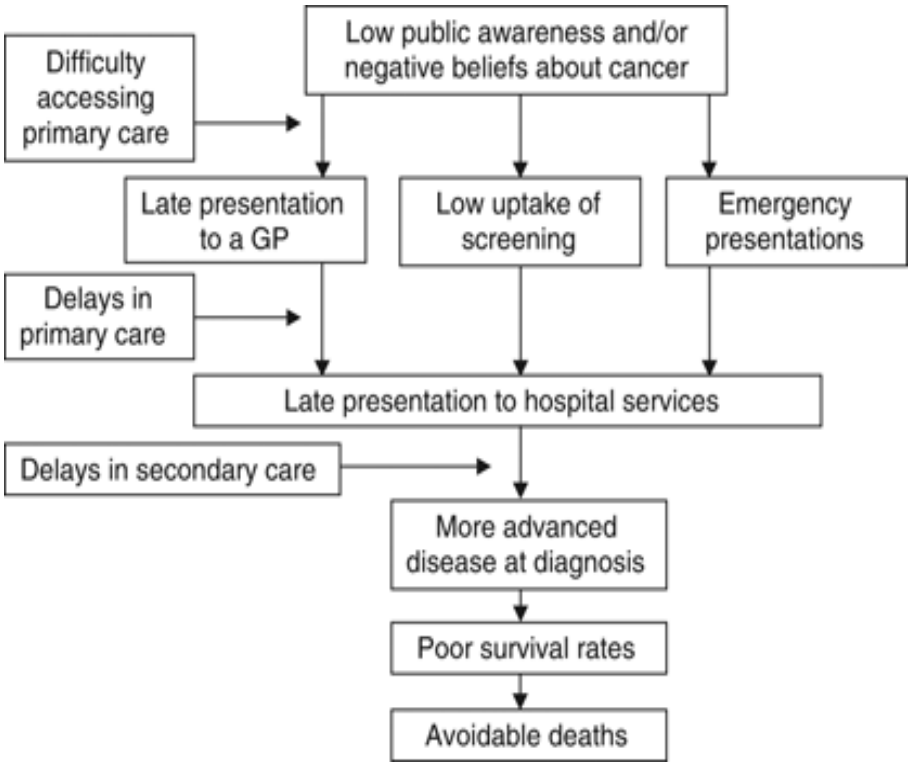


Figure 1.1. The National Awareness and Early Diagnosis initiative (NAEDI) pathway (Richards 2009)

It can be seen that the model includes screening, but does not solely focus on it, reflecting that the majority of cancers in the UK are diagnosed as a result of symptoms experienced by the individual rather than through screening (Richards 2009b). Many people present to primary care with cancer symptoms, making it the first point of contact along the diagnostic pathway (Allgar and Neal 2005a, Allgar and Neal 2005b, Evans et al. 2014, Macleod et al. 2009). A recent study of cancer symptomatic presentation in a UK population sample reported that for around 75% (n=177) of study participants, the first step towards cancer diagnosis was discussing symptom concerns with their GP (Simon et al. 2010). Awareness and presentation are key areas at the start of the NAEDI pathway, with the gate-keeping role of primary care shown in the pathway (see Figure 1.1). In ovarian cancer, there has been a move towards symptom awareness due to uncertainty regarding the clinical effectiveness of ovarian cancer screening (Menon et al. 2009) and low levels of ovarian cancer symptom awareness in the UK public (Cooper et al. 2012, Richards 2009a).

Even if people do become aware that they are experiencing cancer symptoms, this does not necessarily mean that they will seek help for these symptoms. Barriers to presentation to healthcare services are often reported as an explanation for delaying presentation or not presenting at all. Perceived barriers cover and include service and personal barriers. Service barriers include expectations of the GP's response, whether the GP will take concerns seriously and appointment processes (Eadie and MacAskill 2008, Robb et al. 2009). Personal barriers include fear of what the doctor might find, symptom type, embarrassment and fear of diagnosis (Ramirez et al. 1999, Robb et al. 2009). The relationship between perceived barriers and presentation is complicated and is mediated by other factors such as the nature of symptoms, GP reputation and the doctor–patient relationship (Eadie and MacAskill 2008). Vague symptoms have been associated with longer presentation times due to difficulty attributing symptoms to possible cancer (Goff et al. 2000). GP reputation and fear of the consultation have a more complex relationship with presentation. A positive doctor-patient relationship can facilitate presentation; however, if patients perceive that their GP will not take their concern seriously, this can lead to longer presentation (Smith et al. 2005b).

Unsurprisingly, endorsing more barriers has been shown to increase time to presentation to health services (Robb et al. 2009).

1.5 Psychological background to ovarian cancer risk management strategies

Women at increased genetic risk of ovarian cancer may use risk management strategies to manage their increased risk status (Howard et al. 2009). The main options of ovarian screening, RRSO and symptom awareness and presentation have been presented. Drawing on studies that examine the determinants of uptake of these risk management strategies can inform about the psychological background to being at genetic risk for ovarian cancer. When considering the psychological determinants of these risk management strategies, it is important to distinguish between screening and symptom awareness and presentation behaviours. Symptomatic presentation involves self-determined awareness and cues to action, whereas screening depends partly on external drivers, such as participation invites and reminders. Whilst screening uptake is a different behaviour to symptom awareness and presentation, findings from studies on predictors of screening uptake can be extrapolated to aid understanding of determinants of symptomatic presentation due to similar study populations.

1.5.1 Psychological determinants of screening uptake

Studies with women participating in familial ovarian cancer screening provide insight into how women at increased genetic risk may attempt to manage their risk status, and their use of screening as a strategy for maintaining psychological wellbeing. Higher levels of ovarian cancer worry have been reported to be associated with higher perceived risk in women with a family history (Lerman et al. 1994). Ovarian cancer worry and the number of affected relatives was found to be positively associated with ovarian cancer screening uptake in a sample of women at increased genetic risk for ovarian cancer (Schwartz, Lerman et al 1995). Similarly, Andersen et al. (2002) reported that women who were at increased genetic risk for ovarian cancer who engaged with ovarian cancer screening more frequently had higher levels of worry. The frequent engagement with screening by women with high levels of worry was

interpreted by Schwartz et al. (1995a) as an attempt by these women to reduce their levels of distress. However, the cross-sectional nature of this research needs to be considered when interpreting the results, as it is difficult to establish causality in such research. The role of worry and perceived risk in screening participation was also explored in a study of cancer related anxiety levels in women who were attending ovarian cancer screening (Hensley et al. 2003). Pre-menopausal women were reported to have higher levels of anxiety than post-menopausal women. Hensley et al. (2003) also observed that participants had high levels of perceived risk, with women who were pre-menopausal more like to overestimate their personal risk of ovarian cancer.

Women at increased genetic risk of ovarian cancer are also at increased risk of breast cancer (Andersen et al. 2003a), therefore studies of breast cancer screening in women at increased genetic risk may also be useful for understanding the psychological determinants of ovarian cancer risk management strategies. A longitudinal study by Diefenbach et al. (1999) reported that cancer worry was a predictor of mammography use in women at increased genetic risk for breast and ovarian cancer. In particular, moderate levels of worry were associated with greater participation in screening (Diefenbach et al. 1999). Andersen et al. (2003b) reported an inverted u-shaped relationship between worry and mammography use in women with a family history of breast or ovarian cancer, whereby those with lower or higher levels of worry were less likely to use mammography. This finding suggests that the relationship between worry and breast cancer screening uptake is not linear, and that high levels of worry can act as a barrier to screening uptake. However, again, the cross-sectional nature of the research needs to be acknowledged. A meta-analysis conducted by Hay et al. (2006) identified twelve prospective studies with a sample of women at increased risk for breast cancer, and reported that higher breast cancer worry was associated with more engagement with breast cancer screening, regardless of how worry was measured. The prospective nature of studies included in the meta-analysis enhances understanding of the role that worry plays in breast cancer screening uptake, and adds to the findings from studies on ovarian cancer screening suggesting that higher levels of cancer

related worry in women at increased genetic risk prompt greater engagement in cancer screening.

The impact of participating in cancer screening for women at increased genetic risk is also important to consider, because in the absence of screening, the needs that were met by screening must be met in other ways. Participating in screening has been described by women as a proactive approach to ovarian cancer detection (Lifford et al. 2013b) and therefore women may feel a sense of loss and helplessness in the current absence of routine screening. A prospective study that evaluated the psychological impact of familial ovarian cancer screening highlighted the importance of screening for women at increased genetic risk (Brain et al. 2012). Screening helped women to maintain psychological wellbeing, with considerable reassurance gained from being part of a screening programme which acted as a safety net (Brain et al. 2012). Feelings of reassurance and reduced distress as a result of participating in ovarian screening were similarly reported by Lancastle et al. (2011). Women at increased genetic risk of ovarian cancer may therefore need to seek out other sources of support in order to replace the proactive approach to cancer detection and reassurance that they previously gained through participation in screening.

1.5.2 Psychological determinants of risk reducing salpingo-oophorectomy

Although a proven method for reducing ovarian cancer risk, not all women elect for RRSO (Hensley et al. 2003). Studies that have examined the beliefs about risk management strategies in women who have chosen to have the procedure help to explain the possible determinants of this risk management option. Uptake of RRSO has been shown to be motivated by desire to reduce anxiety and worry, and to minimise the uncertainty surrounding potential cancer diagnosis at a later stage in life (Hallowell 1998, Hurley et al. 2001, Meiser et al. 1999).

A systematic review of 43 articles by Howard et al. (2009) identified three types of factors that influence risk management decisions in women at increased genetic risk of

developing ovarian cancer. The first set of factors related to medical and physical factors, such as BRCA1/2 status, age, parity and menopausal status. The consideration of age related factors demonstrates that risk management decisions are not made at one time point, but are re-evaluated as women progress through different stages of their life. The second set involved psychological factors, including perceived risk, worry, anxiety and distress. Again, this demonstrates how women may choose RRSO in order to reduce the worry and anxiety associated with their increased risk status. The final set concerned social factors, such as personal experiences of cancer in the family and family obligations (Goff et al. 2004), highlighting the importance of wider social contexts in risk management decisions. Some women who initially chose ovarian cancer screening as a risk management option later opt for RRSO. Reasons for discontinuing screening to undergo RRSO were explored by Lifford et al. (2013a). Interviews with a sample of women at increased genetic risk of ovarian cancer who were involved with UKFOCSS but who had elected for RRSO revealed varying factors that were catalysts to the decision to have RRSO. The main factors included abnormal screening results and age related factors (Lifford et al. 2013a). Again, this demonstrates how different risk management strategies are considered by women throughout their life. This highlights the importance of offering different risk management strategies, so that women can choose the best option for their personal circumstances.

1.5.3 Psychological determinants of symptom awareness and presentation

Studies in the general population have revealed low public awareness of cancer symptoms and the need to promote symptom awareness and early presentation to primary care (Robb et al. 2009, Wardle et al. 2001). However, there are no equivalent studies of symptom awareness in women at increased genetic risk of developing ovarian cancer, in whom awareness, attitudes and beliefs about ovarian cancer are likely to differ from those of the general population due to the tendency towards high levels of cancer-related worry and perceived risk (Andersen et al. 2002, Hay et al. 2006, Kash et al 1992, Schwartz et al 1995). It could be expected that the increased saliency of health would lead to earlier symptomatic presentation; however, empirical

evidence is lacking regarding how heightened worry and perceived risk influence symptomatic presentation in women at increased genetic risk.

In the absence of literature on symptom awareness and presentation in women at increased genetic risk of ovarian cancer, evidence regarding the psychological determinants of breast self-examination (BSE) can be considered. BSE can be considered a similar behaviour to symptomatic presentation, since it involves self-determined awareness of breast symptoms which act as cues to action. Norman and Brain (2005) investigated breast self-examination in a sample of women who had a first degree relative diagnosed with breast cancer. Excessive self-examiners had higher levels of breast cancer worry and perceived severity (Norman and Brain 2005). Excessive breast self-examination was also observed among first-degree relatives of newly diagnosed breast cancer patients in a study by Epstein et al. (1997). High frequency of thoughts about breast cancer, high perceived risk and having two or more first degree relatives with breast cancer, were also associated with frequent BSE (Epstein et al. 1997). Confidence has also been reported as an important determinant of BSE, with low confidence in carrying out the behaviour associated with poor adherence to BSE (Kash et al. 1992). A study evaluating the psychological outcomes of breast cancer genetic risk assessment at 6-year follow up identified greater worry as a predictor of frequent BSE and higher perceived risk (Brain et al. 2011). Cancer worry at baseline was also identified as the strongest predictor of cancer worry at 6-year follow up, suggesting that emotional aspects of perceived risk are relatively stable over time (Brain et al. 2011). Findings from the BSE literature suggest that high levels of worry and perceived risk may prompt hyper-vigilant behaviour in women at increased genetic risk. However, as these studies focus specifically on breast cancer, the extent to which the findings generalise to the context of ovarian cancer is unknown.

Evidence regarding the psychological determinants of ovarian cancer and breast cancer screening uptake and BSE support the proposition that women at increased genetic risk for ovarian cancer are more likely to over-present than delay with ovarian cancer symptoms. This behavioural pattern could be problematic not only in terms of

the individual's psychological wellbeing, but also the potential impact on primary care services if women are frequently visiting their GP due to hyper-vigilance (Evans et al. 2014). This also has implications for interventions that promote symptom awareness, with the potential that such interventions could lead to hyper-vigilance and over-presentation in women at increased genetic risk. Understanding of the determinants of anticipated symptomatic presentation in women at increased genetic risk is needed so that interventions can promote appropriate presentation in this population without raising worry levels.

1.6 Summary

There is currently a gap in research concerning determinants of symptomatic presentation in women at increased genetic risk of ovarian cancer. General population studies have revealed low public awareness of cancer symptoms (Robb et al 2009, Wardle et al. 2001), however equivalent studies of ovarian cancer symptom awareness in women at increased genetic risk are currently lacking. There is evidence that genetic risk, levels of cancer worry and perceived susceptibility predict screening uptake (Andersen et al. 2002, Brain et al. 2011, Schwartz et al. 1995a,) but as yet, the impact of risk status on ovarian cancer symptomatic presentation is unknown. In the absence of a screening programme for ovarian cancer, symptom awareness in the context of increased genetic risk needs to be explored and understood. Once this is understood, work can be done to try and increase awareness and encourage appropriate presentation. Symptom awareness tools are a possible way to increase awareness and encourage appropriate presentation, potentially leading to earlier diagnosis (Evans et al. 2014). However, little is known about the number of symptom awareness tools already in existence, their content or development processes. The suitability of such materials for women at increased genetic risk is also unknown. There is concern that encouraging regular self-monitoring through diaries and checklists in women at increased genetic risk may lead to anxiety, hyper-vigilance, and potentially to unnecessary investigations (Brain et al. 1999, Fallowfield et al. 2010, Norman and Brain 2005). In relation to women at increased genetic risk of ovarian cancer, the challenge is

therefore to promote symptom awareness without encouraging excessive self-monitoring.

1.7 Thesis

1.7.1 Rationale

There is a gap in understanding the feasibility and impact of symptom awareness as a risk management strategy for women at increased genetic risk of ovarian cancer. This lack of understanding is particularly concerning due to the current lack of routinely available ovarian cancer screening. As part of the Cancer Reform Strategy, the Department of Health is advocating public awareness of ovarian cancer to promote early presentation and improve cancer outcomes (Department of Health 2007). Symptom awareness is also a key recommendation in the NICE ovarian cancer management guidelines (National Institute for Health and Clinical Excellence 2011).

Interventions to increase symptom awareness may be best aimed at women at increased genetic risk of ovarian cancer (Low et al. 2013a), as these women may have to rely on symptom awareness despite higher levels of worry associated with ovarian cancer risk. Currently there is a lack of understanding of levels of symptom awareness, or the determinants of symptomatic presentation in this population. Research needs to be undertaken to understand the likely presentation behaviour of women at increased genetic risk, because if they are likely to over-present with potential symptoms, interventions which aim to increase symptom awareness will need to address this behavioural response. Interventions should provide symptom information without impeding the psychological wellbeing of the individual or over-burdening primary care services. Currently there is a lack of theory-driven interventions, and it is essential that a clinical management approach based on symptom awareness is guided by research evidence.

1.7.2 Aims

The aims of the PhD are (1) to understand the psychological determinants of symptomatic presentation in women at increased genetic risk of ovarian cancer, and (2) to develop a preliminary ovarian cancer symptom awareness tool.

Objectives for the PhD are: (1) to identify relevant theory for awareness and presentation, and describe women's knowledge, beliefs and attitudes towards ovarian cancer and the potential influence of risk on these factors; (2) to conduct a thorough search and evaluation of existing symptom awareness tools; (3) to identify the factors influencing early presentation behaviour in an increased genetic risk sample in comparison with an existing general population sample, and (4) to develop a preliminary ovarian cancer symptom awareness tool and examine its acceptability/usage with a sample of potential users and providers.

The proposed studies follow the MRC complex interventions guidelines (Craig et al. 2008b) in generating an evidence base for the preliminary development of an ovarian cancer symptom awareness tool for women at increased genetic risk of ovarian cancer. The MRC complex intervention guidelines state that intervention development should be done over four phases of development, feasibility/piloting, evaluation and implementation. As part of the development phase, the guidelines emphasise the importance of understanding existing interventions and developing a theoretical understanding of the area in question (Craig et al. 2008b, Jones et al. 2013). The proposed research represents theoretical/modelling phase work to generate this evidence base which will guide tool development (Craig et al. 2008b). It is anticipated that the current development and feasibility studies will form groundwork for follow-on research to evaluate the clinical utility and actual implementation of the tool in primary care.

1.7.3 Study design

In order to achieve the aims and objectives of the PhD, the project is split in to five phases involving mixed methods:

Phase One will identify and evaluate existing ovarian cancer symptom awareness tools;

Phase Two will examine ovarian cancer symptom awareness and anticipated presentation behaviour. Health beliefs including symptom knowledge, cancer beliefs, barriers to presentation and confidence in symptom detection will be explored in a sample of women at increased genetic risk versus a general population sample;

Phase Three will explore the influence of genetic risk status on help seeking behaviour and the acceptability of an approach based on ovarian cancer symptom awareness using semi-structured interviews with a sample of women at increased risk;

Phase Four will gain consensus on the symptom content and guidance to include in the tool based on empirical evidence (systematic literature search) and clinical evidence (virtual reference group of ovarian cancer experts);

Phase Five will utilise the information gathered in previous phases to develop a preliminary tool before user and provider feedback is gained using cognitive interviews.

1.8 Thesis chapter plan

The thesis continues in Chapter 2 with a description of the theoretical underpinning of the proposed research and description of previous literature which provides the rationale for the research. The subsequent chapters present the five phases of the PhD (Chapters 3-7) followed by an integrated discussion chapter (Chapter 8).

2 Theoretical underpinning

2.1 Chapter overview

This chapter presents the theoretical underpinning of the research project. The psychology of awareness and symptomatic presentation behaviour will be discussed and health behaviour theories will be drawn upon. The importance of health behaviour theories in intervention development will be presented and relevant theories will be introduced. The application of this theoretical underpinning will then be explained in terms of the mixed method approach that will be used in subsequent chapters.

2.2 Introduction

As detailed in the previous chapter, the National Awareness and Early Diagnosis Initiative (NAEDI) outlined a pathway which aims to reduce cancer deaths by increasing awareness and early diagnosis (Richards 2009a). The first stage of this pathway consists of public awareness and/or beliefs about cancer. The development of such a pathway highlights the importance of awareness and beliefs about cancer and the important role they play in the cancer diagnostic pathway. The role of cancer awareness and beliefs has been explored frequently in the literature through the use of various participant populations and study methodology. These studies help create an understanding of the psychology of awareness and symptomatic presentation behaviours. Understanding of the psychology is important because once the determinants and beliefs surrounding awareness and presentation are understood, these can be targeted in interventions to increase awareness and promote timely presentation. This process is endorsed as part of the development process in the MRC complex intervention guidelines (Craig et al. 2008b).

2.3 Health behaviour theories

The research in this thesis concerns understanding awareness and anticipated symptomatic presentation behaviour in women at increased genetic risk of ovarian cancer and therefore it is important to draw upon theories that may help explain such

behaviour. A variety of health behaviour theories are used in research to understand and predict determinants of behaviour. When developing interventions it is important to identify the potential theoretical models so that the appropriate model is applied (Jones et al. 2013, Michie et al. 2005). When applied to intervention development, theories allow for the identification of salient beliefs that influence the target behaviour. These beliefs can then be targeted in order to maximise the likelihood of the target behaviour being carried out. Theoretical understanding is important to allow for identification of how the intervention is working and what elements of the intervention are causing change (Craig et al. 2008b). Through the use of a theoretical framework the components contributing to a target behaviour can be understood and mapped out, enhancing understanding of the target behaviour. Interventions that have a theoretical foundation are considered advantageous as they allow for systematic development based on best available evidence (Craig et al. 2008b).

The importance of an explicit theory based approach to conceptualising anticipated presentation for a variety of cancers is emphasized in a systematic review by Walter et al. (2011). The review reported that most studies investigating patient presentation decisions in cancer diagnosis failed to use theory to guide study content and reporting. The absence of theory led to variation in definitions and study methods used in included studies, which consequently made comparisons between studies of different cancer sites and different medical systems/contexts very difficult (Walter et al. 2011). An overview of health behaviour theories that could be applied to symptom awareness and presentation in women at increased genetic risk of ovarian cancer is presented in the following section.

2.3.1 Overview of theories

Health behaviour theories can be used to help explain determinants of behaviour in a given health context. Different theories have slightly different focal points which allows for theoretical constructs that are most appropriate to the research being undertaken to be applied. Theories that have been widely applied to health behaviour include the Extended Parallel Processing Model (Witte 1992), Health Belief Model

(Rosenstock et al. 1988), Protection Motivation Theory (Rogers 1975), Social Cognitive Theory (Bandura 2004) and Theory of Planned Behaviour (Ajzen 1991).

Table 2.1 outlines the main theoretical constructs and the main focus of the theories. It can be seen from Table 2.1 that the theories include different constructs which determine behaviour and influence what populations/behaviours the theory can be best applied to.

Table 2.1. *Overview of health behaviour theories*

Theory	**Main constructs**	**Theoretical focus**
Extended Parallel Processing Model	• Threat appraisal • Fear • Disregard • Efficacy appraisal • Danger control (constructive response) • Fear control (defensive response)	• Often used to assess behavioural impact of health risk information • Depending on the efficacy appraisal people will be motivated to engage in danger control or fear control
Health Belief Model	• Perceived susceptibility • Perceived severity • Perceived benefits • Perceived barriers • Cues to action • Self-efficacy	• Developed to predict health behaviour • Involves threat perceptions and evaluation of behaviours to counteract this threat
Protection Motivation Theory	• Threat appraisal (severity, vulnerability, intrinsic and extrinsic rewards) • Coping appraisal (response costs, response efficacy and self-efficacy)	• Often used to assess behavioural impact of health risk information • Threat and coping interact to influence motivation for risk reducing behaviour
Social Cognitive Theory	• Self-efficacy • Goals • Behaviour • Outcome expectations (physical, social) • Socio-structural factors (facilitator, impediments)	• Focuses on expectancies of environmental cue • Motivation and action is based on situation outcome, action outcome and self-efficacy
Theory of Planned Behaviour	• Attitudes • Subjective norms • Perceived behavioural control • Behaviour intention	• Focuses on behavioural beliefs • Does not explicitly cater for emotional or arousal variables

The Extended Parallel Processing Model (EPPM, Figure 2.1) (Witte 1992) and Protection Motivation Theory (PMT, Figure 2.2) (Rogers 1975) have commonalities, both focusing on threat appraisal (Table 2.1). However, there is an emphasis on

arousal in the EPPM that distinguishes it from the PMT. Although fear arousal is an integral part of EPPM, a review of the EPPM reported that fear has a weak effect on attitudes and behavioural intentions (Witte and Allen 2000).

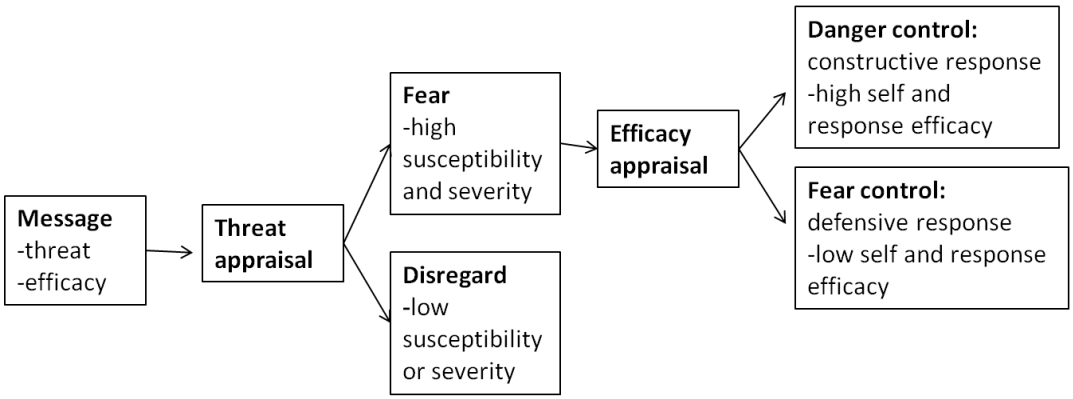


Figure 2.1. The Extended Parallel Process Model (adapted from Witte 1992)

A meta-analysis of 12 studies that used the PMT in health related research reported that self-efficacy was the most consistent correlate of behavioural intention, and that coping appraisal variables collectively were reported to be more predictive than the threat appraisal variables (Milne et al. 2002). A criticism of both of these theories is the emphasis on the processing of threats in a careful manner in order for behaviours to be considered, which is potentially problematic due to people not always processing information this way. This could especially be the case for women at increased genetic risk of ovarian cancer, who may not process threats in a considered manner due to their increased risk status and possible heightened threat levels. The predictive ability of these models has also been questioned in the literature (Armitage and Conner 2000). Specifically, the ability of the PMT to predict future behaviour has been reported as weak (Milne et al. 2002).

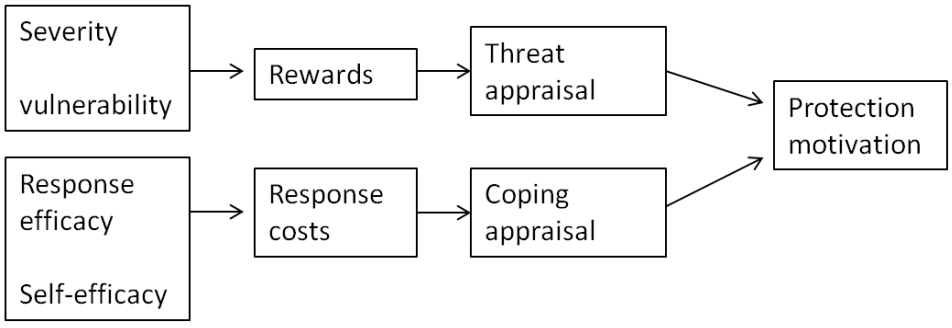


Figure 2.2. Protection Motivation Theory (adapted from Rogers 1975)

Unlike the EPPM and PMT, self-efficacy is the main focus of Social Cognitive Theory (SCT, Figure 2.3) and is determined by the individuals' beliefs about whether the given behaviour is in their control (Bandura 2004). The theory also includes wider influences, such as environmental cues, which act as either facilitators or barriers to behaviour. SCT also emphasises the importance of social systems surrounding the individual, with people in the individuals' environment shaping and influencing beliefs (Bandura 2004). Self-efficacy has been reported to be the most predictive variable within the model (Armitage and Conner 2000). Self-efficacy could be important for women at increased genetic risk of ovarian cancer due to their inherited risk status potentially influencing their beliefs about the amount of personal control they have over behaviours.

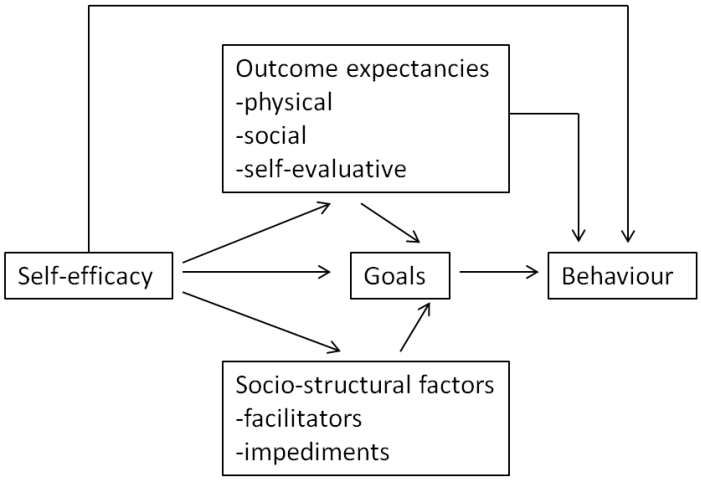


Figure 2.3. Social Cognitive Theory (model from (Bandura (2000))

The Health Belief Model (HBM, Figure 2.4) states that when faced with a potential health threat people consider their susceptibility and the severity of the health threat when deciding whether to act, as well as the benefits and barriers to carrying out the behaviour (Conner and Norman 2005, Rosenstock et al. 1988). Studies have reported fewer perceived barriers and higher perceived susceptibility to be the strongest determinants of behaviour (Lashley 1987, Wyper 1990). Knowledge has also been reported to be an important determinant of behaviour in cancer contexts including breast self-examination and cervical screening (Burak and Meyer 1997, Lashley 1987).

The inclusion of susceptibility could make this theory particularly applicable to women at increased genetic risk of ovarian cancer as it enables exploration of the influence of their risk status on help seeking decisions. The construct self-efficacy, as discussed in the SCT was not included in the original HBM, but was later included in extended versions of the HBM (Rosenstock et al. 1997). A recent meta-analysis of 18 studies by Carpenter (2010) concluded that perceived barriers and perceived benefits were the most consistent predictors of behaviour.

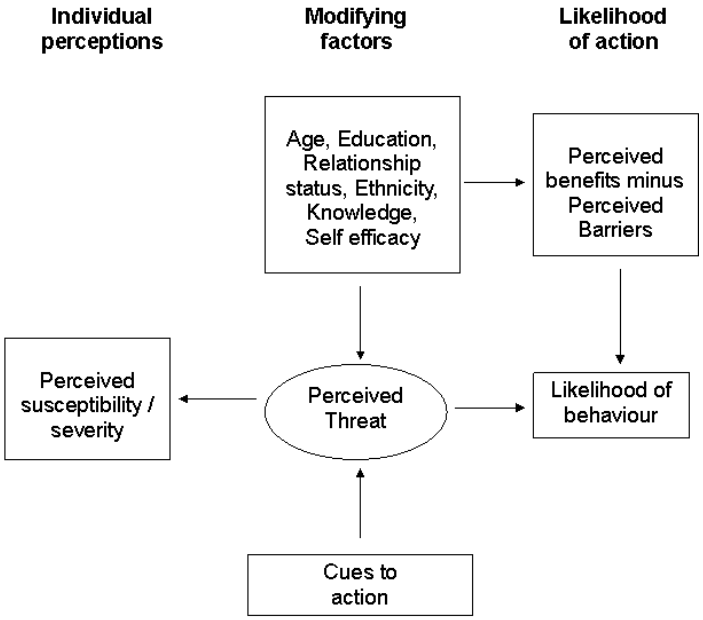


Figure 2.4. The Health Belief Model (from Stretcher & Rosenstock (1997) in Glanz et al (2008))

The Theory of Planned Behaviour (TPB, Figure 2.5) focuses on behavioural beliefs, with little attention paid to emotional or arousal variables (Table 2.1). Subjective norms and perceived behavioural control were identified as influencing intention in relation to testicular self-examination (Brubaker and Wickersham 1990). Subjective norms have also be shown to be strong determinants of intention for breast cancer screening attendance (Rutter 2000). However, the subjective norms construct has been reported to be a weak predictor of intentions in a meta-analysis on the efficacy of the TPB by Armitage and Conner (2001). The meta-analysis also reported that the TPB may be better at predicting intention and behaviour when applied to self-reported behaviour as opposed to observed behaviour (Armitage and Conner 2001). As emotional and

cognitive representations of risk are thought to be influential for women at increased genetic risk of ovarian cancer (Andersen et al. 2002, Brain et al. 1999, Kash et al. 1992), TPB may not be best applied in the current context.

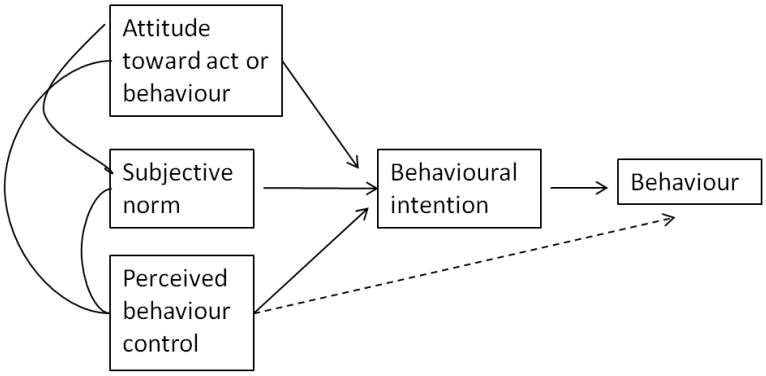


Figure 2.5. The Theory of Planned Behaviour (source Ajzen 1991)

It is evident that there is some overlap in the constructs between the theories discussed, with this reflecting the considerations that need to be made when applying a theory to a health behaviour (Ogden 2003). Of the health behaviour theories presented, the HBM constructs could be best applied to explain awareness and anticipated symptomatic presentation in women at increased genetic risk of ovarian cancer. The focus on the benefits and costs of performing a behaviour, and the inclusion of the constructs perceived susceptibility and self-efficacy could make it particularly useful in the current context. In women at increased genetic risk of developing ovarian cancer, the impact that perceived susceptibility has on anticipated presentation is particularly important to understand. As a result of the HBMs applicability when applied to ovarian cancer awareness and anticipated symptomatic presentation, the HBM will be the main theory used to guide the research in this thesis. The HBM is presented in more detail in the following section.

2.3.2 Choice of theory

The HBM has been widely used in health behaviour research and has been used for predicting the likelihood of actual and hypothetical behaviours in a variety of cancer

contexts (Cohen 2006, Grunfeld et al. 2002, Kash et al. 1992, Norman and Brain 2005, Sohl and Moyer 2007). The model has also been frequently used in the development of interventions over the past 40 years (Jones et al. 2013). The HBM focuses on personal characteristics and cognitive processes in order to explain the likelihood of a behaviour being carried out (Wyke et al. 2013). The HBM comprises theoretical constructs including knowledge, self-efficacy, perceived benefits, barriers, severity and susceptibility, threat and cues to action (Rosenstock et al. 1997).

2.3.3 Constructs of the Health Belief Model

The conceptualisations of HBM constructs are shown in Figure 2.4. Constructs are grouped under the headings Individual Perceptions, Modifying Factors and Likelihood of Action.

Perceived threat is an important construct within the model (see Figure 2.4). The HBM states that perceived threat and its emotional consequents predict health belief action (Jones et al. 2013). Individual perceptions comprise how individuals perceive their susceptibility to, and the severity of, the health problem. The construct of perceived susceptibility is important in encouraging health related behaviour. The more susceptible people perceive themselves to be, the more likely they will engage in behaviour to reduce that risk (Rosenstock et al. 1988). Perceived susceptibility is closely linked to perceived severity and relates to the perceived seriousness of the disease (Rosenstock, Strecher et al. 1997). Perceived benefits comprise both medical and psychosocial benefits of engaging in health promoting behaviours (Rosenstock et al. 1997). Perceived barriers consist of practical barriers to performing the behaviour as well as the psychosocial costs associated with performing the behaviour, and judgements as to whether the new behaviour is better than current behaviours (Rosenstock et al. 1997). Perceived benefits and barriers are grouped under the 'likelihood of action' heading, as it is the consideration of the benefits and barriers that determine the likelihood of the behaviour being carried out. Perceived benefits and barriers are integral to behaviour uptake, with behaviour more likely to be conducted

if more benefits are perceived to carrying it out than barriers (Conner and Norman 2005, Rosenstock et al. 1988). It is therefore important to highlight the benefits of presenting with possible symptom concerns, whilst at the same time addressing and minimising barriers.

Cues to action are needed for people to engage in behaviour that address the health threat and can take various forms, including a physical symptom, health education leaflets, direct guidance from a health care professional, mass media and influences of significant others. Modifying factors are personal variables that influence the health behaviour, such as age, education, symptom knowledge and self-efficacy. The HBM hypothesises that these constructs influence the likelihood of behaviour (Rosenstock et al. 1997).

When applied to anticipated ovarian cancer symptomatic presentation, the HBM specifies that those who perceive themselves to be susceptible to ovarian cancer, and believe ovarian cancer to be a serious threat are more likely to be motivated to engage in behaviours that are targeted towards this threat. The HBM will be used in this thesis to help identify salient health beliefs in women at increased genetic risk of ovarian cancer and a general population sample, which will lead to an understanding of awareness and anticipated presentation in different risk populations. Once identified, these determinants can be included and targeted in an intervention that addresses these issues. It is anticipated that the HBM will guide intervention components aimed at encouraging appropriate symptomatic presentation whilst maintaining psychological wellbeing in women at increased genetic risk of developing ovarian cancer.

2.4 Anticipated presentation and barriers

It is important to draw on existing literature about awareness and symptomatic presentation in order to make predictions for the present research based on best available evidence. When presentation times are discussed in the literature, the

potential contributors to longer presentation are sometimes attributed to the patient, and are termed 'patient delay' (Andersen et al. 1995). Patient delay refers to the time after the individual notices a sign or symptom to the time taken to seek medical advice (Andersen et al. 1995). However, in recent formulations, this term is viewed as somewhat judgemental due to the negative connotations and blame associated with the term "delay", thus "patient interval" is now preferred (Walter et al. 2011). Contributors to this decision to seek medical advice can be explored using the concepts of the HBM that have previously been described.

Drawing on existing literature will enable understanding to be gained on how the constructs have worked in other populations or contexts. This could aid understanding of the complex relationship between awareness and presentation. Cancer awareness involves not only increasing knowledge about symptoms, but also increasing confidence and motivation to present promptly in the presence of such symptoms (Forbes et al. 2011). Empirical research can be drawn on to determine whether or not there is evidence for the constructs outlined by the HBM for reflecting determinants of awareness and anticipated presentation. Literature from the wider cancer context will be considered due to the current lack of research in samples of women at increased genetic risk of ovarian cancer.

2.4.1 Population studies of cancer symptom awareness and presentation

The focus on awareness and beliefs in cancer demonstrates that delayed presentation is thought to be associated with poorer survival (Macleod et al. 2009, Ramirez et al. 1999). A population based survey of public awareness of cancer in Britain was conducted by Robb et al. (2009). Multivariate analysis revealed an association between higher symptom awareness and shorter anticipated presentation, suggesting that symptom awareness directly translates to shorter presentation times (Robb et al. 2009). The most commonly endorsed barriers to presentation were difficulty getting an appointment, worry about wasting the doctor's time and worry about what the doctor might find (Robb et al. 2009). In line with the HBM, the endorsement of more

barriers was associated with longer anticipated presentation. These findings suggest that improving cancer symptom awareness and reducing barriers could lead to earlier presentation. Robb et al. (2009) also reported that those who were more educated were more likely to report longer anticipated presentation.

Differences in cancer awareness and beliefs were explored in an international study of cancer survival differences in six countries (Australia, Canada, Denmark, Norway, Sweden and the UK) (Forbes et al. 2013). There was a lack of difference between symptom awareness between the countries, however differences were found in cancer beliefs. The UK, which has the poorest cancer survival outcomes out of the participating countries, had the lowest awareness of the age related risk of cancer. The UK population also reported more negative beliefs towards cancer and endorsed more barriers to anticipated presentation compared to the other countries, with worry about wasting the doctor's time the most prominent barrier (Forbes et al. 2013). These findings suggest that a focus on improving the doctor-patient interaction in primary care is needed in order to help reduce barriers to presentation. As outlined by the HBM, reducing such barriers and negative beliefs could bring about early anticipated presentation, which in turn could improve survival outcomes.

The data from the UK countries within the Forbes et al. (2013) study (England, Northern Ireland and Wales) was also analysed separately to provide more of an insight into the patterns of cancer awareness and beliefs held by the UK population (Quaife et al. 2013). Analysis indicated that higher education was associated with better recognition of individual cancer symptoms. Better recognition of cancer symptoms was related to earlier anticipated presentation times, whereas endorsing the belief that it would be difficult to see a doctor was associated with longer anticipated presentation times (Quaife et al. 2013), again, demonstrating the negative impact of endorsing barriers to presentation as outlined by the HBM.

UK population sample data from Simon et al. (2010) retrospectively examined associations between symptom awareness and longer anticipated presentation times. Participants were asked whether they had been to see a doctor with symptoms they thought might have been cancer within the previous three months. Better symptom knowledge helped people recognise symptoms, which in turn reduced appraisal and presentation delays (Simon et al. 2010), highlighting the potential modifying role of symptom knowledge on behaviour, as outlined by the HBM. More positive attitudes were reported to reduce presentation delay (Simon et al. 2010). Similar findings were also reported in a synthesis of 32 qualitative studies by Smith et al. (2005b), where the most common determinant of longer anticipated presentation was poor symptom recognition.

2.4.2 Ovarian cancer awareness and presentation

Few research studies have been conducted that focus on awareness and symptomatic presentation in ovarian cancer. Lockwood-Rayermann et al. (2009) investigated awareness of ovarian cancer risk factors and symptoms in a general population sample in the USA. Similar to studies concerning general cancer symptom awareness, low levels of ovarian symptom awareness were reported. Those who were less educated had poorer levels of awareness of ovarian symptoms and risk factors (Lockwood-Rayermann et al. 2009). However, whilst this study provides insights to symptom awareness specific to ovarian cancer, it did not explore the potential influence of ovarian cancer symptom awareness on anticipated presentation.

A UK study investigating the influence of symptom awareness on anticipated presentation conducted by Low et al. (2013b) reported a lack of association between awareness of gynaecologic cancer symptoms and anticipated presentation. These findings contrast with those of studies examining the relationship between general cancer symptom awareness and anticipated presentation (Quaife et al. 2013, Robb et al. 2009) and could be indicative of different mechanisms underlying these processes which are specific to ovarian cancer. The historic view that ovarian cancer is an

asymptomatic disease (Goff et al. 2007) could lead to a lack of connection between symptoms and anticipated presentation because people do not associate symptoms with ovarian cancer (Cooper et al. 2011, Goff et al. 2000, Lockwood-Rayermann et al. 2009). An alternative explanation for the lack of association could be that ovarian cancer awareness is indirectly associated with anticipated presentation. It could be that symptoms alone are not always enough to warrant seeking medical advice, with awareness influencing anticipated presentation through other mechanisms (Smith et al. 2005b). The indirect influence of symptom knowledge is outlined in the HBM, where symptom knowledge is described as indirectly influencing anticipated presentation through other components of the model, including perceived threat and perceived benefits and barriers to presentation (see Figure 2.4). More research needs to be done to understand the relationship between awareness and presentation for ovarian cancer in order for this process to be fully understood.

2.4.3 Contributors to longer presentation in ovarian cancer

Awareness about cancers may be influenced by public awareness campaigns (Eadie and MacAskill 2008, Forbes et al. 2011), with this evident in more common cancers which are paired with large-scale public campaigns, such as being breast awareness and anti-smoking campaigns (Redeker et al. 2009). People may have knowledge about well-known cancers but often possess little knowledge about less well known cancers (Stubbings et al. 2009). In the wider cancer context, some symptoms of cancer are viewed as cues to action because of the specificity of the symptom as an indicator of cancer (e.g., breast lump, irregular bleeding, and mole). These symptoms are often termed ‘red flag’ symptoms (Macleod et al. 2009) because they are easily recognised, and therefore can be more readily attributed to possible cancer (Ramirez et al. 1999, Robb et al. 2009). However, in the case of ovarian cancer, the main signs and symptoms are less specific and could be attributed to many other reasons e.g. diet, lifestyle, Irritable Bowel Syndrome, diverticulitis (Austoker 2009, Goff et al. 2000, Hamilton et al. 2009).

A possible explanation for the patient interval in presentation in ovarian cancer could be that these symptoms may be attributed to a benign condition or not taken seriously, and therefore are not perceived as red flags or cues to action. In ovarian cancer this could be particularly relevant for the non-pelvic symptoms which are vague in nature (Fitch et al. 2002, Goff et al. 2000). Non-recognition of the importance of symptoms has been reported as a determinant of presentation in the wider cancer context (Bish et al. 2005, Macleod et al. 2009, Quaife et al. 2013). This is echoed by Smith et al. (2005b) who reported that it is not just knowledge or recognition of symptoms that is important, but also the interpretation of them that plays an important role in presentation.

Issues surrounding attribution of symptoms of ovarian cancer have been highlighted in the literature. Goff et al. (2000) asked women diagnosed with ovarian cancer to recall symptoms and presentation experiences in a survey included in an ovarian cancer newsletter. Women who had experienced non-pelvic symptoms such as fatigue, gastrointestinal or urinary symptoms were significantly more likely to have ignored their symptoms. Symptoms were also commonly misattributed to benign causes such as menopause, ageing and daily stressors (Goff et al. 2000). However, it should be noted that participant bias may be a problem in this study as the recruitment pool consisted of subscribers to a newsletter, and the sample may therefore not be representative of people not yet diagnosed with ovarian cancer or those at other stages of diagnosis and treatment. Another potential problem is recall bias, with the time elapsed from diagnosis to time of participation an important factor influencing the accuracy with which participants recall information relating to experiences before their diagnosis. It was reported that 50% of participants received their diagnosis more than two years prior to the study, which is arguably too long to expect people to accurately recall symptoms experienced. In addition, participants in this study were not asked about family history of ovarian cancer or risk status, therefore it is not known whether the sample included women at increased risk of ovarian cancer. Therefore the applicability of these findings for women at increased genetic risk is not known. Similarly, Evans et al. (2007) reported delays in presentation as a result of

misattributing symptoms of ovarian cancer to stress, menopause or benign conditions and not recognising symptom seriousness. Again, neither the risk status of the participants, nor the time lapse from diagnosis to participation was stated, limiting the conclusions that can be drawn from these data.

The UK Collaborative Trial of Ovarian Cancer Screening (UKTOCS) is a large scale study in the UK that is evaluating the effectiveness of ovarian cancer screening. Data were gathered on awareness of ovarian cancer risk factors alongside beliefs and attitudes towards screening (Fallowfield et al. 2010). Less than half of women recognised the increased risk of developing ovarian cancer after the menopause, even though in postmenopausal women 90% of ovarian cancers develop sporadically (Menon et al. 2009). Lack of awareness of the age related risk of cancer could therefore be a barrier, and could be especially problematic if older people have poorer symptom knowledge (Fallowfield et al. 2010). Misconceptions concerning ovarian cancer are frequently reported in the literature, with many women falsely believing that the cervical smear test detects ovarian cancer (Cooper et al. 2011, Jones et al. 2010, Lockwood-Rayermann et al. 2009, Meisel et al. 2013, Tiller et al. 2005). Similar misconceptions also arose in the UKTOCS study, where there were beliefs that an abnormal smear test was indicative of ovarian cancer (Fallowfield et al. 2010). Such erroneous beliefs are problematic, especially when they concern detection because women may believe they are having a form of ovarian cancer screening, when in fact they are not. If people believe they are being monitored for the presence of a disease, they may not pay attention to bodily changes that could be indicative of the disease because they believe that potential problems will be detected by 'screening'. These misconceptions could be due to confusion with other cancers or diseases, and highlight the need for clarity and education in relation to ovarian cancer.

From these studies it can be seen that awareness and beliefs play a role in the cancer diagnostic pathway and that these beliefs reflect the constructs of the HBM. However, the research to date has not included those at increased genetic risk of ovarian cancer, hence it is difficult to determine what pattern of beliefs or levels of awareness within

this population, or how these influence presentation with possible ovarian cancer symptoms.

2.5 Impact of increased genetic risk status on symptom awareness and presentation

The previous study findings are useful for understanding possible barriers to presentation and cancer awareness in the general population, however a different pattern may be seen in those at increased genetic risk. At risk populations for specific cancers may possess more knowledge about the disease, may have different beliefs, such as increased worry, and endorse different barriers as a result of their risk status and perceived susceptibility (Fallowfield et al. 2010). The importance of risk status is highlighted in the HBM through the inclusion of the 'perceived susceptibility' construct (Rosenstock et al. 1988).

Fatalistic beliefs regarding cancer outcomes could possibly contribute to delay in both the general population and those at increased genetic risk (Beeken et al. 2011, Robb et al. 2009, Von Wagner et al. 2011). However, these beliefs may be more prominent in women at increased genetic risk who may have experienced ovarian cancer in family members diagnosed with the disease. If people have had negative experiences with ovarian cancer these beliefs could lead to a circular process whereby negative outcome expectancies could cause delayed presentation, which in turn leads to later stage at diagnosis and is then related to poorer outcomes (Von Wagner et al. 2011). Fear of cancer could lead to irrational responses to cancer symptoms and consequently, delayed presentation (Eadie and MacAskill 2008). In such a scenario, delays in presentation could therefore be attributed in part to a combination of poor symptom awareness and possessing negative beliefs towards cancer (Grunfeld et al. 2002), with this also supported by the HBM.

Experience with illness could also act as a cue to action (Andersen et al. 2004, Lockwood-Rayermann et al. 2009, Von Wagner et al. 2011). Experience with cancer

and fear of cancer could therefore influence symptom appraisal and presentation behaviour in different ways (Eadie and MacAskill 2008). Women at increased genetic risk of ovarian cancer have often seen family members diagnosed, and these experiences could shape their own beliefs about ovarian cancer (Lockwood-Rayermann et al. 2009, Tiller et al. 2005, Trask et al. 2001). Fallowfield et al. (2010) reported that women who had a family member affected by ovarian cancer had better knowledge of the disease compared to those without this experience. Personal experience has also been shown to be influential in breast cancer awareness (Absetz et al. 2003). The personal experience that many women at increased genetic risk of ovarian cancer have had may influence aspects of their own beliefs and behaviours about the disease, and can be conceptualised as 'cues to action' within the HBM (see Appendix 2). Andersen et al. (2009) suggest that an individual's understanding of bodily sensations relating to a specific cancer are nested within the social and cultural context of the individual. The personal experiences women at increased genetic risk of ovarian cancer have had may therefore influence their own perceptions of the signs and symptoms of disease.

The empirical studies presented are useful in exploring the relationship between symptom awareness and anticipated presentation and provide evidence for the utility of the HBM constructs in the current context. The studies also highlight the gap in research concerning determinants of symptomatic presentation in women at increased genetic risk of ovarian cancer. In order to understand the possible influence of increased genetic risk status on awareness and presentation in ovarian cancer, research needs to be undertaken with the target population ideally in comparison with a general population sample. Educational materials can then be created with the aim of maximising awareness and reducing potential barriers to presentation in different risk populations.

2.6 Foundations to mixed method approaches

Different methodological approaches will ensure that salient health beliefs for awareness and symptomatic presentation for women at increased genetic risk of ovarian cancer can be explored and represented in a draft symptom awareness tool. The multiple approaches to answering the research question offered by the mixed method approach will allow for an inclusive understanding of the research question. A mixed method approach will allow for the MRC complex intervention guidelines to be followed, ensuring thorough theoretical and modelling phases of development, including identifying the evidence base and identifying/developing appropriate theory (Craig et al. 2008b). The use of mixed methods will also help to generate a strong evidence base for the preliminary ovarian cancer symptom awareness tool. Complex interventions are often used in public health and are commonly used for education purposes that have health consequences (Craig et al. 2008a). The MRC guidelines propose that a strong theoretical understanding is crucial through all stages of development, allowing for insight to be gained regarding how the intervention causes change, how to identify strong and weak determinants of change, and how to determine and effectively measure the active ingredients within the intervention that are causing change (Craig et al. 2008a). The theoretical foundations therefore have reach beyond the development of the intervention and are also crucial for understanding and evaluating the impact of the intervention.

As the PhD phases progress, the mixed methods approach enables the findings from previous phases to be drawn upon in order to guide subsequent phases. This will allow the symptom awareness tool to be developed based on rigorous methods which were carried out using a sample of likely tool users and providers. The use of different methods will lead to a thorough understanding of awareness and anticipated symptomatic presentation in women at increased genetic risk of ovarian cancer, and will also permit comparisons to a general population sample to be made. The philosophical foundations of a mixed method approach enables the problem context to be explored from multiple angles. Sequential phases will allow for the research to be more specific and tailored to what is important to the target population.

Phase One will identify existing ovarian cancer symptom awareness tools using a systematic search method and will evaluate the quality, content and format of these tools. This evidence will then be utilised in later phases of the PhD, when the draft tool is being created. The systematic search follows the MRC complex intervention guidelines, which state that researchers should understand what is already known about similar interventions and what methods were used to create them (Craig et al. 2008b).

A survey guided by the HBM will be carried out in Phase 2 with women at increased genetic risk of ovarian cancer and compared to an existing dataset consisting of a general population sample. The analysis of the quantitative survey data from two different risk populations will enable the identification of the mechanisms underlying awareness and anticipated presentation in women at increased genetic risk of ovarian cancer in comparison to those in a general population sample. For example, emotional barriers may be more salient in determining awareness/anticipated presentation in the context of increased genetic risk. The research will be undertaken to develop a theoretical understanding of the determinants of anticipated symptomatic presentation and will lead to an understanding of how a change in anticipated presentation may be achieved. This process will help develop the rationale for the intervention (Craig et al. 2008a) and will allow for identification of any determinants that are unique to women at increased genetic risk of developing ovarian cancer and those which are shared with the general population sample. Identifying common and unique determinants is important because interventions may work best if they are tailored to personal circumstances (Craig et al. 2008b). The data collection method for this phase of work will be advantageous as quantitative research allows for large amounts of data to be gathered without geographic restrictions and in short time frames (Black 1994, Johnson and Onwuegbuzie 2004). It is therefore useful for studying large numbers of people in a standardised way. Quantitative research allows for testing of theories, as well as for testing hypotheses made prior to data analysis. However, such methods can be restrictive as respondents are usually restricted to

answers based on pre-determined response options. Therefore, if the researcher has not accurately reflected response categories it could lead to oversights (Green and Thorogood 2013, Johnson and Onwuegbuzie 2004). The testing of hypotheses could also be too narrow, with confirmation bias a potential problem associated with quantitative methods.

Qualitative, semi-structured interviews will be conducted in Phase 3 in order to further explore salient health beliefs as outlined by the HBM in Phase Two. A sample of women at increased genetic risk of ovarian cancer from Phase Two will be invited to participate in the interviews which will also explore the acceptability/feasibility of a risk management approach based on ovarian cancer symptom awareness. Using the quantitative findings from the previous phases to influence and inform the qualitative phase is an advantage of the mixed method approach (Johnson and Onwuegbuzie 2004). In qualitative research responses are not restricted, so that participants can express their own understanding and meanings of the topic area (Black 1994, Green and Thorogood 2013). Qualitative research allows for smaller numbers of participants to be understood in detail, and can be particularly useful when the subject matter is sensitive, complex or personal in nature (Smith 1996). Unlike quantitative research, which traditionally tests a hypothesis, qualitative research has an emphasis on hypothesis generation based on what the participants deem to be important (Black 1994, Green and Thorogood 2013). Due to traditionally small sample sizes, the findings may not be as generalisable as those from quantitative studies (Johnson and Onwuegbuzie 2004, Keeble et al. 2014). Qualitative research can also be a time consuming process, both in terms of data collection and analysis. As the data involves unrestricted responses, the analysis of data is less systematic and is more susceptible to researcher bias. Mixed method approaches allow for a blend of traditional quantitative and qualitative research approaches. Combing the two approaches in subsequent phases lets the researchers draw on the strengths, and minimize the weaknesses of each method (Johnson and Onwuegbuzie 2004). Another consequence is the potential for stronger conclusions to be made based on the combining the findings from different phases, with different methodologies.

Phase Four will gain consensus on the symptom content to include in the tool based on empirical evidence (systematic literature search) and clinical evidence (virtual reference group of ovarian cancer experts). The systematic search method allows for the best available information regarding symptoms which are indicative of ovarian cancer to be identified and synthesised and presented to a group of ovarian cancer experts in order to elicit their clinical expertise and opinion. Both sets of evidence can then be synthesised in order to guide choices about what symptom information to present in the awareness tool.

Finally, the findings from these phases can be synthesised for the development of the preliminary tool in Phase Five. The draft tool will then undergo user testing with cognitive interviews with a sample of the target population and potential providers, with this process providing a further opportunity to involve stakeholders in the development process (Craig et al. 2008a). Cognitive interviews will involve presenting participants with the draft tool and then applying cognitive interview techniques to elicit understanding of the tool and opinion on content. The feedback and opinions will then be considered, with any potential changes made in order to create the final tool.

2.7 Conclusion

The present chapter has demonstrated how theory will form an integral part of the PhD and has proposed how the HBM will be used to develop a symptom awareness tool that addresses the specific needs of women at increased genetic risk of ovarian cancer. Research has been presented that helps to define the problems for ovarian cancer symptomatic presentation and an underlying theory has been presented (Craig et al. 2008b, Smith et al. 2012). The gap in research on ovarian cancer awareness and anticipated presentation in women at increased genetic risk has also been highlighted. Whilst the relationship between awareness of symptoms and presenting to get medical advice is not simple, it is known that delaying getting medical help after noticing symptoms is likely to lead to poorer prognosis (Allgar and Neal 2005b,

Austoker et al. 2009, Richards 2009a). It is therefore important to educate women about what the symptoms of ovarian cancer are, what to do in their presence and also to try to reduce the fear and barriers relating to consultation (Smith et al. 2005b). The described mixed method approach will lead to the development of a tool that is the product of theoretically based research involving the target audience. The research discussed in this chapter has explored the determinants of symptom awareness, in addition to the potential personal and service facilitators and barriers to presentation in the context of the HBM. Levels of awareness, and facilitators and barriers to presentation in women at increased genetic risk are not currently understood, and as discussed, these beliefs could be different in this population due to their risk status.

This chapter has demonstrated how the use of the HBM throughout the phases will allow for a deep understanding of the constructs within the model that are influencing ovarian cancer awareness and anticipated presentation. As the thesis progresses, the project will start to identify what constructs should be targeted in the intervention, and how they can be best incorporated into the intervention. This will lead to the development of a theoretically driven and empirically based symptom awareness tool which addresses the specific needs of women at increased genetic risk of ovarian cancer.

3 A systematic search of ovarian cancer symptom awareness tools

3.1 Chapter overview

When creating an intervention it is an important first step to identify and evaluate what interventions already exist. A systematic search of ovarian cancer symptom awareness tools is presented, followed by a critical appraisal of the content and quality of identified tools. An appreciation of the strengths and limitations of existing tools, particularly in relation to theoretical grounding is emphasised in the MRC complex intervention guidelines (Craig et al. 2008b) and will assist in developing an ovarian cancer symptom awareness tool for women at increased genetic risk.

3.2 Introduction

3.2.1 Background to ovarian cancer symptom awareness tools

Symptom awareness tools are an increasingly popular method of sharing information about a specific topic, due to the low cost associated with production and the ease at which large populations can be reached (Evans et al. 2014). In the context of ovarian cancer, there has been a move towards symptom awareness due to the uncertain effectiveness of screening programmes (Menon et al. 2009) and low levels of ovarian cancer symptom awareness in the UK public (Cooper et al. 2012, Richards 2009a). Symptom awareness tools provide information about ovarian cancer symptoms and encourage women to seek medical advice if symptoms are experienced.

A wide variety of ovarian cancer symptom awareness tools exist, yet there is a lack of research into the content and evaluation of such tools. Little is known about the range and quality of information in awareness tools that are available to women, especially those who search for information about ovarian cancer symptoms on the internet. In the context of the PhD, whether a symptom awareness tool exists that is specifically aimed at women at increased genetic risk of ovarian cancer is of particular interest. Women at increased genetic risk may have different health beliefs about ovarian

cancer compared to women in the general population and a tool for this population may need to be targeted at specific beliefs. Potential differences in those at increased genetic risk include higher levels of ovarian cancer worry (Andersen et al. 2002, Kash et al. 1992), different barriers to presentation and different attitudes towards ovarian cancer, such as negative cancer beliefs (Bennett 2009, Ramirez et al. 1999). These differences could be a result of increased saliency of health threat (Schwartz et al. 1995) and perceived susceptibility in women at increased genetic risk (Brain et al. 1999, Schwartz et al. 1995).

The lack of evaluation of existing tools may not be specific to ovarian cancer symptom awareness, with Abraham et al. (2007) suggesting that "there appears to be a general dearth of research into the content of health promotion and patient information leaflets"(p36). Ideally, health information should be theory based and have undergone an extensive development process particular to the specific health issue (Craig et al. 2008b). If an assessment of the quality and content of a tool has not been carried out, little is known about the quality of the information provided to users.

3.2.2 Theoretical background to ovarian cancer symptom awareness tools

In terms of evaluating existing symptom awareness tools the most relevant theoretical components of the HBM will be perceived susceptibility, perceived severity, cues to action, perceived benefits and perceived barriers. Perceived threat cannot be directly assessed in an evaluation of existing tools because it arises as a result of Individual Perceptions, with these constructs varying according the individual characteristics (Rosenstock et al. 1988). Similarly, Modifying Factors will not be evaluated due to these constructs depending on the individual who is reading the material. Mapping the content of the identified symptom awareness tools on to the HBM will reveal whether the tools include constructs that the theory states will increase the likelihood of a behaviour being carried out. Specifically, this will be whether the tools are likely to achieve their aim of increasing symptom awareness and/or early symptomatic presentation.

3.2.3 Symptom content

Content of symptom awareness tools can be guided by the latest medical and government guidelines. Regulated government guidelines, which are medically and scientifically grounded are not only useful to guide the content of symptom awareness tools, but can also help medical professionals access standardised information in order to aid their daily practice. Such guidelines are particularly important when the history of ovarian cancer is taken into account, with its transition from a "silent killer" (Goff et al. 2007) to the "disease that whispers"(Twombly 2007) with recognisable symptoms (Bankhead et al. 2008, Goff et al. 2007, Hamilton 2009).

Although the symptoms identified by the Department of Health (2009) and National Institute for Health and Clinical Excellence (2011) guidelines are very similar, clear guidance on what to do if these symptoms are experienced is lacking. This information concerning how long a symptom should be experienced for and with what frequency of occurrence reflects the lack of clinical consensus on symptom duration and frequency. The National Institute for Health and Clinical Excellence (2011) guidelines state that if symptoms are "experienced more than 12 times per month" medical advice should be sought, with the Department of Health (2009) stating that advice should be sought "if symptoms occur on most days". The message regarding frequency and duration of symptoms that are experienced is therefore unclear and it will be important to identify symptom guidance provided in existing ovarian cancer symptom awareness tools.

3.2.4 Systematic searches

Systematic searches may involve searching academic databases as well the grey literature in order to identify available content on a specific topic (Liberati et al. 2009). Searching academic databases enables journals, unpublished articles and abstracts to be identified that are relevant to the search terms entered. The identified articles can then be screened for their relevance to the topic in question before the articles are synthesised to provide results which summarise the literature in the area. However, as there is little published information surrounding ovarian cancer symptoms awareness

tools, it was considered necessary to search other sources. Many people turn to the internet in search of health information (Cooper et al. 2011), with health related websites amongst the most widely used (Wilson and Risk 2002). This is reflected in the increasing number of patients asking doctors in consultations about information they have found on the internet (Bass 2003). The presence of information on the internet is potentially problematic in terms of health professionals not knowing what information patients have had access to, with this exacerbated by the lack of regulation over information that is shared on the internet. This could lead to potential variation in the quality and content of information that is freely available to large amounts of people. It was therefore considered relevant to systematically search the internet as well as the academic literature for symptom awareness tools.

3.2.5 Critical appraisal of ovarian cancer symptom awareness tools

Ovarian cancer symptom awareness tools have not previously been systematically identified and evaluated, hence it is useful to refer to existing validated extraction and evaluation forms to aid this process. Michie et al. (2005) set out theoretical domains for investigating the implementation of evidence based practice in the context of behaviour change, which is in essence what ovarian cancer awareness tools should aim to do: provide women with information concerning symptoms that is based on research evidence. The validated theoretical framework aids the identification of theoretical constructs that are involved in behaviour change, such as knowledge, beliefs, skills and motivation (Michie et al. 2005). If symptom awareness tools are to increase awareness or promote timely symptomatic presentation it is important to identify whether behaviour change constructs are incorporated into existing tools.

The International Patient Decision Aid Standards (IPDAS) Collaboration provides a set of criteria which assess the quality of decision support technologies (Elwyn et al. 2006). The criteria are assessed in a simple checklist format to facilitate quick, easy and comparable data collection. Although symptom awareness tools are not considered a decision aid, some of the IPDAS criteria are relevant as they capture information on

content, development processes and whether the tools have been guided by theory (Elwyn et al. 2006). Zaza et al. (2000) developed a "Data Abstraction Form" for standardized extraction of data from articles, with this process increasing consistency, validity and reliability, whilst reducing bias in the extraction process. The form consists of 26 items which describe the characteristics of the intervention and 23 items which assess the quality of the studies' execution (Zaza et al. 2000). The distinction of two sections highlights that information not only needs to be gathered on tool content, but also on the quality of the execution of this information. Although these extraction forms were not created specifically for cancer symptom awareness tools, the systematic approach to the extraction of information regarding the quality of information can be applied to awareness tools. These validated sources will be integrated to aid data extraction in the present study.

A new form was created for this systematic search as existing forms would not have captured all information that needed to be extracted. The inclusion of items from Michie et al. (2005) in the extraction form allowed identification of theoretical constructs. The IPDAS criteria (Elwyn et al. 2006) helped influence items which capture information on content, effectiveness and the developmental process, with the form from Zaza et al. (2000) helping ensure items covered both the content of the tool and the quality with which the tools execute this information. Drawing from these existing forms, which were created based on rigorous methods, enabled data to be systematically extracted and summarized.

3.2.6 Aims of the present study

A search was conducted in order to identify existing ovarian cancer symptom awareness tools. The specific aims were to (1) systematically review existing ovarian cancer symptom awareness tools, (2) evaluate the quality and content of existing tools using a bespoke checklist that was adapted from existing sources, (3) map the identified tools on to the theoretical components of the HBM, and (4) make

recommendations for a proposed symptom awareness tool for women at increased genetic risk.

3.3 Methods and Design

3.3.1 Definitions

For the purpose of this search, symptom awareness tools were defined as educational materials such as leaflets, factsheets, pamphlets, videos and posters (Chung et al. 2007) which are related to ovarian cancer and include symptoms of ovarian cancer.

3.3.2 Development of a search protocol

A comprehensive search strategy was developed to ensure that the maximum number of tools was identified. The search consisted of two components to ensure that all possible tools were identified and was developed with the help of SysNet (Cardiff University Systematic Review Network). First, a systematic search of databases was conducted using PsychInfo, Medline and Embase, with relevant studies identified through titles and abstracts. A systematic search of the internet was carried out separately as it was anticipated that most of the tools would be hosted on websites. The protocol for the internet search (i.e. 'grey literature') consisted of a list of search terms which were generated in order to reflect what terms women may use when looking for information regarding ovarian cancer symptoms. As this type of search is different to the usual systematic search process, a pilot study was conducted in order to test the feasibility of the grey literature search protocol.

3.4 Materials

3.4.1 Grey literature search strategy

Pilot study

A pilot search was conducted to ensure that the grey literature search strategy was comprehensive. This pilot was run on five consecutive days from Monday 15th April 2012 to determine whether the search needed to be run on multiple days. The search was run on Google, BING, Yahoo and ASK, as these accounted for 90% of search

engines used in the UK at the time of the study (Hitwise 2012). All four search engines were included to establish whether they all needed to be included in the full search. The search term *ovarian cancer symptoms* was typed in to each of the above mentioned search engines, with all generated website results on the first three pages extracted to a database. This process was repeated on each of the five days for the four search engines. A summary of the website's name was entered into the database in order to easily identify the order in which the websites appeared on consecutive days, and to identify whether any new results were generated by the different search engines. The terms were typed with and without speech marks. Speech marks were used because if the term *ovarian cancer symptoms* was entered, the search would pick up any information where either the word *ovarian* or *cancer* or *symptoms* was mentioned, whereas if *"ovarian cancer symptoms"* was searched it would only generate results for the whole term as written. However, as members of the general public may not search this way, the search was also run without speech marks.

In order to check consistency between search results generated by the different search engines the 'BEAT symptom checker' was chosen as a benchmark. This tool was the first website result on Google on day one of the pilot. The search results showed that the BEAT tool was generated in the search results for all four search engines, with the placement of this tool being consistent on each day the search was run (see Table 3.1). Decisions about how many days the search should be run were made based on column three in Table 3.1, which shows the number of new websites generated by each search engines on days 2-5 that were not identified in the search on day one. At first glance, this number of new websites may be interpreted such that the search should be conducted on consecutive days; however, these websites were all found at the end of the third page of results, and none of these websites were relevant to the search criteria. These findings suggested that there was little to be gained by running the search on consecutive days. Few new tools were found on the third page of search results and therefore it was decided to use only the first two pages of results in the full search. This complements research suggesting that 70% of internet users will not search beyond the second page of search results (Ryan et al. 2006).

Table 3.1. *Websites generated by Google, Bing, Yahoo and Ask in the pilot search of grey literature*

Search engine	Number of websites generated on day 1	Number of websites generated on days 2-5 that were not identified on day 1	Position of NHS Live Well (where BEAT tool was found)	Number of websites generated that were not identified by Google
Google	36	7	1	n/a
Bing	38	1	8	15
Yahoo	40	2	8	3
Ask	32	9	9	21

When looking at the content of the search results differentiated by search engine, Yahoo generated the least number of different results compared to Google (Column five, Table 3.1), in contrast ASK generated the most different links compared to Google. However, these were not relevant results with most being sponsored results (such as Omega supplements) or were non sponsored and irrelevant (such as London Bridge Hospital). These pilot findings influenced the number of search engines that were included in the full search (column five, Table 3.1). BING provided additional relevant website results to those that were generated via Google. Although ASK generated 21 different websites to Google, only three of these were actually related to ovarian cancer. Paired with the statistic that Google powers 84% of UK searches, BING accounts for 4%, Yahoo 2% and ASK 2% (Hitwise 2012), this suggests that it would be beneficial just to include Google and Bing. The inclusion of BING is important as in America, BING and Yahoo account for around 20% of searches and Google 67% (Hitwise 2012).

Generating search terms for grey literature search

In order to generate grey literature search terms, contact was made with ovarian cancer charity Target Ovarian Cancer who provided information on the search terms used by visitors to their website (www.targetovariancancer.org.uk). The search terms were generic, with the top three out of 50 terms being *symptoms ovarian cancer*, *ovarian cancer symptoms* and *signs of ovarian cancer*. The only specific term used was *pelvic pain*, with no other references to individual symptoms used. Target Ovarian

Cancer also received site visits from people searching for information in relation to ovarian cysts and their signs and symptoms.

In addition to the search terms provided by Target Ovarian Cancer, an electronic survey was sent to members of staff in the Cochrane Institute of Primary Care and Public Health in the School of Medicine at Cardiff University asking "*If you wanted to gain information about the symptoms of ovarian cancer, what would you type in to a search engine (eg Google), to find such information?".* Respondents were encouraged to reply with as few or as many search terms as they felt necessary. The most frequently used term was "ovarian cancer symptoms". In contrast to search terms provided by Target Ovarian Cancer, many respondents indicated that they would search for the symptoms they were experiencing. The combined information from Target Ovarian Cancer and the departmental survey led to a list of 25 terms which would be used in the grey literature search (Appendix 1).

3.4.2 Academic database search strategy

The search strategy for the academic database search was developed with the help of SysNet. The search strategy is provided in Appendix 2.

Critical appraisal

A data extraction form was created to allow for reliable and consistent extraction of data from identified tools. The form integrated aspects of existing checklists and extraction forms (Elwyn et al. 2006, Michie et al. 2005, Zaza et al. 2000). The extraction form was designed to extract sufficient information to evaluate the tools, with sections comprising characteristics of the source, provision of information, communication, format, symptoms, risk information and medical guidance (see Appendix 3).

The draft extraction form was appraised by project supervisors, with alterations and expansions made as a result of this review process. Changes were made to incorporate

items which covered classification of information, descriptive information about the intervention as well as quality of the source and execution quality of the tool (Zaza et al. 2000). Additional items included length of time to complete, number of pages, a brief description of the website (charity, NHS etc) and adding the URL to the extraction form. The extraction form was piloted for quality assurance, by completing the extraction process on the BEAT symptom checker. The extraction form (see Appendix 3) was designed to be self-explanatory and easy to use, as well as allowing consistent, standardised and reliable accumulation of data.

Double rating

To ensure the reliability of the extraction form and to reduce rater bias, nine of the extractions (23%) were double rated. Only three discrepancies were found across all nine double extractions involving 80 items per extraction form, suggesting that the form was clear and robust. The discrepancies were minor, arising from oversights of information, such as not noting the presence of a picture, overlooking a version date and forgetting to put “leaflet” in tool format. Once these differences had been discussed, 100% agreement was achieved.

3.4.3 Theoretical content

Items from the extraction form that mapped on to the HBM (Rosenstock et al. 1997) were identified allowing for a score out of 14 to be given to each tool. A higher score reflected more theoretical construct coverage in that tool and allowed for the identification of underlying theoretical constructs that were implicit in the tools to be identified. The 14 items reflected the HBM constructs perceived susceptibility, perceived severity, perceived benefits, perceived barriers and cues to action (Rosenstock et al. 1997) (see Appendix 6).

3.4.4 Inclusion/exclusion criteria

Tools were included if they were English language, included symptoms of ovarian cancer, and concerned either symptom awareness or presentation to a health professional with symptoms. Included tools were educational materials such as leaflets, factsheets, pamphlets, videos and posters which were related to ovarian cancer and included symptoms of ovarian cancer. Tools that did not meet these inclusion criteria were excluded. When more than one version of a tool was identified, the most recent version was retained.

3.5 Results

The following section covers (1) tool descriptions and (2) tool content and quality, which will lead to (3) tool symptom content and (4) mapping the theoretical content of the tools.

3.5.1 Tools identified from systematic search

Each website identified in the search was searched exhaustively to determine whether they hosted an awareness tool. The flow diagram of tool identification is presented in Figure 3.1. A total of 2,000 websites were identified and searched in the grey literature search. Once duplicates were removed 388 website remained. Of these, 350 were excluded as they did not meet the inclusion/exclusion criteria, leaving 38 eligible tools (see Figure 3.1). The database search identified 3,102 articles. Screening of title and abstracts for relevance led to the exclusion of 3,079 articles. Twenty three full text articles were assessed for eligibility, with this leading to a further 22 articles excluded due to not meeting the inclusion/exclusion criteria (see Figure 3.1).

The total number of included tools was 39. All 39 authors were contacted to ask for any additional information they wished to provide about the tools. Responses were received from 15 authors (38%), with this additional information included in the "Author" column of the data extraction form.

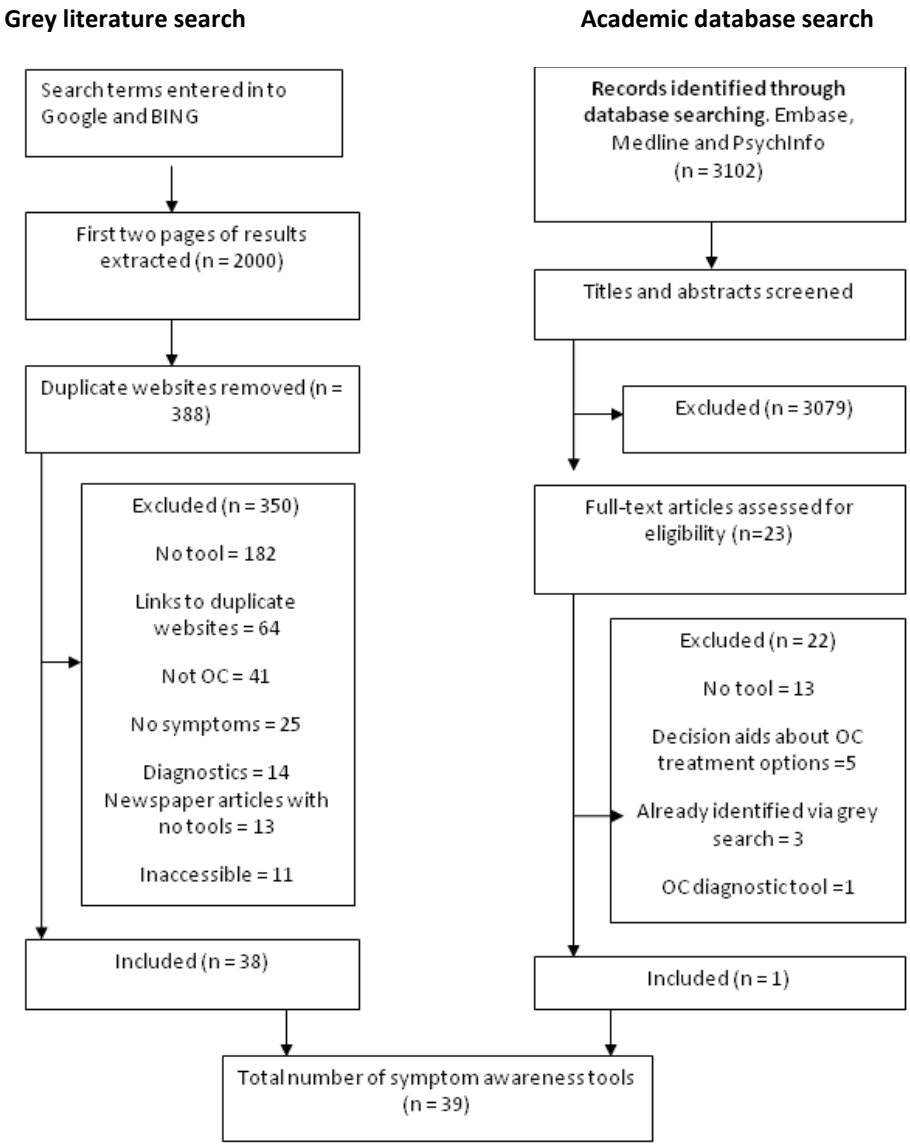


Figure 3.1. Flow diagram of tool identification in grey literature search and database search (oc= ovarian cancer)

3.5.2 Tool descriptions

The 39 tools (see Appendix 4) included leaflets (12) were most popular, followed by diaries (9), factsheets (4), quizzes (4), flyers (2), bookmarks (2), wallet sized card (1), symptom checker (1), slideshow (1), diagram (1), TV commercial (1) and risk calculator (1). The tools originated in five different countries; USA (17), UK (11), Australia (7), Canada (3) and New Zealand (1). The majority of tools were hosted on charity websites (n=28, 72%).

3.5.3 Tool content and quality

A summary of tool content is shown in Table 3.2. Contact information was provided in 82% (n=32) of cases (see Table 3.2), with a further 15% (n=6) providing contact details on the website hosting the tool. Contact information was not found for extraction 39 (tool identified in Mahon (1996) via database search), nor could a website for the tool be found. References to academic papers as sources for information provided within the tool were included in five (13%) tools, with a further 14 (36%) providing this information on their website. The majority of tools (n=25, 64%) were printable (see Table 3.2). Images or diagrams were used in 21 (54%) tools, with two (5%) tools using a personal account of symptom experience within the tool (Table 3.2). Funders who contributed to the tools were mentioned by seven (18%). A version number or date of last modification was present in 12 (31%) tools. Twenty three tools (59%) included numerical information in the form of percentages, frequencies or probabilities. Only 19 (49%) tools that provided numerical information did so in a consistent format. An information standard approval was present in 10% of tools (extractions 20, 21, 22 and 25). Three tools (8%) clearly stated the target audience: ("Ashkenazi Jews" (extraction 12), "the UK population" (extraction 18) and "women of average risk" (extraction 33).

Table 3.2. *Characteristics of identified ovarian cancer symptom awareness tools*

Tool name	Images/ Diagram	Printable	References	Contact information	Funders	Version number
1. Australia awareness Brochure		✓	✓	✓	✓	✓
2 Early detection Australia	✓	✓		✓		
3. Dr Oz	✓	✓		✓		
4. Australia symptom diary		✓	✓	✓		✓
5. OC: Australia factsheet	✓	✓		✓	✓	✓
6. TV advert	✓			✓		
7. No one knows your body like you do	✓	✓		✓	✓	✓
8. It's time to shout out	✓	✓		✓		
9. OC Canada Knowledge Centre						
10. Think Ovarian!		✓		✓		✓
11. NZ Gynaecological leaflet	✓	✓		✓		✓

12. Ashkenazi Inheritance:	✓	✓		✓		✓
13. BEAT Symptom Checker	✓					
14. BEAT Symptom Tracker	✓			✓		
15. Detecting OC: CRUK	✓	✓		✓		
16. OC diary: Innermost secrets		✓		✓		
17. Ovarian Cancer Action diary				✓		✓
18. Qrisk Ovary	✓		✓			✓
19. Remember the Symptoms	✓	✓		✓		
20. Swollen tummy?	✓	✓		✓		✓
21. Target quiz				✓		
22. What women need to know…	✓	✓		✓		
23. 15 Symptoms women ignore	✓					
24. Break the silence conversation starter		✓		✓		
25. CDC diary	✓	✓		✓		✓
26. NOCC Bookmark		✓		✓		✓
27. NOCC Quiz						
28. Ova-1 calendar		✓		✓		
29. Ova-1 quiz				✓		
30. OC symptoms		✓	✓	✓		
31. OC warning signs	✓					
32. OCNA app				✓	✓	
33. OCNA symptom diary	✓	✓	✓	✓	✓	
34. OCNA factsheet		✓		✓		
35. OAK Symptom Card		✓		✓		
36. Ovations for the future	✓			✓		
37. WCN understanding your risk		✓		✓	✓	
38. WCN womens guide		✓		✓	✓	
39. Mahon (1996) paper	✓					
N(%)	21 (54%)	25 (64%)	5 (13%)	32 (82%)	7 (18%)	12 (31%)

3.5.4 Peer reviewed articles

One tool was identified in a peer reviewed article via the database search (see Figure 3.1), and two tools identified via the grey literature search were also accompanied by

peer reviewed articles. A description of the content in the associated academic papers will be presented in the following section. An explanation for why these two additional tools were not included in the database search is also provided.

(1) The Gynecologic Symptom diary (extraction 25) was identified in the grey literature search and was accompanied by three articles by the Centre for Disease Control (CDC) (Cooper et al. 2011, Rim et al. 2011, Trivers et al. 2011). These three papers were identified in the database search. However, as the grey literature search was conducted first, these papers had already been identified when the tool was identified in the grey literature search. Subsequently, these three papers were excluded from the database search due to duplication, with this represented in the extraction process as 'already identified via grey search =3" (see Figure 3.1). These papers provide information on the rationale and processes leading up to the tool development. The papers detail how CDC identified poor knowledge of an array of gynaecological and non-gynaecologic symptoms as part of a national general population HealthStyles survey (Trivers et al. 2011). These findings, along with a literature review (Rim et al. 2011) led CDC to consider developing the symptom diary. As part of the development of the diary, focus groups (n=132) were held with women from the general population in four American cities (Cooper, Polonec et al. 2011). The articles outline that the diaries development was guided by Social Cognitive Theory (Bandura 2004). The focus groups further explored the signs, symptoms and risk factors of gynaecologic cancers that women were unfamiliar with (Cooper et al. 2011). These findings contributed to the content of the CDC "Inside Knowledge: Get the facts about gynaecologic cancer campaign". This is a national campaign for the USA which covers cervical, ovarian, uterine, vaginal and vulvar cancers (Rim et al. 2011).

(2) QriskOvary (extraction 18) is a risk calculator for developing ovarian cancer that was identified in the grey literature search. This risk calculator uses an algorithm based on responses that are entered in order to generate a risk status for developing ovarian cancer. This tool met the study inclusion criteria as it explicitly asks about symptoms that have been experienced. It was developed to be used by clinicians but can also be

filled out by non-clinicians as it is freely accessible on the internet. The algorithm used in the QriskOvary calculator has also featured in a journal article (Hippisley-Cox et al. 2007), with this paper focusing on the mathematical capabilities of the formulas used to predict the risk of developing ovarian cancer. As the paper focuses on the risk algorithm and does not include symptom content relevant to this search, it was not identified in the database search.

(3) The database search identified one eligible paper (Mahon 1996) which contained a leaflet designed to educate women visiting the Cancer Screening Centre in St Louis about early detection of ovarian cancer (extraction 39). The paper details that the leaflet was developed following requests from women attending the centre who asked for information about recommendations for gynaecological cancer screening (Mahon 1996). No theory is stated for the development of the leaflet, instead the leaflet was developed by the clinical team to meet the specific need in their working environment based on information requests by women (Mahon 1996). Before use, the leaflet was reviewed by 17 nurses, a medical oncologist, a pathologist, a gynaecologist, 13 women who used the centre and staff from the public relations office (Mahon 1996).

3.5.5 Information on ovarian cancer symptoms

The number of ovarian cancer symptoms included in each tool was noted (see Table 3.4). If symptoms were duplicated in a tool, only the first occurrence was counted. The average number of symptoms was eight (SD 4, range 3-25). A breakdown of the symptoms included in each tool is provided in Appendix 5. It was not possible to collate the overall frequency of each individual symptom due to differences in wording or phrases used, such as “abdominal or back pain”, “increase in abdominal size or bloating”, “abdominal bloating and feeling of fullness” and “difficulty eating/feeling full quickly”. Each of these phrases was counted as one symptom as it was presented in the same statement and was presented separately from other symptoms within the tools. As most symptoms were presented in this way, it was not possible to count each

individual occurrence due to overlap within the phrases and the different wording used.

Referring back to the key symptoms stated in the Department of Health (2009) and National Institute for Health and Clinical Excellence (2011) guidelines it can be seen that the wording of symptoms differed between guidelines. However, it was possible to extract words that were used in both guidelines i.e. “bloating”, “pelvic or abdominal pain” and “full”. Instances of these phrases in the tools could then be counted to ascertain if the tools were using similar words to the guidelines to describe symptoms. Due to the issues associated with inconsistent terminology, only those symptoms which matched this wording used in the clinical guidelines were counted. It can be seen in Table 3.3 that this wording occurred frequently in the tools, with 95% (n=37) using the term “bloating”, 69% (n=27) using the phrase “abdominal pain and/or pelvic pain” and 87% (n=34) using the word “full”.

Table 3.3. *Presence of three key symptoms in identified tools*

Tool name	**Bloating**	**Pelvic and/or abdominal pain**	**Full**
1. Australia awareness Brochure	✓	✓	✓
2 Early detection Australia	✓	✓	
3. Dr Oz	✓	✓	✓
4. Australia symptom diary	✓	✓	✓
5. OC: Australia factsheet	✓	✓	✓
6. TV advert	✓		✓
7. No one knows your body like you do	✓		✓
8. It’s time to shout out	✓		✓
9. OC Canada Knowledge Centre	✓		
10. Think Ovarian!	✓		
11. NZ Gynaecological leaflet	✓	✓	✓
12. Ashkenazi Inheritance:	✓	✓	✓
13. BEAT Symptom Checker	✓	✓	✓
14. BEAT Symptom Tracker	✓	✓	✓
15. Detecting OC: CRUK	✓		✓
16. OC diary: Innermost secrets	✓	✓	✓
17. Ovarian Cancer Action diary	✓	✓	✓
18. Qrisk Ovary			
19. Remember the Symptoms	✓	✓	✓
20. Swollen tummy?	✓	✓	✓

21. Target quiz	✓		✓
22. What women need to know…	✓	✓	✓
23. 15 Symptoms women ignore	✓	✓	✓
24. Break the silence conversation starter	✓	✓	✓
25. CDC diary	✓		
26. NOCC Bookmark	✓	✓	✓
27. NOCC Quiz	✓	✓	✓
28. Ova-1 calendar	✓		✓
29. Ova-1 quiz	✓	✓	✓
30. OC symptoms	✓	✓	✓
31. OC warning signs	✓		✓
32. OCNA app	✓	✓	✓
33. OCNA symptom diary	✓	✓	✓
34. OCNA factsheet	✓	✓	✓
35. OAK Symptom Card	✓	✓	✓
36. Ovations for the future	✓	✓	✓
37. WCN understanding your risk	✓	✓	✓
38. WCN womens guide	✓	✓	✓
39. Mahon (1996) paper			✓
	37 (95%)	27 (69%)	34 (87%)

3.5.6 Guidance on symptomatic presentation

Twenty three (59%) tools provided specific information about time frames in which women should act on potential ovarian symptoms and present to a medical professional. This information varied, with such guidance informing women to seek medical help after symptoms had been present for two weeks all the way up to and over a month (see Table 3.4). Vague information which directs women to simply visit the doctor if they are experiencing symptoms was often included. Seven (18%) tools incorporated information which aimed to facilitate the interaction between patient and doctor (see Table 3.4). These sections provided a list of questions for women to ask their doctor at the appointment, with some encouraging women to fill out their own answers to the questions and others having the questions as prompts to encourage discussion.

Table 3.4. *Number of symptoms and symptom guidance information in identified tools*

Tool name	**Number of symptoms**	**Symptom time frame**	**Frequency of symptoms**	**"new for you", "not normal" or "unusual"**
1. Australia awareness Brochure	10	2 weeks	On most days	✓
2 Early detection Australia	10			✓
3. Dr Oz	4	2 weeks		✓
4. Australia symptom diary	10	4 weeks	12 times	
5. OC: Australia factsheet	10			✓
6. TV advert	7			✓
7. No one knows your body like you do	7			✓
8. It's time to shout out	11	2 weeks		✓
9. OC Canada Knowledge Centre	9	3 weeks		✓
10. Think Ovarian!	9	3 weeks	1 or more symptom	
11. NZ Gynaecological leaflet	11	2 weeks		✓
12. Ashkenazi Inheritance:	3	A month	12 days	
13. BEAT Symptom Checker	4			
14. BEAT Symptom Tracker	25			
15. Detecting OC: CRUK	9	A month	Several times	✓
16. OC diary: Innermost secrets	11	A month	Most days	
17. Ovarian Cancer Action diary	7	A month	Most days	
18. Qrisk Ovary	6			
19. Remember the Symptoms	8		Occur on most days	✓
20. Swollen tummy?	7	A month	12 times	✓
21. Target quiz	4		Most days	
22. What women need to know…	3		Most days	✓
23. 15 Symptoms women ignore	4	More than a few weeks		
24. Break the silence conversation starter	16	2 weeks	2 or 3 of these symptoms	
25. CDC diary	6	2 weeks		
26. NOCC Bookmark	10	2 weeks	Daily	
27. NOCC Quiz	8			
28. Ova-1 calendar	10	4 weeks		✓
29. Ova-1 quiz	4			
30. OC symptoms	9	More than a few weeks		✓
31. OC warning signs	12			
32. OCNA app	4			✓

33. OCNA symptom diary	4	A month	12 days	
34. OCNA factsheet	10			
35. OAK Symptom Card	10	More than a few weeks	Almost daily	
36. Ovations for the future	4	2 or 3 weeks	Daily	
37. WCN understanding your risk	10	2-3 weeks	Almost daily	✓
38. WCN womens guide	10	2-3 weeks	Almost daily	✓
39. Mahon (1996) paper	4			

3.5.7 Theory Mapping

One tool (extraction 25) was explicitly guided by Social Cognitive Theory. However, as previously stated, content of all tools was mapped on to the HBM in order to identify the theoretical coverage. The mapping of relevant items from the data extraction form on to the HBM was achieved through discussion with the supervisory team and led to the identification of 14 items which covered the HBM constructs. The theoretical coverage of the tools is provided in Appendix 6.

Perceived susceptibility: Four items that mapped on to the construct of perceived susceptibility were covered to varying degrees by the tools. Risk factors were well covered, with 27 (69%) tools including some information of this nature, whereas a personal risk status was only generated in three (8%) tools. Ways to reduce risk and information regarding family history were included in 11 (28%) and 10 (26%) tools respectively. Ten tools (26%) failed to cover any items that related to perceived susceptibility. In contrast, two tools (extractions 32 and 37) included information relating to all four of these items.

Perceived severity: One item reflected this construct, with 26 (67%) tools providing facts about ovarian cancer.

Perceived benefits: Three items reflected the construct of perceived benefits. The most well covered of these was 'directly suggesting places to get information', which was addressed in 31 (79%) tools and referred readers to additional resources about the disease which provided information about the importance of early disease diagnosis. The benefits of symptom awareness was addressed in 20 (51%) tools, and confidence

was addressed in 14 (36%) tools. Eight tools (21%) covered all three of these items and four tools (10%) did not cover any of these items.

Perceived barriers: Of the three items which related to the construct of perceived barriers, dispelling myths was the item with the most extensive coverage, with 23 (59%) tools including information of this nature. Fifteen (38%) included information about the vague nature of the symptoms of ovarian cancer, with nine (23%) including information that reduced fear or distress relating to ovarian cancer symptoms and help seeking. Four tools (10%) included information on all three items, with ten tools (26%) not including information on any of these items.

Cues to action: Three items make up the cues to action construct. Information regarding symptom duration was provided in 23 (59%) tools, with 18 (46%) tools providing information regarding symptom frequency. Only 15 (38%) tools provided information regarding both symptom duration and frequency. Thirteen (33%) tools failed to provide information about either item. Information about when to re-visit the GP with symptom concerns was the least covered item, with this included in 11 (28%) of tools. All three items were included in 8 (21%) tools, and 13 (33%) tools failed to include any of these items.

Two tools had the most extensive theoretical construct coverage, with the Australia Awareness Brochure (extraction 1) and the 'Swollen Tummy?' leaflet by UK based charity Target Ovarian Cancer (extraction 20) both covering 12 of 14 theoretical constructs of the HBM (Appendix 6). The two constructs that were not covered by these two tools were both from Perceived Susceptibility. A personal risk status was not generated by either tool. The Australian Awareness Brochure also did not address family history, whilst the Target Ovarian Cancer leaflet did not include information about how to reduce risk. Most of the tools had less extensive theoretical coverage, with an average score of 6.2 (SD 2.8). Four tools had the least theoretical construct coverage (extraction 6, 23, 28 and 39), each covering only two items.

3.6 Discussion

The present study was the first study that systematically identified, reviewed and evaluated existing ovarian cancer symptom awareness tools. The search identified a wide variety of ovarian cancer symptom awareness tools, with variation observed in evidence base, format, content and theoretical coverage. The majority of tools were found on websites, particularly charity websites, with very few tools featuring in peer reviewed articles.

3.6.1 Tool content and quality

A variety of tool formats were identified, with leaflets and symptom diaries the most popular. Whilst varying formats were observed, the majority of tools were printable, possibly reflecting the importance of physical copies of information to users. The use of diagrams, pictures or personal narratives are possible ways of making tools more user friendly (Baumeister and Newman 1994), with such techniques used to varying degrees by the tools. Some tools incorporated a section providing information to facilitate the interaction between patient and doctor. The presence of such initiatives could reflect a possible anticipated lack of confidence that women have in the consultation process. The use of these sections in tools could be a way to address the potential barriers to presentation that have been reported in population based awareness and presentation studies, such as confidence in talking to the GP and feeling embarrassed (Robb et al. 2009). Most of the tools used numerical information to aid information exchange, but the majority failed to provide this numerical information in a consistent format. Discrepancies between using percentages, frequencies and probabilities could lead to confusion for the reader, with consistent formats advantageous (Edwards et al. 2013).

Country of origin is an important piece of information to include in tools because the guidelines for ovarian cancer detection and healthcare systems may vary by country. It is therefore important to state country of origin to make it clear to the reader whether the information is relevant to their healthcare context. This is highlighted by the tools

identified in this search originating from five different countries. Paired with the finding that most tools were found on the internet, this means that people can remotely access information which may not be relevant to them due to country specific differences. Similarly, the majority of tools did not state their target audience. In such cases it could be assumed that the tools are aimed at the general population. Clarification of the target audience is particularly important as different groups of women may have different information needs and preferences in relation to ovarian cancer symptom awareness and presentation. For example, emotional barriers may be more salient in women at increased genetic risk (Kash et al. 1992), as they may be more concerned about the disease as a result of their risk status. The problems arising as a result of omitting country of origin and target audience could be easily rectified by including a short statement on the tools.

The name of funders who contributed to the tool development was expected to have been higher considering the amount of tools originated in the USA, which has a health service that is heavily influenced by pharmaceutical and insurance companies. A similar lack of information was found for sources of information for tool content. When information is provided on the internet this information is particularly important as it can be hard to determine the credibility of information unless sources are explicitly identified. Whilst references for sources of information was lacking in the majority of tools, contact information had much better coverage. Contact information allows users to find out more about the information within the tool and is best placed on the tool itself, as if other websites host the tool, or if the tools are printed, this information could be lost. As two thirds of the tools in this search were printable, this scenario could occur. An additional internet specific problem for tools is that it is not always easy or obvious to identify how old the information is. Whereas information materials that are distributed in community areas or doctors surgeries may be updated and old materials removed, this is not always the case with the internet. A way to overcome this is to provide a version number or date on the tool. The majority of identified tools failed to provide a version number or date and as a result people reading the tools may not know the relevance of the information they are reading.

3.6.2 Ovarian cancer symptom coverage

On average, many more symptoms were included in tools than the number of symptoms stated in current UK guidelines. Including so many symptoms could be overwhelming and deemed excessive considering the current National Institute for Health and Clinical Excellence (2011) guidelines state four key symptoms of ovarian cancer, and the Department of Health Key Messages (2009) state three. One tool included 25 symptoms, when realistically it would not be feasible to ask women to remember or track the presence of all 25 symptoms. Even tracking the average of eight symptoms could be burdensome and potentially anxiety provoking. Including fewer symptoms that reflect the key symptoms could improve the focus of the tool, with this possibly increasing the chance of users remembering the symptom information within the tool.

The search identified that the description of symptoms within tools was not standardised, with large variation observed between tools in the wording of symptoms. A wide variety of phrases were used to convey what should be the same information. This was further demonstrated by the results of the search for the presence of the key symptom terms as highlighted in the UK guidelines. To identify the coverage of key symptoms within the tool the instances of these exact phrases were counted. It could be argued that counting the instances of these exact phrases is unfair for tools which included these three symptoms but used different phrasing. However, having so many different ways of describing a symptom is problematic because it is likely to create confusion, both in health professionals and the public. The use of consistent terms for symptoms could considerably reduce this problem.

3.6.3 Guidance on ovarian cancer symptomatic presentation

The emphasis on symptoms of ovarian cancer representing a change from normal state was often used. This type of guidance shifts the responsibility of identifying symptoms to the individual and encourages them to know their bodies and become familiar with what is normal for them. Similar techniques have been employed in breast cancer

awareness, with women encouraged to know their bodies as opposed to conducting ritualistic self-breast examinations (Austoker et al. 2009, Forster et al. 2013). However, it may be hard to convey this change from normal to the GP if the individual is not very confident. Some tools utilise symptom diaries which could help women feel more confident in discussing the symptoms they have experienced. However, the use of symptom diaries could also lead women to become fixated on possible symptoms, with this having possible negative psychological consequences and leading to hyper-vigilance (Epstein et al. 1997, Norman and Brain 2005). Symptom diaries and tracking of symptoms could be particularly problematic for women at increased genetic risk of developing ovarian cancer, as due to their risk status these women may be more alert to bodily changes, and may associate such changes more readily with possible ovarian cancer (Kash et al. 1992). This scenario emphasises the importance of providing clear information about ovarian cancer symptoms, as well as additional information such as symptom frequency and duration. It is important for women to know what to do if the symptoms are experienced and when to seek medical advice if concerned about possible symptoms.

In the majority of identified tools, there was a lack of specific, action orientated guidance for symptomatic presentation. As discussed, such information is important in enabling women to know whether and when to act if they are experiencing symptoms. This means that while all of the identified tools attempted to raise awareness of the symptoms of ovarian cancer, they have not directly encouraged awareness to be translated into presentation (if symptoms are experienced). Providing information on what specific behaviours to carry out, and how to carry out such behaviours, is an imperative part of a successful health intervention (Soames Job 1988). The absence of guidance about symptomatic presentation is concerning in the context of ovarian cancer, due to the vague nature of the symptoms and the frequency with which they will naturally occur in most women at some time in their life as part of everyday bodily changes (Bankhead et al. 2008, Hamilton et al. 2009). This finding highlights the need for clear medical consensus on symptom frequency and duration information. It could be argued bad practice to simply make women aware of the symptoms without

providing information on what to do if they are experienced. Without such information, fear could be increased (Ruiter et al. 2003, Soames Job 1988).

3.6.4 Theory mapping

There was varying coverage of HBM theoretical constructs within the tools, with information relating to cues to action having the poorest coverage. Whilst risk factors for ovarian cancer were the most well covered item relating to the construct perceived susceptibility, the appropriateness of the risk factors presented may be dependent on the target audience. If the target audience are at increased genetic risk and have undergone genetic assessment to determine their risk, there may be less need to provide information on risk factors such as the role of the BRCA1/2 genes. This example highlights the importance of identifying and understanding the target audience in order to create an effective tool. In addition, the possible psychological impact of including risk factor information in the absence of medical supervision needs to be considered. Provision of facts about incidence and mortality rates for ovarian cancer can highlight the severity of the disease. In the context of symptom awareness tools, ovarian cancer statistics may encourage people to be more aware of symptoms or to act in a more timely fashion if they are experienced; however, they could discourage people due to fear or worry. Benefits and barriers were covered by most of the tools, although items relating to reducing fear/distress were not well covered. Benefits and barriers are areas that could be easily included if tools are developed based on theory because the theoretical understanding of the determinants of awareness and presentation of the target audience would outline the benefits and barriers perceived by that population.

Of the tools that had the most extensive theoretical construct coverage, neither provided a personal risk status. Awareness of personal risk status is important as the HBM outlines that people are more likely to engage in health behaviours if they believe they are personally susceptible (Rosenstock et al. 1988). However, it is a complex process to accurately generate a personal risk status of developing ovarian

cancer and would not be feasible for most tools. It would also be unethical to provide this information in a stand-alone awareness tool, as this type of information should be provided in consultation with a medical professional.

3.6.5 Study limitations

A limitation of the current search, is that it is out dated almost immediately. Since the search was conducted, the CDC national campaign for gynaecological cancers has added to its materials, with an ovarian cancer symptom awareness tool now included in the campaign. While this is a positive step for theory based ovarian cancer symptom awareness tools, the tool development was based on methods including American women from the general population and the information provided may not be relevant to the UK context or women at increased genetic risk.

Whilst it was deemed necessary and appropriate to use a newly constructed data extraction form, it was not validated. Documentary analysis may be a useful method to consider when similar searches are carried out in the future (Sixsmith and Murray 2001). Documentary analysis allows for systematic and detailed analysis of identified written materials and benefits from enabling researchers to analyse documents which take different formats and have varying content (Appleton and Cowley 1997, Sixsmith and Murray 2001). Due to the current search being the first systematic search of symptom awareness tools, the search protocol and data analysis were driven by experience with traditional systematic reviews and the research objectives (to identify and evaluate existing ovarian cancer symptom awareness tools). Based on the type of tools that were identified in this current study, with hindsight, documentary analysis could have been applied and should be considered in similar searches in the future. Documentary analysis would enable a systematic and structured analysis of tools, which could complement the systematic nature of the identification of tools (Appleton and Cowley 1997).

A further limitation could be the search strategy itself, as it aimed to identify existing tools via peer reviewed articles and the internet. This search method could therefore have excluded tools that are physically available in places such as GPs, hospitals and support groups. Whilst it was anticipated that most tools of this nature would also be hosted on websites, it was not feasible to identify tools that may exist in purely physical formats in such places.

The use of UK guidelines for symptom information could also be a limitation, especially considering that the identified tools originated from five different countries. However, the symptoms in country-specific guidelines are comparable to those for the UK and as the research concerns awareness in UK women, it was decided that the UK guidelines should be the main focus. This enables the findings to contribute to the development of a symptoms awareness tool that will be directly relevant for the target population.

3.6.6 Implications and future research

Very few of the ovarian cancer symptom awareness tools identified in the current search had an explicit theoretical foundation. When the tools were mapped on to the HBM to identify theoretical groundings, none of the tools addressed all of the theoretical constructs. This could reflect potential inefficiency in identified tools to increase symptom awareness and encourage timely presentation.

In order to be effective, symptom awareness tools should not only state the symptoms of ovarian cancer, but also provide information about what to do if symptoms are experienced. This could be an important step in translating symptom awareness into presentation. This search has highlighted that multiple ovarian cancer symptom awareness tools exist and that they are not consistent. If tools are created, based on guidelines such as the MRC guidelines for complex interventions (Craig et al. 2008b) and described in full, then the formula for creation can be replicated, whereby the successful components can be followed and unsuccessful ones avoided (Jones et al. 2013). In future, collaborations between governments, researchers and charities could

lead to well-developed information being easily delivered to the target populations. This would be especially useful due to many of the tools being found on charity websites, and the increasing use of the internet when searching for health information (Cooper et al. 2012). Such collaborations could be a possible for overcoming the flaws that were found in many of the tools, such as failure to identify the target audience, presence of potentially overwhelming number of symptoms, and failure to elaborate or action plan if symptoms are experienced.

3.6.7 Summary

The present search has highlighted that although a variety of symptom awareness tools already exist there is currently no theory based awareness tool for women at increased genetic risk of ovarian cancer. Development of a tool for women at increased genetic risk would enable the information needs of this population to be addressed, at the same time as raising awareness and encouraging appropriate symptomatic presentation without increasing distress. The needs of women at increased genetic risk will be explored in subsequent chapters, with surveys and interviews used to explore awareness, beliefs, confidence and worry in relation to ovarian cancer. In order to identify whether the health beliefs are unique to women at increased genetic risk, health beliefs will also be explored in relation to a sample of women from the general population. It is essential to understand the needs of the specific target audience so that they can be addressed within the tool, with interventions that follow this process more likely to be successful (Austoker et al. 2009).

4 Determinants of anticipated presentation with ovarian cancer symptoms in women from different risk populations

4.1 Chapter overview

Previous literature on awareness, presentation and beliefs about cancer has focused mainly on the general population. Few studies have been conducted involving samples of people at increased genetic risk for ovarian cancer, where symptoms are vague (Evans et al. 2007). A cross-sectional questionnaire study is presented that tests the ability of the Health Belief Model (Rosenstock et al. 1988) to identify variation in anticipated time to presentation to primary care with ovarian cancer symptoms. The determinants of anticipated presentation to a healthcare professional with suspected ovarian cancer symptoms in a sample of women at increased genetic risk of ovarian cancer was compared to determinants identified in a general population sample. The findings will be used to guide the content of a symptom awareness tool with tailored content for women at increased genetic risk of ovarian cancer.

4.2 Introduction

A study that explores and compares the determinants in an increased genetic risk population and a general population sample would allow for recommendations to be made based on contributors to anticipated presentation that are unique to each group. This exploration process is important as interventions are more likely to be effective if they are relevant to the user (Craig et al. 2008b). Understanding of anticipated presentation behaviour will also provide insight into what the possible impact on health services would be if awareness is increased, and early presentation is promoted.

4.2.1 Health Belief Model constructs

Cancer worry relates to thoughts of developing the disease and the impact these thoughts have on mood and daily function (Andersen et al. 2007). Worry is thought to

play an important part in help seeking decisions for women at increased genetic risk of ovarian cancer, and its conceptualisation within health behaviour theory is therefore important. Although the original HBM does not explicitly include the construct 'worry', it can be incorporated into the model through the concept of perceived threat. In previous studies, perceived threat has been the combination of perceived susceptibility and perceived severity (Glanz et al. 2008, Rosenstock et al. 1988). However, the operationalization of the perceived threat concept allows for the integration of the concept 'worry'. The role of worry in the HBM is discussed by Hay et al. (2005), where worry is considered to be an affective representation of perceived susceptibility. Hay et al. (2005) conducted a review of empirical literature on the role of cancer worry in screening, in which theoretical approaches to understanding and conceptualising worry were discussed. Cancer worry was proposed as an aspect of susceptibility or severity, with measures of worry embedded within susceptibility or severity (Hay et al. 2005). Worry was therefore incorporated into the HBM in the current study (see Figure 4.1).

The conceptualisation of the constructs in the HBM are shown in Figure 4.1. Constructs are grouped under the headings Individual Perceptions, Modifying Factors and Likelihood of Action. Individual perceptions are linked to the outcome of anticipated presentation (likelihood of behaviour) indirectly via perceived threat. Perceived threat is a latent, unobserved variable, and is the combination of the Individual Perceptions items. Individual Perceptions items are perceived susceptibility and ovarian cancer worry (see Figure 4.1).

In the HBM, knowledge (also known as symptom recognition) is a modifying factor that is indirectly linked to the outcome via the other HBM components. Confidence in symptom detection represents the construct of self-efficacy, and is also a modifying factor linked to the outcome via other HBM components. Demographic variables including age, education level, relationship status, and ethnicity are also modifying factors that have indirect effects on the outcome through the other HBM constructs.

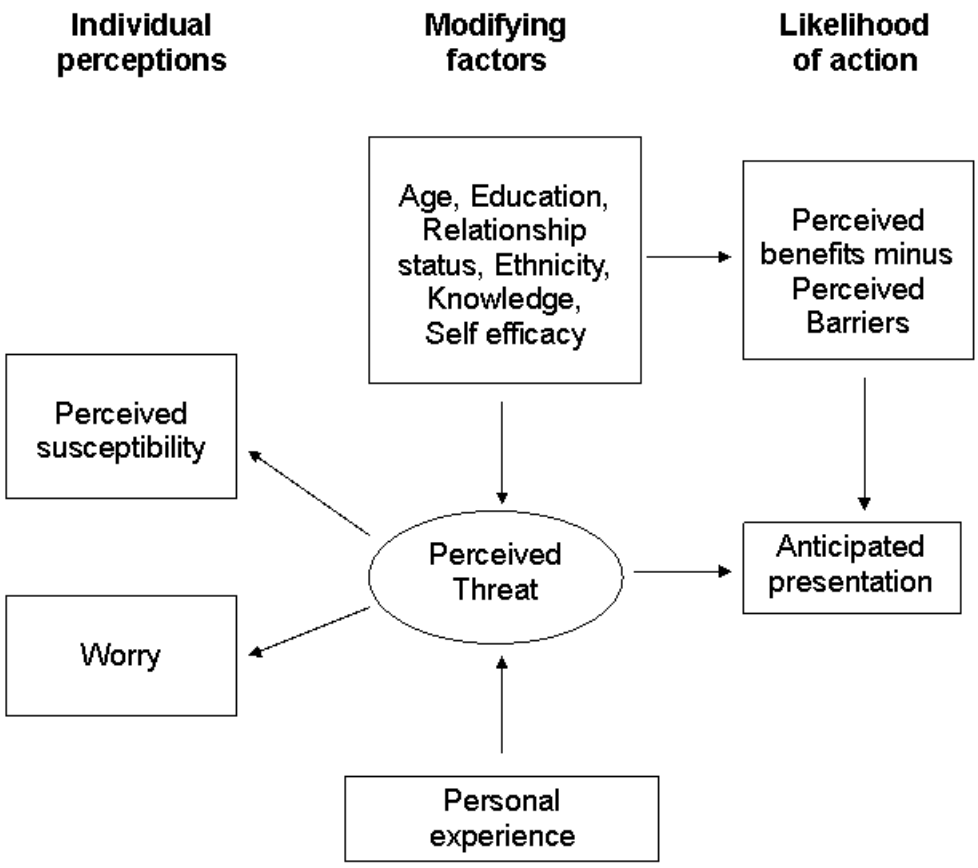


Figure 4.1. The Health Belief Model, adapted for this study from Rosenstock et al. (1997)

Cues to action are linked to outcome indirectly via perceived threat, with cues increasing perceptions of threat. Perceived benefits and barriers to presenting with suspected ovarian cancer symptoms are a measure of likelihood of action, with this construct linked directly to outcome. In summary, the HBM proposes that two variables directly influence likelihood of anticipated presentation behaviour: (1) perceived threat, and (2) the belief that the benefits of carrying out the action outweigh the barriers.

4.2.2 The role of worry in the HBM

Explanations for the patient interval in ovarian cancer presentation can be considered based on the HBM model. The impact of worry should be considered both in terms of women's psychological wellbeing as well as the potential over burdening of the health system by women concerned about possible symptoms (Evans et al. 2014). If worry is

determining presentation it is important to identify mechanisms through which this can be reduced or managed, so that ovarian cancer symptom information can be given to women without harming their psychological well-being. The role that worry plays in presentation to primary care with suspected ovarian cancer symptoms in an increased genetic risk sample is not currently known. Evidence suggests that a higher level of ovarian cancer worry is associated with higher perceived risk in women with a family history (Lerman et al. 1994). Ovarian cancer worry and the number of affected relatives has been found to be positively associated with ovarian cancer screening uptake in women at increased risk for ovarian cancer (Andersen et al. 2002, Schwartz et al. 1995a). For women at increased genetic risk of ovarian cancer, worry may therefore be a contributor to symptom-driven presentation times. Although it is possible to extrapolate from studies of ovarian cancer screening uptake, specific research needs to be undertaken in order to understand the nature and direction of the influence of worry on symptomatic presentation to primary care in women at increased genetic risk.

4.2.3 Gaps in knowledge

The need for a test of the entire HBM model for anticipated presentation of ovarian cancer symptoms will be addressed in the current study. Structural equation modelling (SEM) will be used to test the HBM model and to identify correlates of anticipated time to presentation. SEM is a statistical technique that allows for the simultaneous test of multiple causal relations (Kline 2011) and can be used to test theoretical models such as the HBM in novel health contexts. SEM is an advantageous method as it allows for a deeper exploration of the relationships between variables than standard regression analysis. Particularly, SEM allows for theoretical models to be tested, for simultaneous analysis to be conducted, and for latent (unobserved) variables to be modelled.

4.2.4 Aims of the present study

The HBM was used to identify correlates of anticipated presentation in a sample that included women at increased genetic risk of ovarian cancer and women drawn from

the general population. As there is evidence for health beliefs to be different among different risk populations (Chapter 2), the study also aimed to test whether the model was invariant across two risk groups. If the model is adequate the determinants of the two risk groups will be explored separately in order for comparisons to be made. In order for this to be achieved, a dataset comprising women from the general population (who are at, or near population risk) and women at increased genetic risk of ovarian cancer was analysed. Practically, this could aid decisions about whether tailored interventions are needed for the general population and women at increased genetic risk. Based on research in other health contexts and empirical evidence, it was expected that the HBM would be a good fit for anticipated symptomatic presentation behaviour in ovarian cancer. It was hypothesised that susceptibility and worry would form part of the same latent construct. The increased genetic risk group were hypothesised to differ from the general population group on the HBM constructs, with higher levels of worry, knowledge, perceived susceptibility, perceived threat, benefits and barriers to presentation, more personal experience with ovarian cancer, and earlier anticipated time to presentation than the general population group. The model was hypothesised to be invariant by group.

4.3 Methods

Recruitment and study procedures are presented separately below for the increased genetic risk and general population samples. Ethical approval for the study was received from Cardiff University School of Medicine Research Ethics Committee (see Appendix 7).

4.4 Increased genetic risk sample

4.4.1 Participants

Participants were recruited by the PhD student from the database of participants in PsyFOCS (psychological evaluation of familial ovarian cancer screening) or via an ovarian cancer charity (Ovacome). PsyFOCS was the psychological partner study of UKFOCSS, a large scale UK clinical study involving over 200,000 women which aimed to evaluate the effectiveness of screening in women at increased genetic risk for ovarian

cancer (Jacobs et al. 1999). From the UKFOCSS sample, 3224 women were invited to participate in PsyFOCS, which concerned the psychological and behavioural impact of ovarian cancer screening for women at increased familial risk of ovarian cancer (Brain et al. 2012). A total of 1,999 women participated in PsyFOCS, all of whom were identified as being at increased risk of familial ovarian cancer based on a detailed pedigree-based assessment carried out at familial cancer clinics. Of the PsyFOCS sample, 446 participants accepted the offer of an end of study summary, which included an opportunity to register interest in a further study on ovarian symptom awareness. Further participants were recruited from the UK based charity Ovacome, which included a piece about the study in the letters section of their summer 2012 newsletter. The piece asked readers to register interest in receiving information on research concerning ovarian cancer symptom awareness via an email address. Twenty nine people registered interest in this way.

4.4.2 Inclusion/exclusion criteria

Respondents who indicated that they had had a procedure to remove one or both ovaries were excluded from analysis due to the potential confounding influence on their awareness and beliefs as a result of this reduction in ovarian cancer risk.

4.4.3 Procedures

Survey data were collected from October-December 2012. A study pack including an information sheet, consent form, questionnaire (see Appendix 8) and stamped pre-addressed return envelope was sent to women who had registered interest in taking part in the study. A web address for the online version of the survey was also included in the study pack for those who wished to complete it electronically.

4.5 General population sample

4.5.1 Participants

Women aged over 50 years were recruited using random probability sampling as part of the International Cancer Benchmarking Partnership (Forbes et al. 2013). Computer assisted telephone interviews were completed by 1,043 women.

4.5.2 Inclusion/exclusion criteria

Women aged over 50, residing in Wales and able to give verbal consent were included. Women who had a personal diagnosis of ovarian cancer, or who had had their ovaries removed were excluded from this sample in a screening question at the start of the questionnaire (Brain et al. 2014).

4.5.3 Procedures

Random probability sampling was used to achieve a population-representative sample using electronic telephone directories as the sampling frame. Where more than one person was eligible, the Rizzo method was used to randomly select one person to be interviewed, thereby giving an equal chance of selection to all eligible people living in the household (Rizzo et al. 2004). Survey data were gathered by trained interviewers using computer assisted telephone interviews (see Appendix 9 for questionnaire). Recruitment and data collection was outsourced to the company IPSOS-MORI.

4.5.4 Measures

Individual perceptions

Perceived susceptibility

Perceived susceptibility was measured using the question "Compared to most other women your age, how likely do you think it is that you will get ovarian cancer at some time in your life?" (adapted from Tyndel et al. (2007). Responses were: much less likely, a little less likely, about the same, a little more likely, and much more likely.

Ovarian cancer worry

Ovarian cancer worry was measured with the Ovarian Cancer Worry Scale (Andersen et al. 2007), which is an adaptation of the Cancer Worry Scale (Lerman et al. 1991). The Ovarian Cancer Worry Scale consists of three questions, which assess frequency of worry ("How often, if at all, do you worry about getting ovarian cancer someday?"), the impact this has on mood ("How often, if at all, does your worry about getting ovarian cancer affect your ability to perform your daily activities?") and the impact on daily functioning ("How often, if at all does your worry about getting ovarian cancer

affect your ability to perform your daily activities?"). Questions were answered on a five point scale, where 1=not at all, 2=rarely, 3=sometimes, 4=often and 5=almost all the time, giving the scale a range of 3-15. (Cronbach's α for increased genetic risk sample =0.80, for general population = 0.69).

Modifying factors

Knowledge (Ovarian cancer symptom awareness)

Eleven statements were included in the questionnaire to assess ovarian cancer awareness and were adapted from the ovarian cancer awareness measure (CAM) (Simon, Wardle et al. 2012). The question "Do you think the following could be a sign of ovarian cancer?" was followed by 11 symptoms, with the response options of 'yes', 'no' and 'don't know'. Responses 'no' and 'don't know' were combined, with responses coded as 1=yes and 0=no, creating a knowledge score from 0-11. The 11 symptoms were: a persistent pain in the abdomen, a persistent pain in the pelvis, vaginal bleeding after the menopause, persistent abdominal bloating, increased abdominal size on most days, not wanting to eat because feel persistently full, difficulty eating usual amounts of food on most days, passing more urine than usual, a change in bowel habits, extreme tiredness and back pain. Items were adapted from the validated ovarian CAM (Simon et al. 2012b) and included less common symptoms (change in bowel habit, fatigue, back pain) to reflect the UK Department of Health's 'Key Messages' on ovarian cancer for health professionals and the public (Department of Health 2009).

Self-efficacy (confidence in symptom detection)

Confidence in symptom detection was measured using the question "How confident are you that you would notice a symptom of ovarian cancer?" Scores ranged from 1 (not at all) to 4 (very confident) (Simon et al. 2012b).

Demographic variables

Participants provided their age in years and the highest level of education they attained (coded as: up to 16 years old, post 16 (e.g. BTEC, NVQ, HND, HNC, A levels),

undergraduate college or university, graduate or post graduate school, other) and their relationship status (married or cohabiting, in a relationship but not married or cohabiting, widowed and not living with another partner, divorced and not living with another partner, single). Participants indicated their ethnic origin ("How would you describe your ethnic origin?") according to the following categories: English/Welsh/Scottish/ Northern Irish/British, Irish, Gypsy or Irish Traveller, White and Black Caribbean, White and Black African, White and Asian, Indian, Pakistani, Bangladeshi, African, Caribbean, Arab, Chinese and Other.

Cues to action

Personal experience with ovarian cancer

Increased genetic risk group: The external cue of experience with ovarian cancer was measured with the question "Have you, or any friends or family members been diagnosed with ovarian cancer?" Response options were; yes (self), yes (friend or family member; if yes to this option, what is your relationship to this person?), and no. Those who responded 'yes self' were excluded as this sample does not include women diagnosed with cancer. The responses were then coded as 0= no ovarian cancer experience, 1= ovarian cancer experience.

General population group: Women were asked "Have you, or any friends or family members that are close to you, ever been diagnosed with ovarian cancer?" Those who indicated that they had had a diagnosis of ovarian cancer were not given the survey. Response options were coded as 0= no experience of ovarian cancer and 1= experience of ovarian cancer.

Likelihood of action (perceived benefits and barriers)

Eleven items were used to develop scales for perceived benefits and barriers (Brain et al. 2014, Forbes et al. 2013, Simon et al. 2012b). For eight of the items, participants were asked to "indicate whether any of the following might put you off going to the doctor if you thought you had a symptom of ovarian cancer". The eight items were (1) I

would be too embarrassed, (2) I would be too scared, (3) I would be too worried about wasting the doctor's time, (4) I would have too many other things to worry about, (5) I would be worried about what the doctor might find, (6) I wouldn't feel confident talking about my symptom with the doctor, (7) it would be difficult for me to get an appointment and (8) I would be too busy to make time to go to the doctor. The response options for these eight items were yes often (code =3), yes sometimes (code = 2) and no (code =1). For the remaining three items, participants were asked "please indicate how much you agree or disagree with each statement". The statements were (9) If ovarian cancer is diagnosed early, it can be treated more successfully, (10) If found early, ovarian cancer can often be cured and (11) going to the doctor as quickly as possible after noticing a symptom of ovarian cancer could increase chances of surviving. The response options for these items were strongly disagree (code = 1), tend to disagree (code = 2), tend to agree (code=3), strongly agree (code =4).

Likelihood of behaviour *(Anticipated presentation time)*

Participants were asked "If you had a symptom that you thought might be a sign of ovarian cancer, how long would it take you to go to the doctors from the time you first noticed the symptom?"(Simon et al. 2012b). Response options were; I would go as soon as I noticed, up to one week, over one week up to two weeks, over two weeks up to three weeks, over three weeks up to four weeks, and more than a month. Responses were re-coded as '0= I would go as soon as I noticed, no delay' and '1= any delay, up to a week to more than a month'.

4.5.5 Data analysis

Data screening identified one participant reporting a score of 15 for ovarian cancer worry (sample mean = 6.15 (SD= 1.94)). This case was removed from analysis due to varying from the mean and standard deviation of the rest of the sample. The case was removed in screening and cleaning and therefore was not included in the data analysis. Sample characteristics and descriptive statistics are presented for the two risk groups separately in order to show the profiles of the two risk groups. Separate principal

components analyses with varimax rotation on *a priori* HBM items were conducted for the two groups in order to identify the salient factors contributing to the HBM scales for each risk group.

The increased genetic risk sample (N=283) and general population sample (N=1,043) were combined (N=1,326) for an overall test of the structural relations in the HBM model. Initially, a measurement model was created in order to observe whether perceived susceptibility and ovarian cancer worry were part of the same latent trait complex perceived threat. A full structural equation model (SEM) was then used to examine relations between this latent complex and other constructs. Specifically, a SEM was computed investigating whether individual perceptions, modifying factors, perceived threat, cues to action and likelihood of action predicted the behavioural outcome of anticipated time to presentation. Constructs were subject to preliminary screening to test the normality of the distributions before fitting the model. All constructs met the assumptions of normality. A baseline model was created, with the same parameters used for configural models for analysis of invariance. The invariance tests examined equivalence of model parameters (intercept, regression coefficients, means, covariance and residuals) between the two risk groups.

Fit of the overall model was determined from five fit indices: (1) chi-square (CMIN) not significant at the 0.05 level of significance indicates a model with good fit (Byrne 2009); (2) relative chi-square (CMIN/df) with a ratio within 3:1 indicates good fit (Kline 2011); (3) a comparative fit index (CFI) and (4) Tucker-Lewis Index (TLI) greater than 0.95 indicates a model with good fit (Hu and Bentler 1999), (5) a standardised root-mean square error of approximation (RMSEA) close to 0.06 indicates good fit (Hu and Bentler 1999).

4.6 Results

Results are presented in the following sections covering (1) sample characteristics, (2) principal components analysis (PCA) of HBM items, (3) SEM for all participants, and (4) SEM for increased genetic risk and general population groups separately.

4.6.1 Response rate in the increased genetic risk group

The questionnaire was sent to 475 women, of whom 164 (35%) did not return the form and 28 (6%) were excluded due to having undergone a procedure to remove their ovaries. The final sample was 283, giving a final response rate of 63%. Twenty nine respondents were recruited from the Ovacome newsletter (10%) and the remaining 254 (90%) participants from the PsyFOCS recruitment pool. Four participants completed the electronic version of the survey.

4.6.2 Response rate in the general population

As a result of the data collection method, it is hard to estimate true response rates for this sample (Brain et al. 2014). Random digit dialling means it is not possible to estimate the number of eligible participants. Of the 1385 female respondents, 315 were excluded due to a personal history of ovarian cancer or having had a procedure to remove one or both ovaries. The final sample was 1043.

4.6.3 Sample characteristics of the two risk populations

Sample characteristics for both risk groups are provided in Table 4.1. All comparisons were significantly different. The majority of the increased genetic risk group respondents were over 50, were married or cohabiting and were educated beyond age 16. The general population responders were mainly in the 50-69 years old age bracket, and there was an almost even split of participants who were married or cohabiting and not married or cohabiting. Most of the general population sample was educated up to age 16.

Table 4.1. *Sample characteristics and comparison statistics of the increased genetic risk and general population*

Variable	Increased genetic risk (n=283)	General population (n=1043)	Statistic
Age, years n (%)	m=52.87 (sd=10.40)	m=64.53 (sd=9.49)	$t_{(1313)}$=-17.86, p<0.001
30-49	123 (44%)		
50-69	135 (48%)	735 (71%)	
70+	22 (8%)	300 (29%)	
Relationship status n(%)			$x^2_{(1)}$=53.81, p<0.001
Married or cohabiting	209 (74%)	515 (49%)	
Education n(%)			$x^2_{(2)}$=66.11, p<0.001
Up to 16	81 (29%)	570 (56%)	
Secondary	105 (37%)	254 (25%)	
Degree and above	96 (34%)	197 (19%)	
Anticipated time to presentation n (%)	m=0.59 (sd=0.49)	m=0.51 (sd=0.52)	$x^2_{(5)}$=30.38, p<0.001
I would go as soon as I noticed	115 (41%)	507 (51%)	
Up to 1 week	46 (17%)	239 (24%)	
Over 1 up to 2 weeks	43 (16%)	101 (10%)	
Over 2 up to 3 weeks	23 (8%)	51 (5%)	
Over 3 up to 4 weeks	28 (10%)	57 (6%)	
More than a month	22 (8%)	43 (4%)	
Confidence in symptom detection n (%)	m=2.20 (sd=0.70)	m=2.34 (sd=0.93)	$t_{(586)}$=-3.01, p<0.01
Not at all	41 (14%)	213 (21%)	
Not very	151 (54%)	350 (34%)	
Fairly	85 (30%)	347 (34%)	
Very	5 (2%)	108 (11%)	
Perceived susceptibility n (%)	m=4.21 (sd=0.71)	m=2.40 (sd=0.95)	$t_{(579)}$=-34.04, p<0.001
Much less likely	2 (1%)	194 (21%)	
A little less likely	1 (0.5%)	276 (29%)	
About the same	30 (11%)	392 (41%)	
A little more likely	144 (53%)	69 (7%)	
Much more likely	94 (34.5%)	17 (2%)	
Experience with OC n (%)			$x^2_{(1)}$=437.36, p<0.001
Yes	257 (91%)	238 (22%)	
Symptom knowledge m (sd, range)	6.1 (0-11, 2.6)	6.9 (0-11, 2.7)	$t_{(1324)}$=--4.28 ,p<0.001
Worry m (sd, range)	6.2 (1.9, 3-12)	5.3 (1.4, 4-12)	$t_{(495)}$=-6.24, p<0.001

Note: valid % reported in cases where data were missing. OC= ovarian cancer

Under half of the increased genetic risk sample (41%) anticipated presenting immediately after noticing a possible ovarian cancer symptom, with 51% of the general population anticipating presenting immediately. When asked about confidence levels in detecting possible symptoms of ovarian cancer, 32% of the increased genetic risk group, and 35% of the general population group felt confident. Only 2% of the increased genetic risk group and 11% of the general population reported feeling 'very confident' in detecting a symptom. The majority of the increased genetic risk sample (88%) perceived that they were more likely to get ovarian cancer compared to other women of the same age, with only 1% perceiving they were less likely to get ovarian cancer. Only 9% of the general population perceived that they were more likely to get ovarian cancer compared to other women of the same age. Most of the increased genetic risk respondents had personal experience of ovarian cancer (friend or family), whereas most of the general population sample had no personal experience of ovarian cancer. The average ovarian cancer worry score for the increased genetic risk sample was significantly higher than that in the general population sample.

4.6.4 Knowledge of ovarian cancer symptoms

The most frequently recognised ovarian cancer symptom was persistent abdominal bloating (n =247, 89%) for the increased genetic risk group, and vaginal bleeding after the menopause (n= 912, 92%) for the general population group (see Figure 4.2 for all symptoms). Passing more urine than usual was least recognised by both the increased genetic risk (n=76, 28%) and general population (n= 334, 38%) groups. The general population group had significantly better symptom knowledge (reported in Table 4.1), with an average knowing of 6.9 of symptoms, versus the increased genetic risk group knowing 6.1 symptoms.

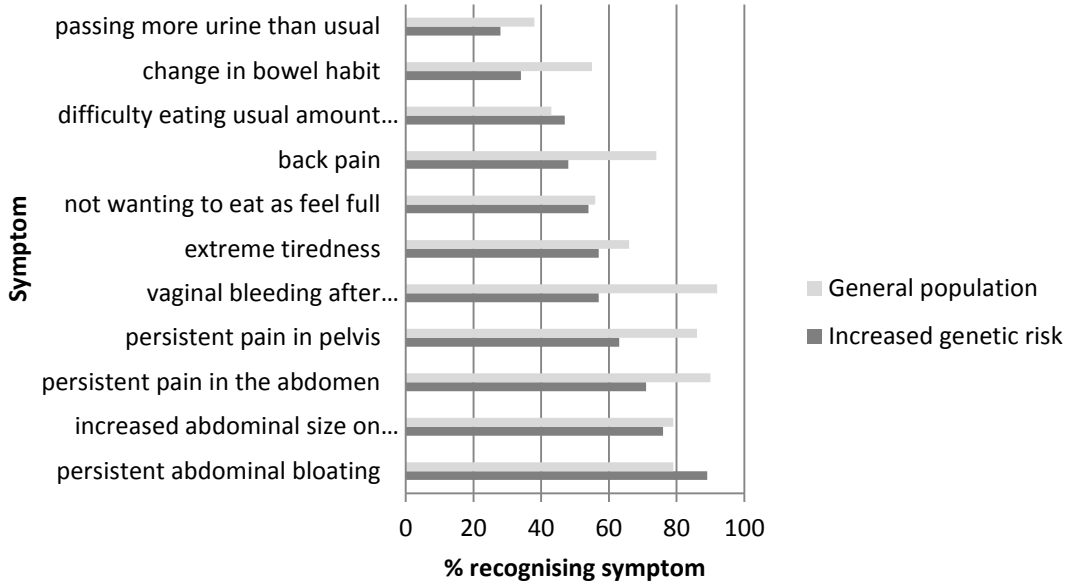


Figure 4.2. Recognition of individual ovarian cancer symptoms for both risk populations (valid % presented in cases where data were missing)

4.6.5 Principal components analysis of HBM items

Increased genetic risk group

Four factors were extracted which explained a total 63.12% of the variance (see Appendix 10). The factors were labelled Perceived Barriers (26.60% of variance, eigenvalue 3.19, Cronbach's a=0.72, range 6-8, mean score 7.94, sd=2.17), Perceived Benefits (16.42% of variance, eigenvalue 1.97 Cronbach's a= 0.81, range 3-12, mean score 10.04, sd=1.90), Fear (11.57% of variance, eigenvalue 1.39 r=0.72, p<0.001) and Perceived Susceptibility (8.52%, eigenvalue 1.02). Fear referred to fear of what might be discovered (see Factor III in Appendix 10), therefore the purpose of SEM, the factor-derived scales for fear and perceived barriers were combined to create a Perceived Barriers construct (8 item scale Cronbach's a= .75). As the HBM defines the likelihood of action as perceived benefits minus barriers, calculations were made in SPSS version 20 creating a likelihood of action scale which ranged from -15 to 4. Scores at the negative end of the likelihood of action scale represented more perceived barriers than benefits, and scores at the positive end of the scale indicated more perceived benefits than barriers.

General population group

Four factors were extracted which explained 57.84% of the variance (see Appendix 11). The factors were labelled Emotional Barriers (23.96% of variance, eigenvalue 2.88, Cronbach's a=0.67, range 5-15, mean score 6.02, sd=1.65), Practical Barriers (15.71% of variance, eigenvalue 1.89, Cronbach's a=0.59, range 3-9 mean score 3.51, sd=1.02), Perceived Benefits (9.78, eigenvalue 1.17, Cronbach's a= 0.68, range 3-12 mean score 10.94, sd=1.29) and Perceived Susceptibility (8.39% of variance, eigenvalue 1.01). The emotional barriers and practical barriers were combined to create a perceived barriers construct for use in SEM (8 item scale Cronbach's a= .72). The Likelihood of Action scale was created in the same way as for the increased risk group (range -10 to 4).

4.6.6 Structural equation modelling for total sample

Prior to the SEM, a measurement model was created in order to observe whether perceived susceptibility and ovarian cancer worry were part of the same trait complex. The measurement model showed the conceptualisation of the perceived threat component. The other components of the HBM were then added in order to create the structural model. The measurement model, consisting of perceived susceptibility, ovarian cancer worry and the latent variable perceived threat can be seen embedded in the structural model in Figure 4.3. The full structural equation model for the total sample is shown in Figure 4.3. The goodness of fit statistic was significant ($_x^2$=115.68, df=11, p<.05), indicating a bad fit. Fit indices were CFI=.90 and RMSEA=.09, indicating marginal good fit, with TLI=.66 and relative chi-square x^2/df= 10.52 indicating bad fit (see Appendix 12 for correlation matrix of model variables).

Perceived susceptibility and ovarian cancer worry were both significant indicators of perceived threat in the measurement model. The likelihood of action construct, which consists of perceived benefits and barriers, was significantly negatively correlated with anticipated presentation. Participants who perceived more benefits than barriers to presentation were therefore more likely to report earlier anticipated presentation.

Older participants perceived significantly more benefits than barriers to presentation, and perceived significantly lower threat.

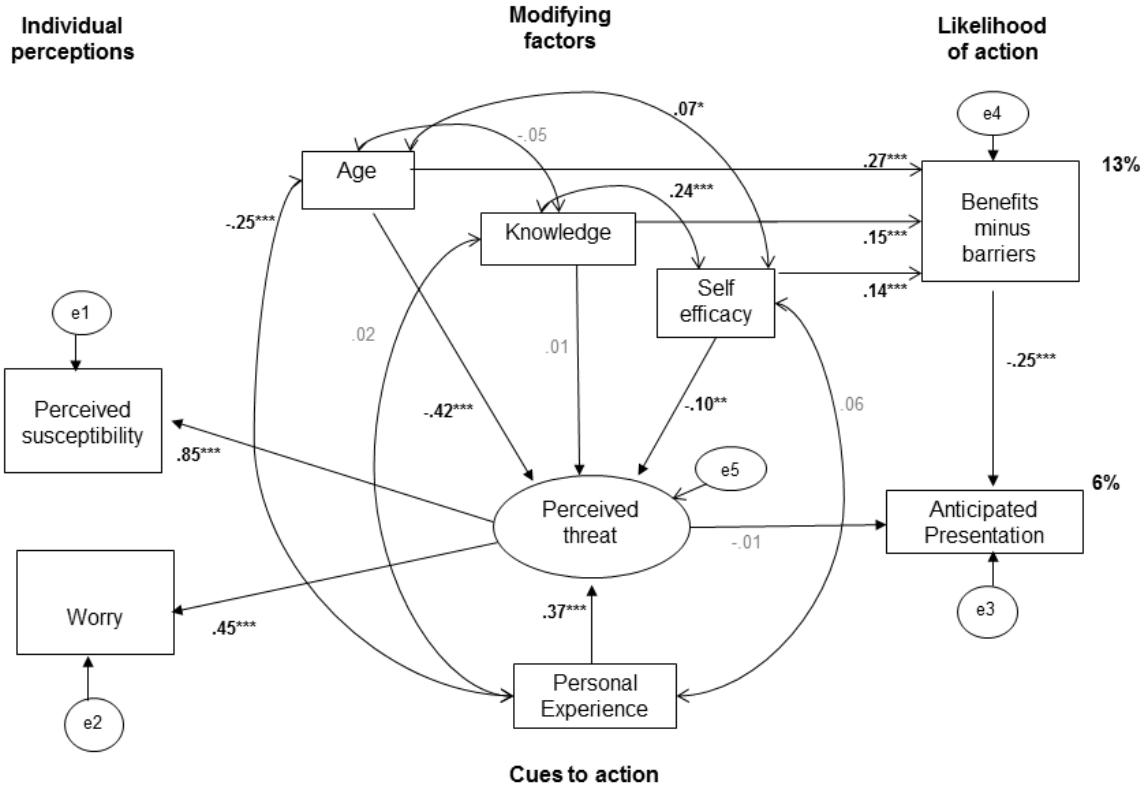


Figure 4.3. The Health Belief Model applied to anticipated presentation to medical professional with potential ovarian cancer symptoms for all participants. Values displayed are standardised regression weights (→), covariances (↔) and percentage of variance accounted for. *p<0.05. **p<0.01, ***p<0.001. Grey font indicates paths with no significant associations.

Participants reporting higher self-efficacy perceived significantly more benefits than barriers to presentation, and also had lower perceived threat. Participants with more personal experience of ovarian cancer had higher levels of perceived threat. There was no significant correlation between perceived threat and anticipated presentation. Knowledge was not significantly correlated with either perceived threat or likelihood of action; however, it was positively correlated with self-efficacy. Covariances for personal experience were not significantly correlated with variables within the model. Age, knowledge and self-efficacy accounted for 13% of the variance in perceived benefits minus barriers. The constructs of the HBM predicted 6% of variance in anticipated presentation.

4.6.7 Tests of invariance across the two risk populations

Analysis of invariance was carried out to identify differences in fit between the increased genetic risk and general population groups. The increased genetic risk and general population data were analysed simultaneously in a configural model with the same parameters as the baseline model. Goodness of fit statistics for the configural model were x^2(118.28), df=24, p<.001, x^2/df= 4.93, CFI=.77, RMSEA=.05. Constraints were then applied to the parameters to test invariance in loadings and structure across groups (see Table 4.2). Δx^2 indicated invariance for model 1, indicating that when the structural weights (i.e., path coefficients) were constrained the model was variant between groups. When other constraints were successively added (intercepts, means, covariances, residuals, see Models 2-5) the model was invariant. ΔCFI indicated the model was not invariant across groups for all models. These results indicated that model fit could be poor because the nature of associations among variables (path coefficients) differed between the increased genetic risk and general population group.

Table 4.2. SEM invariance analysis across different risk populations

	x^2	*Df*	Δx^2	Δ*df*	CFI	ΔCFI
Configural model	118.28	24			.77	
Model 1	132.57	32	**14.29**	8	.75	.02
Model 2	201.47	33	83.19*	9	.58	.19
Model 3	793.96	37	675.68*	13	.00	.77
Model 4	1076.58	47	958.30*	23	.00	.77
Model 5	1236.45	49	1118.17*	25	.00	.77

Note. Δx^2 =difference in x^2 between models; Δ*df*= difference in degrees of freedom between models; ΔCFI = difference in CFI between models. Numbers in bold indicate goodness of fit. Model 1= constrained structural weights. Model 2= constrained structural weights and intercepts. Model 3 = constrained structural weights, intercepts and means. Model 4= constrained structural weights, intercepts, means and covariance's. Model 5 = constrained structural weights, intercepts, means, covariance's and residuals. *p<.05.

4.6.8 Structural equation modelling for separate groups

Due to the tests of invariance indicating that the model did not hold its meaning across groups, separate SEMs were tested in the individual groups to identify model

differences between the two risk groups. The results of the increased genetic risk SEM and the general population SEM are presented together in Figure 4.4.

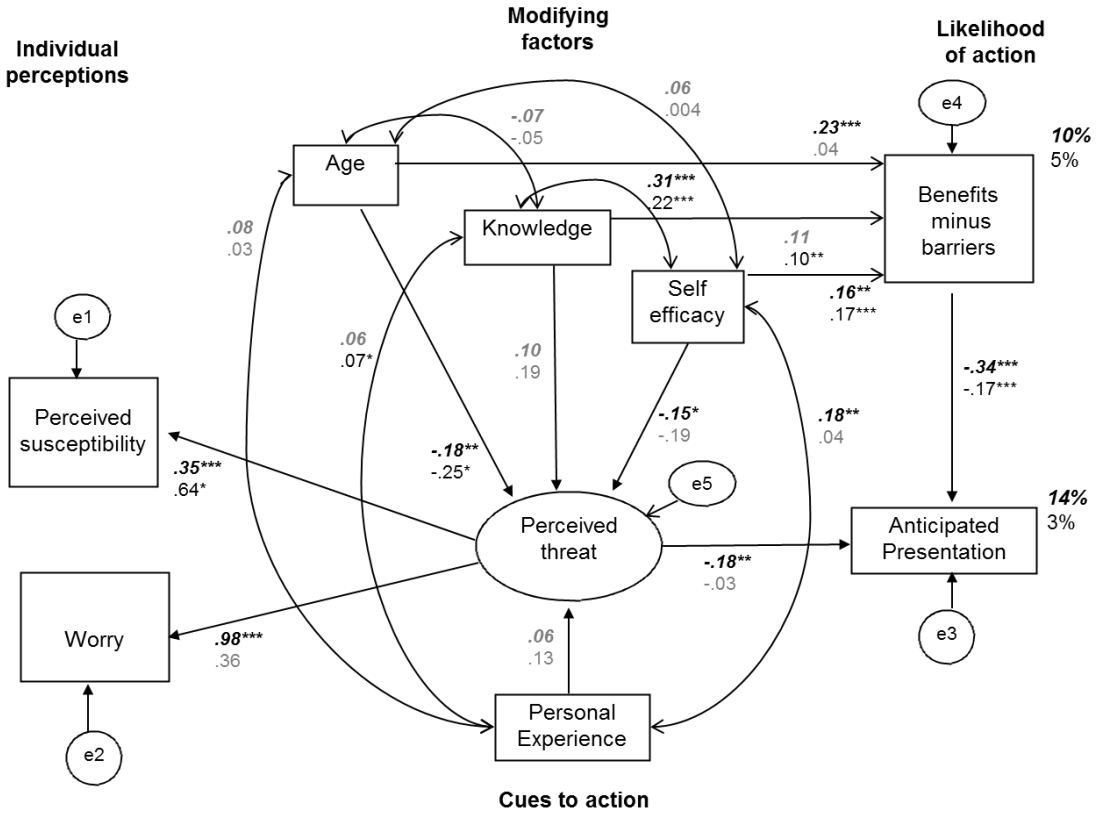


Figure 4 4. The Health Belief Model applied to anticipated presentation to medical professional with potential ovarian cancer symptoms for increased genetic risk (top coefficient) and general population participants (bottom coefficient). Values displayed are standardised regression weights (→), covariances (↔) and percentage of variance accounted for. *p<0.05. **p<0.01, ***p<0.001. Grey font indicates paths with no significant associations. Italic font represents the increased genetic risk group. Non italic font represents the general population group.

4.6.9 SEM model fit in increased genetic risk group

The goodness of fit statistic was significant at the .05 level ($_x^2$=23.54, df=12, p<.05), indicating bad fit. The relative chi-square ($_x^2$/df=1.96) was under the recommended 3:1 range and indicated good fit. The CFI=.92 indicated marginal good fit, RMSEA=.06, good fit, and TLI=.76 a bad fit. The observed relationships between the variables in the increased genetic risk model are provided in the correlation matrix in Appendix 13.

The constructs of the HBM predicted 14% of variance in anticipated presentation for the increased genetic risk group (see Figure 4.4). Perceived threat was determined by perceived susceptibility and ovarian cancer worry, with both of these variables being significant indicators of perceived threat in the measurement model. High perceived threat was associated with earlier anticipated presentation in this group. Age was positively correlated with likelihood of action (benefits minus barriers), with older participants perceiving significantly more benefits than barriers to presentation. Age was significantly negatively correlated with perceived threat, with older participants having lower perceived threat. Higher self-efficacy was associated with perceiving significantly more benefits than barriers to presentation.

Higher self-efficacy was also significantly associated with lower perceived threat. Again, knowledge was not significantly correlated with either perceived threat or likelihood of action. However, a significant positive covariance of knowledge with self-efficacy was observed. Personal experience was not significantly correlated with perceived threat, but those with personal experience had significantly higher self-efficacy. Age, knowledge and self-efficacy accounted for 10% of the variance in the likelihood of action construct, perceiving more benefits than barriers was significantly associated with immediate presentation.

Analysis of invariance was carried out for the dichotomous demographic variables marital status and education level. Both groups (married and not married) were analysed simultaneously in a configural model with the same parameters as the baseline model. Goodness of fit statistics for the configural model were; x^2(34.13, df=24, p=.08, x^2/df= 1.42, CFI=.93, RMSEA=.04. Constraints were then applied to the parameters to test invariance and structure across groups (see Appendix 15). Again, to test for invariance across education status, both groups (highly educated and not highly educated) were analysed simultaneously in a configural model with the same parameters as the baseline model. Goodness of fit statistics were x^2(33.49, df=24, p= .09, x^2/df= 1.40, CFI=.92, RMSEA= .04. Constraints were then applied to the parameters to test invariance and structure across groups (see Appendix 16).

4.6.10 SEM model fit in general population

For the general population group, the goodness of fit statistic was significant at the .05 level ($_x^2$=26.31, df=12, p<.05), indicating a bad fit. The relative chi-square ($_x^2$/df=2.19) was under the recommended 3:1 range that indicates good fit. Other fit indices were CFI=.92 and RMSEA=.04, indicating marginally good fit, with TLI=.72 indicating a bad fit. The relationships between the variables used in the general population model are provided in the correlation matrix in Appendix 14. The constructs of the HBM predicted 3% of variance in anticipated presentation for the general population group (see Figure 4.4).

In the general population group, only perceived susceptibility was a significant determinant of perceived threat. The correlation between perceived threat and anticipated presentation was not significant in this group. Age was negatively correlated with perceived threat, with older participants having lower perceived threat. High self-efficacy was associated with perceiving more benefits than barriers to presentation. Knowledge was significantly correlated with likelihood of action in the general population, with knowledge amplifying the benefits of presenting. Age, knowledge and self-efficacy accounted for 5% of the variance in the likelihood of action construct, similarly to the increased genetic risk group, perceiving more benefits than barriers to presentation was associated with earlier anticipated presentation in the general population group.

4.6.11 Summary of model fit for the three structural models

The fit indices for the three structural models can be seen in Table 4.3. Fit indices indicated that the model fit best when applied to the increased genetic risk sample.

Table 4.3. *Goodness of fit according to fit indices for Health Belief Model structural models for total sample, increased genetic risk sample and general population sample*

	Comparative fit index (CFI)	**Standardised root mean square error (RMSEA)**	**Tucker-Lewis Index (TLI)**	**Relative chi square (x^2/df)**
Total sample (n=1326)	0.90	0.09	0.66	10.52
Increased genetic risk sample (n=283)	0.92	0.06	0.76	1.96
General population sample (n=1043)	0.92	0.04	0.72	2.19

4.7 Discussion

The HBM was used to test theoretical determinants of anticipated symptomatic presentation in a sample of women comprising two risk populations. The evidence from the present study suggests that the HBM is a good model to use in identifying determinants of anticipated presentation with potential ovarian cancer symptoms. Tests of invariance across the two risk groups showed, however, that the model was not invariant across the two risk groups, indicating that the constructs of the HBM influencing anticipated presentation differ according to whether women are at risk for ovarian cancer. This was the first study to explore the nature of perceived threat and its influence on action was found to differ according to risk status. Perceived threat comprised both affective (worry) and cognitive (susceptibility) aspects in women at increased genetic risk, but only cognitive aspects in the general population sample. In those at increased genetic risk, the affective component of risk perception predominated, and may override cognitive aspects of anticipated presentation behaviour. Overall, the current findings support the need for a symptom awareness tool with tailored content for women at increased genetic risk of ovarian cancer.

4.7.1 Is the Health Belief Model a useful model?

Structural equation modelling provided evidence that the constructs proposed by the HBM are important determinants of anticipated presentation to a medical professional with suspected ovarian cancer symptoms. However, the HBM predicted a greater proportion of the variance in anticipated presentation for the increased genetic risk

group (14%) than for the general population (3%). Tests of invariance indicated that the difference between the two groups was as a result of differences in the magnitude of path coefficients in the model, rather than differences in levels of predictors (e.g. mean susceptibility). The path differences suggest that health beliefs in women at increased genetic risk are determined by perceived threat, with affective representations of this latent variable important in this population.

The varying model fit could be explained in terms of the study populations. The model may not fit the general population so well because it does not represent the health beliefs of this group, or their notion of threat, as well as it does for the increased genetic risk group. The inclusion of perceived susceptibility and ovarian cancer worry in the HBM could mean that the theory is directly relevant to women at increased genetic risk of ovarian cancer, as the theory accounts for the impact of their increased risk status. The HBM proposes that when faced with a potential health threat, people consider their susceptibility to and the severity of the health threat when deciding whether to act, (Rosenstock et al. 1988), with such considerations more salient in those at increased genetic risk. This could also explain the greater proportion of variance in anticipated presentation that was accounted for by the model in women at increased genetic risk.

4.7.2 What is perceived threat?

Perceived threat is an integral component of the HBM and was shown to vary according to risk context. Findings suggest that whilst cognitive and affective components are determinants of perceived threat, it is the affective component that is the predominant influence on anticipated presentation in the context of increased genetic risk. In the increased genetic risk group, high levels of perceived susceptibility (cognitive) and high levels of ovarian cancer worry (affective) were demonstrated in those with high perceived threat. Perceived threat is therefore associated with both cognitions and emotions in the increased genetic risk group, but only cognitions in the general population.

Previous operationalizations of perceived threat have focused on the cognitive aspects of perceived threat by including perceived susceptibility and severity (Glanz et al. 2008, Rosenstock et al. 1988), whereas the current study has operationalized perceived susceptibility and ovarian cancer worry. Aspects of affective components of threat are embedded in perceived susceptibility and severity (Hay et al. 2005), however the inclusion of a variable focused on the affective component of threat in this study means that it explicitly includes both cognitive and affective components of threat. This study has demonstrated that including an affective threat variable can help increase understanding of the role perceived threat plays in help seeking behaviour, in particular anticipated symptomatic presentation. In future research, both affective and cognitive components of perceived threat should be considered, with worry and susceptibility particularly important considerations in increased risk samples.

4.7.3 What predicts anticipated presentation?

Perceived threat was found to influence anticipated presentation behaviour in different ways, depending on risk status. In the increased genetic risk group, high perceived threat was associated with earlier anticipated presentation, whereas in the general population the influence of perceived threat was not significant. This suggests that it is both the cognitive and affective representations of perceived threat that are influencing anticipated presentation with ovarian cancer symptoms. The HBM outlines that higher perceived threat increases the likelihood of engaging in behaviour that is likely to manage/reduce this threat (Rosenstock et al. 1988). The present findings elaborate this further by demonstrating that the affective component of threat may be a greater motivator for those at increased genetic risk. A possible explanation is that those with high worry present to the doctor with symptoms in attempts to manage their worry. However, due to the cross-sectional nature of the research it is hard to infer causality. This pattern of results complements research on familial ovarian cancer screening uptake, where worry is a key determinant of screening uptake (Andersen et al. 2002, Schwartz et al. 1995a). Whilst it is hard to put a value on an “appropriate level” of worry, or infer causality, the current study findings suggest that cancer-related worry experienced in the increased genetic risk sample is higher or more

salient than in the general population, and is a key determinant of anticipated presentation.

It is also difficult to conceptualise appropriate levels of delay. In the current study, a dichotomous no delay/any delay presentation cut off was used. This was chosen as any delay in presentation may be deemed problematic, based on survival rates for earlier detection and earlier diagnosis of ovarian cancer (Quaye et al. 2008). This choice of cut off means that findings from the current study will allow a deeper understanding of the health beliefs and determinants of presentation in those who anticipate presenting immediately, and those who anticipate waiting for any length of time.

4.7.4 Which components of the HBM are relevant for anticipated presentation?

Factor analysis for the HBM scales revealed a similar pattern of underlying constructs for the two risk groups, with the exception of barriers. For the increased genetic risk group, the extracted factors for barriers differentiated fear of the discovery of ovarian cancer, whereas for the general population the extracted factors differentiated practical barriers involving time constraints. This differentiation has implications for education and awareness tools about ovarian cancer, providing support for the need to tailor tool content according to risk status.

Personal experience was not a significant determinant of perceived threat in either risk group. It was anticipated that participants who were at increased genetic risk would have familial experience with ovarian cancer that would influence their perceived threat. The only notable influence of personal experience of ovarian cancer in the increased genetic risk group was in combination with self-efficacy, suggesting that having close relatives who have experienced ovarian cancer is more influential on learning than having friends or distant relatives who have experienced it.

There was no significant association between knowledge and perceived benefits and barriers in the increased genetic risk group, although an association was observed for

the general population. However, knowledge was still important in the increased genetic risk group, influencing anticipated presentation indirectly via self-efficacy (women with greater knowledge had more self-efficacy). In turn, self-efficacy was identified as being a significant determinant of perceived threat. Women at increased genetic risk with lower self-efficacy had higher perceived threat. Symptom awareness could therefore influence anticipated presentation indirectly via self-efficacy, and improving confidence could be a mechanism for translating awareness to presentation. Those with higher self-efficacy also perceived more benefits than barriers to presentation. This is consistent with predictions of the HBM, which state that the likelihood of action is higher if the individual perceives more benefits to the behaviour than barriers to carrying it out (Becker 1974).

Older participants in the increased genetic risk group perceived more benefits than barriers to presentation. Older participants in both risk groups reported lower levels of perceived threat, with lower levels of perceived threat associated with longer presentation times. This finding is particularly interesting in light of the risk of developing ovarian cancer increasing with age (Quaife et al. 2013). Younger people reporting higher perceived threat could reflect media attention surrounding the diagnosis of cancer in high profile, young celebrities.

The lack of a direct association between ovarian cancer symptom awareness and anticipated presentation that was observed in the current study was also reported by Low et al. (2013b), and could be indicative of mechanisms underlying these processes which are specific to ovarian cancer. Modelling using the HBM suggests that ovarian cancer awareness (or knowledge) is indirectly associated with anticipated presentation, with awareness influencing anticipated presentation through mechanisms such as self-efficacy, perceived benefits and barriers to presenting, and in women at increased genetic risk perceived threat.

4.7.5 Study limitations

The cross-sectional nature of the study design and use of intent-to-present have implications regarding the temporal stability and interpretation of the current findings. Prospective research would allow real symptoms and presentation behaviour to be measured, and could provide a more accurate understanding of women's appraisal process when deciding whether to present to primary care with ovarian cancer symptom concerns.

In the current study, a higher percentage of women anticipated presenting in a shorter time frame than has been reported in the literature concerning actual presentation. The Royal College of General Practitioners national audit of cancer diagnosis in primary care (RCGP 2011) reported that 50% of ovarian cancer patients present within one month of developing symptoms. Goff et al. (2000) also reported that women who had been diagnosed with ovarian cancer took an average of 2-3 months before seeking medical advice. The differences could reflect discrepancies between anticipated and actual presentation (Low et al. 2013a, Sheeran 2002). It could also reflect a problem with the measure used in the current study, as anticipated time to presentation may not be an accurate representation of actual presentation time (Andersen et al. 2009, Robb et al. 2009). Results in the current study indicated that women from the general population had higher symptom awareness and anticipated presenting in shorter time frames than the increased genetic risk sample (see Table 4.1). This counter-intuitive finding could reflect beliefs held by women at increased genetic risk, such as beliefs that ovarian cancer is an asymptomatic disease. Women at increased genetic risk could have their perceptions about the disease shaped by their family members (Andersen et al. 2009), with negative experiences of the disease in family members potentially influencing personal beliefs about the disease. The observed difference between the two risk populations could also reflect that women at increased genetic risk rely on screening as their main detection strategy and therefore place less emphasis on symptom awareness and symptomatic presentation.

The use of a dichotomous variable for anticipated presentation could also obscure nuance in this variable. The categories chosen for the anticipated presentation variable were “immediate presentation” versus “any delay”. Since there is no clinical consensus on the optimal time to present with ovarian cancer symptoms, in addition to the notion that degree of delay is not as important as presence of delay, this cut off was considered acceptable. Of the increased genetic risk sample, 41% reported that they would anticipate presenting immediately after noticing a symptom, compared to 51% of the general population sample. Based on these results, having a cut off reflecting those anticipating presenting “immediately” and those with longer anticipated presentation enables recommendations to be made based on those who have high levels of perceived threat. It also seems reasonable to propose an "immediate presentation" versus "any delay" dichotomy, as there is currently little data to support fine grained differences between waiting for a week, month etc.

Symptom recognition scores were aggregated in the current study, whereas better understanding may be gained if symptoms are examined on an individual basis, or if knowledge of ‘red flag’ Versus ‘non red flag’ symptoms are explored. However, the sample was too small to examine symptom recognition in this way. A further limitation relating to symptom recognition is that while the measure in the current study informs about the ability of respondents to recognise potential symptoms, it is not informative about the participant’s understanding of these symptoms. The symptom question does not inform about the processes women may go through when appraising and interpreting a symptom, or if indeed the participants are simply guessing whether symptoms are indicative of ovarian cancer. The appraisal process is important to understand in cancer awareness because it is the cognitive process through which people generate a sense of susceptibility, and therefore may help researchers to better conceptualise “delay” (Andersen et al. 2009) and the role of cognitions and emotions in help seeking behaviour.

The potential lack of sample representativeness should also be acknowledged, as the increased genetic risk sample was mainly recruited from a pool of those who had

participated in UKFOCSS and its psychological partner study, PsyFOCS. These women may therefore have different levels of ovarian cancer worry and symptom awareness than women who did not take part. However, PsyFOCS data suggested that non-completers had higher levels of ovarian cancer worry, therefore levels of worry may have been under-represented in the current sample (Brain et al. 2012). Some women were also recruited from Ovacome and there may have been differences according to recruitment source, however, as only a small number were recruited from Ovacome it was not possible to examine the potential effects of recruitment source. Thus the findings may not be generalisable to all women who are at increased risk for ovarian cancer. A further concern is the different sampling methods that were used. The increased genetic risk sample was an opportunity sample whilst the general population sample was a population representative sample. The cases and controls not being drawn from the same population is a known problem for cohort studies (Mann 2003). In addition, it was not possible to confirm the actual risk status of the general population sample. Group differences should be noted as a possible explanation of differences observed in the SEM. The demographic profiles of the two samples could explain differences observed, therefore it could be variables including age and education level rather than cancer awareness, that caused the observed effects.

4.7.6 Application of findings

The present findings have highlighted that cognitive and affective components of perceived threat differ according to risk group, providing justification for tailored health information for those at increased genetic risk in order to address the potential influence of high levels of cancer-related worry on anticipated presentation in this population. Educational information should be provided for women at increased genetic risk of ovarian cancer that focuses on minimising the impact of worry on the cognitive aspects about what to do in the presence of symptoms. Educational information should consider the potential for over-presentation in women at increased genetic risk and include guidance and information on specific time frames in order to educate women on appropriate presentation times.

The current findings have identified some common health beliefs for the two risk populations (self-efficacy associated with knowledge and perceiving more benefits and barriers, and perceiving more benefits than barriers associated with earlier anticipated presentation), as well as unique health beliefs for women at increased genetic risk (the make-up of perceived threat and the association with anticipated presentation). The findings of the SEMs also suggest that women from the general population could benefit from symptom information and education about presentation times. Therefore tailored content that addresses the specific needs of women at increased genetic risk could be embedded within a tool which also contains information that is relevant to women from the general population. This may prove effective as it allows for an all-inclusive approach to education on ovarian cancer awareness, whilst still addressing the specific issues that are unique to women at increased genetic risk, such as ovarian cancer worry. The principal components analysis revealed similar health belief constructs in the two risk populations, with the main exception of barriers. These different barriers for the increased genetic risk population could be addressed in the tailored content that is specific for women at increased genetic risk. The acceptability of an all-encompassing awareness tool, which also has specific content for women at increased genetic risk can explored in later phases of this research project.

Barriers to presentation have also been reported in UK population samples, where worrying about wasting the doctor's time and embarrassment were significant barriers to presentation (Forbes et al. 2013, Simon et al. 2010). The presence of these barriers seen in other study populations could therefore reflect British approaches and beliefs to healthcare. However, the present study has shown that women at increased genetic risk also have the added psychological burden of their risk status, with fear and worry relating to visiting the doctor a barrier to presentation. An intervention which includes tailored content for women at increased genetic risk could be a way for these differing barriers and the specific psychological burdens for women at increased genetic risk to be addressed.

The current findings are applicable to clinicians and health professionals who interact with women at increased genetic risk of ovarian cancer, as the psychological impact of risk status has been highlighted. GPs should be aware of the potential for heightened cancer worry when consulting with increased risk populations. This awareness could also allow for GPs to make potential recommendation or referrals to places for women to discuss the impact of their risk status and help manage or reduce their worry levels.

4.7.7 Future research

Prospective research that examines actual behaviour and that disentangles causal direction is an important next step in this research field. Such research could also help increase understanding of the interplay between affective and cognitive representations of threat. The current study has justified the need for information tools to be developed which contain content tailored according to risk. However, the need remains for firm clinical evidence regarding symptom duration and thresholds. While such clinical information is still developing, the work in the current study has provided insight in to the health beliefs of women at increased genetic risk of ovarian cancer, and how these compare to a general population sample. This research has developed a theoretical understanding of anticipated presentation with ovarian cancer symptoms and has led to an understanding of how change in anticipated presentation may be achieved. This understanding forms the theoretical foundation (Craig et al. 2008b) for the development of an ovarian cancer symptom awareness tool that has core content for all women and tailored content specific for the needs of women at increased genetic risk of ovarian cancer.

4.7.8 Summary

Findings justify the need for an ovarian cancer symptom awareness tool that has specific content that is tailored to the needs of women at increased genetic risk. In those at increased genetic risk, the affective component of risk perception (worry) may override cognitive aspects. An understanding of the determinants of perceived threat have been identified, and attention can now be paid to how perceived threat can be

reduced or managed. This will allow ovarian cancer information to be given whilst maintaining the psychological well-being of the individual. This is important as the psychological well-being of those at increased risk needs to be maintained in the absence of routine ovarian screening.

5 A qualitative study exploring the influence of ovarian cancer experience on anticipated presentation in women at increased genetic risk of ovarian cancer.

5.1 Chapter overview

The present chapter reports a qualitative study with women at increased genetic risk of ovarian cancer, in which women's perceptions of ovarian cancer symptom awareness and symptomatic presentation were explored. This study was conducted to further understand the unique health beliefs that were identified for this population in the survey (Chapter 4) and to guide decisions regarding the content of a symptom awareness tool with tailored content for women at increased genetic risk of ovarian cancer.

5.2 Introduction

Understanding health beliefs is crucial for a risk management approach based on symptom awareness. Theoretical constructs that are identified as important can be incorporated into an awareness tool aimed at encouraging timely symptomatic presentation. Perceived threat was identified as an important health belief, with the determinants of perceived threat differing according to risk status. The affective component of perceived threat (ovarian cancer worry) was associated with how women at increased genetic risk perceived their risk, their health beliefs and anticipated symptomatic presentation. A richer understanding of the influence of perceived threat on emotions and behaviour is therefore needed.

The affective (worry) component of perceived threat is of particular interest as high levels of worry could lead to hyper-vigilance and therefore the potential influence of threat on behaviour also needs to be understood in order to provide guidance to women and manage their expectations. This is important as the psychological wellbeing of those at increased genetic risk needs to be maintained in the absence of routine screening. This behavioural pattern could be problematic not only in terms of

the individual's psychological wellbeing, but also the potential impact on primary care services if women are frequently visiting their GP due to hyper-vigilance.

Other health beliefs that were identified as important determinants of earlier anticipated presentation for women at increased genetic risk of ovarian cancer included high self-efficacy and perceiving more benefits than barriers to presentation (Chapter 4). These constructs identified in Chapter 4 were also explored in greater depth to ascertain whether they should be incorporated into a symptom awareness tool with tailored content for women at increased genetic risk.

5.2.1 Qualitative methods

Qualitative methods enable a deeper and more personal responses than can be gained through quantitative methods (Green and Thorogood 2013). Qualitative methods are particularly useful when the subject matter is reflective and emotionally evocative (Smith 2007), for example the impact of personal experiences of ovarian cancer within the family. Interpretative Phenomenological Analysis (IPA) is idiographic, inductive and interrogative, and is a well-developed qualitative approach to health psychology research (Smith 2004).

IPA aims to explore personal lived experiences and how people make sense of these experiences, with individual perceptions of objects or events an integral part of the theory (Smith 2004). This type of analysis involves trying to understand potential relationships between health status, health beliefs and behaviour (Smith 1996) and is recommended for small samples of around 5-10 participants (Smith 2004, Smith 2007). IPA is similar to thematic analysis in drawing out themes and patterns across participants; however, IPA also focuses on the unique aspects of participants' own experiences (Smith 2004).

5.2.2 Aims of the present study

The aim of the present study was to gain further insight into women's experiences and perceptions of symptom management in the context of living with a family history of ovarian cancer, and the proactive or preventative behaviours they may adopt in the absence of routine ovarian screening. Semi-structured qualitative interviews were carried out with women at increased genetic risk were used to further explore the concept of perceived threat, in particular the affective component of risk perception and its influence on anticipated symptomatic presentation. Perceived benefits and barriers to presentation, as well as the acceptability of symptom awareness as a risk management strategy were also explored. Topics relating to opinions of symptom awareness tools are important as user acceptability is a crucial step in intervention development (Craig et al. 2008b). The use of qualitative methods, and particularly IPA, allowed for elaboration and exploration of how women's personal experiences of ovarian cancer have shaped their perceptions and beliefs about the disease and its management.

5.3 Methods

5.3.1 Participants

Participants were women who had taken part in the earlier study on determinants of anticipated presentation with ovarian cancer symptoms (see Chapter 4) and who had agreed to take part in future research studies about ovarian cancer symptom awareness. A purposive sample was selected to reflect a range of anticipated presentation times and level of worry. Specifically, those who anticipated presenting immediately, those who anticipated delaying a week and those who anticipated delaying for over three weeks were selected. Geographical proximity was also considered due to the face-to-face nature of the interviews, therefore women who lived within two hours travelling distance of the Cardiff research base were invited to participate. In total, 20 women agreed to be interviewed out of 32 invited (65%). Recruitment stopped when 8 interviews had been completed (25%) as it was felt that the data had achieved its goal of representing perceptions about symptom awareness

in women at increased genetic risk of ovarian cancer (Brocki and Alison 2006). It was felt that at this point in recruitment there was coherence in responses and that the accounts given by participants could be discussed in relation to the research question and could be extrapolated to relevant psychological theory (Brocki and Alison 2006). For the remaining 12 women who agreed to participate but were not included in the data analysis, 7 could not be contacted in order to arrange an interview time and the remaining 5 respondents were contacted, informed that the study was no longer recruiting and were thanked for their interest in the study.

5.3.2 Interview topic guide

The main topics were ovarian cancer symptom appraisal, facilitators and barriers to symptomatic presentation, ways to reduce barriers, and acceptability of symptom awareness tools (see Appendix 17). The content of the topic guide was guided by the findings of previous chapters. At the end of the interview participants were asked about the advantages and disadvantages of symptom awareness tools. Participants were then shown two examples of symptom awareness tools that had been identified through the systematic search (Chapter 3). These were shown after opinions of symptom awareness tools had been explored in order to ensure that these initial opinions were unprompted.

A total of four tools were used in interviews in order to reflect the diversity of tools that were identified (see Chapter 3), with each participant shown two tools in order to maximise the feedback on different tool formats. Copies of the tools can be seen in Appendix 18-21. On presentation of the first tool, question 11 from the topic guide (see Appendix 17) was explored, and then this process was repeated with the second tool. Tool 1 was a leaflet developed by Target Ovarian Cancer, which was identified as one of the most comprehensive awareness tools in the systematic search (Chapter 3). Tool 2 was a fact sheet called 'It's time to shout out' and was chosen because the illustrations within the tool highlighted a visual approach to awareness tools. Tool 3 was a symptom diary created by Ovarian Cancer Action. This tool was chosen as an

example of an interactive symptom awareness tool. The final tool was from the 'Be Clear on Cancer' campaign by Cancer Research UK. This tool was not publically available at the time of the systematic search, and was included to represent an up to date symptom awareness tool.

5.3.3 Procedure

Cardiff University School of Medicine Research Ethics Committee provided approval for this study (see Appendix 22). Participants were sent an invitation letter, information sheet and consent form. Those who wished to take part in the interview study returned the signed consent form. Once consent had been obtained, the researcher called participants to answer any questions about the research study and arrange a time for the interview. At the time of the interview, participants completed a further consent form and were given the opportunity to ask any questions. Semi-structured interviews were conducted in the participants' own homes, with the content of the interviews informed by the topic guide. Other topics that arose during interviews were explored through the use of probes and prompts. The interviews were audio recorded and transcribed verbatim. The average length of the interviews was 35 minutes (range 21-61 minutes).

5.3.4 Analysis

Transcripts were analysed using Interpretative Phenomenological Analysis (IPA) (Smith 2004). Each anonymised transcript was read and re-read, and was analysed with themes noted for each transcript. This process was repeated until all themes within transcripts had been identified and noted. Once the themes that represented the different thoughts and feelings about a particular topic had been identified, the themes were clustered into superordinate themes. Abstraction was then used to identify links between emergent themes. A name was then given to each superordinate theme that reflected the themes within the cluster (Smith 2004). Three transcripts were independently coded by another researcher, with discrepancies resolved through

discussion. The data were then entered into NVivo 8 qualitative analysis software package (QSR International Pty Ltd 2008).

Quotes presented in the following section represent examples of the identified themes. Insertions to clarify topic content are denoted by square brackets. The removal of irrelevant information within the quotes is denoted by "….". The characteristics of each participant are presented in parentheses after each quote in the following order: participant number (p1-p8), anticipated time to presentation (immediate, one week, over three weeks) and worry (w3-w8).

5.4 Results

5.4.1 Sample characteristics

Sample characteristics are provided in Table 5.1. Participants were aged 41-77 years, were mostly educated up to secondary level, and had been in ovarian screening between one and ten years.

Table 5.1. *Age, education, screening years, anticipated presentation and ovarian cancer worry levels of participants*

Participant	Age	Education level	Years in ovarian screening	Anticipated presentation time	Ovarian cancer worry
1	70	Up to age 16	6	Immediately	3
2	77	Secondary	4	Immediately	6
3	56	Secondary	1	Up to 1 week	5
4	41	Degree and above	1	Up to 1 week	3
5	68	Secondary	10	Over 3 weeks, up to 4	5
6	54	Degree and above	5	Immediately	4
7	50	Secondary	2	Immediately	7
8	44	Secondary	6	4+ weeks	8

5.4.2 Emergent themes

Key themes that were identified in included personal and familial experiences, personal barriers and facilitators, system barriers and facilitators, ovarian cancer symptom information sources, symptom monitoring behaviour, sources of support, sources of worry and tool format.

5.4.3 Personal and familial experiences

Most women discussed memories and personal experiences of ovarian cancer diagnosis in their family members. These experiences had a strong influence on their own perceptions of ovarian cancer, both in terms of recognising symptoms and disease progression once diagnosed. Women would compare themselves to the family member who had been diagnosed and would use this experience as an information source.

> *I suppose because of my sister having no symptoms… (p2, immediate, w6)*

> *… 'cause I know when my cousin got it, she didn't even realise, realise that she had it [ovarian cancer]. (p5, over 3 weeks, w5)*

In some cases, diagnosis of ovarian cancer within the family was bringing up bad memories which influenced thoughts and feelings about their own ovarian cancer risk on a regular basis.

> *…I think you do get good days and you do get bad days, you know it still hurts now and we're talking six years down the line. (p7, immediate, w7)*

> *It's [ovarian cancer] horrible, I've seen it first hand and it's not nice at all… I mean because if you've seen somebody suffering from it, you think to yourself, I'd never want to be in that situation because it's horrible. (p6, immediate, w4)*

Some women described these experiences as making them act quickly and be more aware of ovarian cancer. In such instances, the negative memories of ovarian cancer in relatives were a driving force, as women were anticipating swift action in order to avoid the same experience themselves.

> *I mean if you've been down the road before, you know… you just wouldn't waste time, would you, because time is precious. (p6, immediate, w4)*

> *… having gone through it all [with Mother and Grandmother who had ovarian cancer] I know roughly what to look for and if there's anything amiss then to go and find out straightaway. (p1, immediate, w3)*

5.4.4 Personal barriers

The most commonly endorsed barrier to presentation was the vague nature of the symptoms of ovarian cancer. The vague nature made it difficult for women to distinguish potential symptoms of cancer from common physical sensations.

> *The only time you find out there's something wrong is when it's advanced and it's too late then. (p3, 1 week, w5)*

> *It can be scary sometimes, because you can look at everything and think, 'I've got that, I've got that.' (p8, over 3 weeks, w8)*

> *They call it the silent killer for one reason. All the symptoms are there but they don't know about it. They think oh well, it could be a period, it could be this, it could be that, it could be what I've eaten. (p6, immediate, w4)*

The nature of the symptoms was frequently mentioned in relation to age. Many women felt that as they were getting older, they were finding it harder to distinguish between what might be a symptom of ovarian cancer and what was part of the natural ageing process.

> *I mean, any young person like you, if you started to get those then you would really start to worry, wouldn't you? Someone my age, you say, well, okay I'll get back ache and get wind a lot, you know, and I get changes in bowel movements so, you know they're always changing. (p2, immediate, w6)*

> *'cause feeling bloated is what you feel like when you know, you go through the menopause. (p5, over 3 weeks, w5)*

The nature of ovarian cancer symptoms and pre-existing medical conditions were also discussed, as women found it hard to differentiate the symptoms of ovarian cancer from those associated with other benign conditions.

> *Feeling full, tummy pain, swollen tummy, it can all be relative to IBS really. I mean I only know because I've got IBS (laughs) so that could be relevant to that. (p1, immediate, w3)*

> *… that would be difficult for me, change of bowel habit, because I've got a stoma, it's very different, so that's a difficult one, you know. (p3, 1 week, w5)*

Fear of diagnosis was also explored. Participants expressed concerns that experiencing symptoms may mean that they automatically have ovarian cancer. This barrier was related to previous familial diagnosis of ovarian cancer and the implications for personal risk of developing the disease.

There's some days and I think I'm definitely going to get it. It's in my history and everything like that, and it's just a matter of time really. (p8, over 3 weeks, w8)

If you've experienced even one of those symptoms, you know, your mind is just going to go frantic because you automatically think, I've got that, and you know, and every human is going to do that [go frantic.] (p7, immediate, w7)

5.4.5 Personal facilitators

Symptoms were frequently mentioned in relation to personal barriers for presentation, but were also commonly endorsed as facilitators to presentation. Women considered symptoms and bodily changes to be very important, with the perception that being aware of their own bodies would make it easier to spot any changes.

If I started to have any symptoms which I thought were unusual, I would immediately go to my doctor. (p2, immediate, w6)

If something was different from every day I would… I wouldn't waste time. I'd go and get it checked straight away. (p6, immediate, w4)

Once the symptoms or bodily changes had been noticed, participants felt that they would act quickly and seek medical advice.

If I started to have any symptoms which I thought were unusual, I would immediately go to my doctor. (p2, immediate, w6)

I think based on the symptoms that I know I'd pick up the phone straightaway [and make an appointment.] (p4, 1 week, w3)

Personal risk status was mentioned as a facilitator to presentation in the presence of symptoms. Participants reported that they would act quickly due to their concerns relating to their increased risk status.

If I had any signs or symptoms yes, knowing the family history, I would go straight away. (p1, immediate, w3)

I would think, 'oh God, this isn't quite right, I have to go and see about it, hopefully it'll be nothing', but perhaps if I weren't in this high risk I would just leave it ride until it's too late or something perhaps…(p7, immediate, w7)

Participants described how worry stemming from their risk status would lead them to act.

Because of the family factor, I would be more aware of it [symptoms.] (p7, immediate, w7)

I might be over, sort of worrying about it, and [thinking] if I haven't actually got the symptoms, but because I know I'm at risk, I get symptoms, twinges, and I think 'I wonder' all the time. (p8, over 3 weeks, w8)

Confidence was also an important facilitator, with participants describing that having confidence made it easier to voice their concerns to the GP. Confidence was often embedded in risk status, with some women describing themselves as being confident and assertive due to their increased genetic risk.

I'm quite confident. I'm not ashamed or afraid to talk to anyone about anything. (p6, immediate, w4)

If I didn't feel the appointment time was quick enough I'd explain the situation over the phone and say why I wanted to see the doctor and spell it out to the receptionist. (p4, 1 week, w3)

It does make you a stronger person [experiencing family members with OC] because you get more determined I do believe, because you get more determined in your way. Because like in the beginning, I was palmed off by my GP as we were with a different practice, not through any fault of his but, oh you're being over-exaggerating, you're being too cautious. (p7, immediate, w7

Women also felt that they had to be very confident in some instances in order to be listened to or taken seriously by health professionals.

There's no leeway for being meek and mild, you have to do what you have to do. (p2, immediate, w6)

So often with the NHS you have to be assertive, which is a shame. (p4, 1 week, w3)

Information was noted as a source of increasing confidence. Women felt that having knowledge and information was important in helping them to prepare for consultations with health professionals.

I find I'm more confident by reading information. (p3, 1 week, w5)

If you're armed with that information then the doctors can't say 'oh you'll be all right, love, you know, it's just a bit of ageing and diverticulitis or whatever'. If you actually know that information it's easier to push. (p4, 1 week, w3)

Positive attitudes were frequently discussed, with beliefs that presenting to get medical help and acting on any worrying symptoms would be beneficial. Women discussed acting on these concerns, and the importance of facing the possible consequences as opposed to ignoring them.

I believe in facing, you know, if you've got a problem then you face it and deal with it. (p2, immediate, w6)

But as I said I think the best is to go, and hopefully it isn't, but if it is, there is a cure. You know, looking at the bright side of it, isn't it? (p7, immediate, w7)

The ostrich in the sand thing doesn't get you anywhere does it? (p7, immediate, w7)

On the other hand, some participants described how they would be initially hesitant as a result of fear if they thought they were experiencing symptoms. However, in such instances participants reported that they would still seek help.

Nature's thing is you'd panic obviously, that is the human thing, but I would…I would go to the GP. (p7, immediate, w7)

5.4.6 System barriers

System barriers relating to difficulty accessing primary health care and difficulties communicating with their GPs were described. Women expressed feelings of difficulty accessing GPs, with anticipated problems with getting GP appointments or long onward referrals.

> *Every day in this region, you can forget it, if anything goes wrong, nothing can be done. (p3, 1 week, w5)*

> *They haven't got time to see anyone, have they? They don't, they're spending so much time on paperwork. (p5, over 3 weeks, w5)*

> *You've got to wait ages, 'cause you have, 'cause the healthcare in [names place] for cancer isn't very good. (p5, over 3 weeks, w5)*

Concerns were also expressed over the lack of time given for GP consultations.

> *Some GPs are too busy. (p4, 1 week, w3)*

> *Unfortunately, a lot of GPs they are busy and they've only got like a 10 minute time slot. (p7, immediate, w7)*

GPs' attitudes were also a consideration, with negative perceptions about how GPs would react if they were to present with ovarian cancer concerns. Feelings of not being taken seriously were discussed, with one participant reporting that GPs would *'palm you off with different things…(p7, immediate, w7)'.*

> *Some GPs don't give a damn and others don't know the information. (p4, 1 week, w3)*

Concerns about how the GP would react in the consultation were often embedded in experiences of their GP not being aware of their personal risk status. Women felt that when the GP did not know their risk status, it was often harder to discuss their concerns.

> *I said… I think it's genetic, and they just turned around and didn't answer. (p3, 1 week, w5)*

They didn't know anything about my family history at all. Okay, my file obviously would be that thick coming from when I was born, 'cause they don't have time to look at it do they? (p5, over 3 weeks, w5)

The GPs' lack of awareness of risk status was described as both a source of frustration and an additional emotional burden. Having to explain their risk status took time and led to heightened emotion associated with re-living the past.

'cause it's frustrating to have to explain to people and upsetting, and annoying as well. (p5, over 3 weeks, w5)

You would have to go through it all [family history] and whatever… you've got to keep going through the same thing all the time. (p1, immediate, w3)

5.4.7 System facilitators

Conversely, having a GP who was aware of their risk status helped some women to feel more confident in presenting and expressing their concerns.

They've [GP] got my medical notes and I would explain to them, I mean, they've taken my blood samples so they would know that I've been on the studies before, so they would just forward it on to the right people. (p6, immediate, w4)

In such instances, there was a sense of relief in not having to reiterate their family history.

It's better to see the same one as you don't have to keep going through the same thing all the time. (p1, immediate, w3)

It seems to give me peace of mind, because you don't have to continually repeat all the time. (p7, immediate, w7)

Continuity of care was also discussed, with feelings that seeing the same GP helps develop a relationship. This relationship made participants feel more comfortable in expressing any concerns.

She's young [GP] and she's very with it and nice to talk to… I would go to her…for her to see you on a regular basis and keep an eye on you. (p2, immediate, w6)

I think it's quite nice [seeing the same GP], because if you get that rapport, I know in a lot of practices you don't see one doctor, you see quite a few… (p7, immediate, w7)

5.4.8 Ovarian cancer information sources

When asked about sources of ovarian cancer information, the Internet was quoted as the most common method: *'I'd go and Google it' (p2, immediate, w6), 'I'd look on the net (p6, immediate, w4)'.* Information was sought for a variety of reasons. Some women felt that information was important for general knowledge about ovarian cancer and to help prepare for the future. Others felt that it was useful as a point of reference before seeking medical help for a specific concern.

I'd go on the Internet first. I use it as, like, as a guide. (p3, 1 week, w5)

I used to keep everything I read about it [ovarian cancer]… and the names of the best specialists. (p5, over 3 weeks, w5)

If you want to check that before you go to your GP, just 'cause you think you're worrying about nothing, you know, it's private. (p8, over 3 weeks, w8)

Some participants discussed how they would avoid information-seeking due to concerns about the credibility of web-based information. This was often as a result of anticipated worry about what they might find.

I just wouldn't want to go down the road of just googling the word and no, no, that would just put my head into override I expect. (p6, immediate, w4)

If you're going back to the Internet, you could start off with something small and end with you've got God knows what wrong with you. (p7, immediate, w7)

High profile media cases of cancer were also highlighted as raising public awareness of ovarian cancer, including Angelina Jolie's recent public announcement of being a BRCA1/2 carrier.

There's been a lot more profile around cancer recently, so you see a lot more posters about and a lot more things on the telly. (p8, over 3 weeks, w8)

5.4.9 Symptom monitoring behaviour

Women described the different ways they monitored themselves in order to spot any symptoms of ovarian cancer. Keeping fit and being aware of their bodies was frequently endorsed. Many discussed how keeping fit and slim helped them notice any changes more easily.

> *I know I don't look fit, but I go to the gym three times a week, I'm careful of what I eat, you know… we know our bodies so well, we know what we are doing to them. (p6, immediate, w4)*

> *I'm sort of fairly slim across my belly, so I think I'd notice bloating. I know one of the ones was bloating that doesn't go down, is it? I think I'd probably notice that, but with a lot of women that may be bigger, they wouldn't actually see that. (p8, over 3 weeks, w8)*

There was also discussion of how family members had been unable to spot symptoms, with this experience being a driving force for their own body monitoring.

> *I think that's what happened with my grandmother and her two sisters. They were all big ladies; they didn't see what going on inside them and it was all kinds of things, and they died of it, you know. So I think it's because they couldn't really see the physical changes. (p8, over 3 weeks, w8)*

In terms of aide memoires, different preferences and techniques were expressed. Some participants said that they would make notes to help them keep track of any symptoms they experienced.

> *I'd probably not make a diary, but make some notes of what my symptoms had been, where and when, yeah make a bit of a diary. (p4, 1 week, w3)*

> *'Cause I think you should diary things, shouldn't you? (p5, over 3 weeks, w5)*

Others said that they would just rely on their recall of symptoms.

> *I'd just sort of store it in my head probably, and then just go to the GP with general, you know, general sort of symptoms and things rather than specific. (p8, over 3 weeks, w8)*

5.4.10 Sources of support

Previous participation in ovarian cancer screening studies was noted as a source of reassurance to most participants. Women felt that through participation and frequent interaction with healthcare professionals, any potential problems would be identified. Some participants went on to discuss how they would not necessarily look out for bodily changes between scans or tests, because they believed that screening would detect anything of concern.

> *I think it's just a comforting fact that you know that if something's going to happen you know they're going to do something about it and you can come from there thinking, well, everything's fine. So it's that feel good factor isn't it. (p7, immediate, w7)*

> *I think I'll always be concerned, and at least if you were part of a screening, at least if you do get it you're picked up early. (p4, 1 week, w3)*

> *I think, 'Yeah, that's me, I'm sorted, I'm okay,' and then I think it's time to have another one. And I do and I don't think about it. (p8, over 3 weeks, w8)*

In the absence of routine ovarian screening, some participants had asked their GPs to continue sending them for tests, while others were paying privately for screening.

> *Well that is what she's doing for me, she's sending me, as I've said, every six months. I think that gives me confidence. (p2, immediate, w6)*

> *I have scans, ultrasound scans every year. I pay for them now because they used to be part of the study that I was taking part in and then that all stopped and the funding stopped and everything. So I thought I'd keep that up and we… My husband is in agreement and we pay for me to have one, well, it was once a year but I might be having them a bit more than that now. But… so that's my way of sort of keeping my eye on things. (p8, over 3 weeks, w8)*

Some women explained how they derived reassurance from regularly visiting the GP.

> *I would rather be too cautious than dead, basically. I know that sounds really dramatic but I do keep on until, you know, I would rather keep on and keep on and keep on and say, look there's nothing, rather than leave it lie and then say 'Oh look, we've got a problem now', which sometimes it's too late isn't it. (p7, immediate, w7)*

You think 'Well actually, I ought to go back to the doctor and get checked again and see if there's any screening or research projects I ought to go on, just to check'. (p4, 1 week, w3)

Information on ovarian cancer was mentioned as a source of comfort, with women turning to literature on ovarian cancer in order to feel reassured that they knew about the disease.

Especially in my situation 'cause I'm classed as high risk, but yeah. No, I'm very pleased that there's information out there. (p6, immediate, w4)

I think any information is a good thing isn't it, prevention is better than cure. My way of looking at it anyway.(p7, immediate, w7)

5.4.11 Sources of worry

Ovarian cancer information was also described as a source of worry. Feelings of being overwhelmed by facts and figures for the disease were expressed. Information was often daunting and there were concerns over the credibility of information that women encountered.

It can be overwhelming sometimes, you get too much information. (p3, 1 week, w5)

If you read some of the literature that says post-surgery or post treatment, so... a certain percentage of women will still successfully be living and that's actually not a great number. And you think, 'Oh well, never mind, they can't do anything about it. Let's forget it, let's carry on without all that faffing about. (p4, 1 week, w3)

'Cause too much information could really put that wheel in your head turning. (p6, immediate, w4)

Genetic factors were also a source of worry, as participants were concerned about their personal risk status.

I find it [being at increased risk] distressing, I've lost so many members of my family [to OC]. (p5, over 3 weeks, w5)

I know I'm high risk, and I know it [OC] could happen, it's in my history, and everything like that, it's just a matter of time really. (p8, over 3 weeks, w8)

Concerns were expressed about what family members might experience if they were to be diagnosed with ovarian cancer. Again, these concerns often stemmed from personal experience with the disease and not wanting to put their family member through these experiences.

I don't want my children to go through that. Obviously they went through it with my mum, but I don't want them to go through it with their mum. (p7, immediate, w7)

I know I'm high risk and I know it could happen, you know, to me for breast or other in, you know… 'cause sometimes there's some days and I think I'm definitely going to get it. It's in my history and everything like that, and it's just a matter of time really. And other days I think… I know cancers can jump generations. (p8, over 3 weeks, w8)

5.4.12 Tool format

Certain aspects of the ovarian cancer awareness tools that were shown to participants were seen as acceptable, including their short length and simple content. The interactive nature of tools was also complimented, in particular the symptom diary (see Appendix 20).

...weeks later [after symptom experience] you think, 'Oh, I should have written it down now'. (p3, 1 week, w5)

I think it's quite a short, precise, you know I've read things that have gone on forever and by the time you've got to the end of it you think right what did I start reading about. (p7, immediate, w7)

Women thought that too much information should be avoided and that the inclusion of pictures was useful. Signposting to additional information was also endorsed. Comments were also made about how such tools would be useful to take to GP consultations.

It's showing a body and obviously, you know, where things are, 'cause it's like that it's easier to retain it. I think this is a really good [material]... whoever designed it is really good. (p3, 1 week, w5)

Yeah, it's really good because then you could go down say 'Well, look I've kept a diary and this is what I'm experiencing and what I'm feeling'. Yeah, I think it's really good. (p5, over 3 weeks, w5)

The interactive nature of the symptom diary (see Appendix 20) was both praised and criticised. Some felt that engaging with the interactive aspects was not feasible, and that the four week time frame for symptom monitoring was unacceptably long.

I thought two to three weeks at the very most, 'cause honestly after one week if you started to tick most of those boxes, I would be worried… it's more worrying in that version because you'd be able to see it all in one place. (p2, immediate, w6)

Others felt the diary may be useful once symptoms had been noticed, but that it was not useful in providing information about the symptoms.

If she [GP] gave me that and said, well, would you fill it out for me and let me know how you get on with it, it would be most useful. But I wouldn't particularly pick that up and do it without any symptoms. (p2, immediate, w6)

Tool content concerning ovarian cancer symptoms and what to do if symptoms were experienced was commonly described as being vague and uninformative.

I am 78 and it… I think it's, you know, it's… it might be useful to say that these things are normal in an older person. (p2, immediate, w6)

I think the only thing that you could do is between say week two and week three you could say, 'If you're scoring yes every day, go and see a doctor now'. (p4, 1 week, w3)

Interest was expressed in having basic and clear information which outlines the symptoms of ovarian cancer. It was felt that this would be useful as it could act as a point of reference and could be referred back to as needed.

It can be overwhelming sometimes, you get too much information. You just want enough, like the symptoms and you know, when to go to the GP. (p3, 1 week, w5)

I mean it [symptom awareness tool] would be a good refresher. (p4, 1 week, w3)

Ovarian cancer statistics and facts provided in the tools were also criticised.

All the percentages and things like that… I wouldn't even bother to look at that part. (p1, immediate, w3)

Well, you almost think, 'Well, that's that then, isn't it? I'm going to die.' (p4, 1 week, w3)

Misconceptions and misunderstandings surrounding cervical screening arose when participants read information dispelling the myth that cervical screening can detect ovarian cancer.

The smear cannot detect [ovarian cancer], is that true? (p2, immediate, w6)

I really thought the smear was some sort of detection, but it says here it's not. (p7, immediate, w7)

Healthcare settings were often suggested as a suitable location for delivering ovarian symptom awareness tools, including from the GP, GP waiting rooms, consultation rooms and family planning centres.

If the doctor said to you then 'Here's a leaflet, keep a diary' and whatever else... you could do it. But if they don't offer them to you I think that they would just... you wouldn't see them. (p1, immediate, w3)

I thought they would be in doctors' surgeries, hospitals. (p3, 1 week, w5)

…would be in your GPs, chemist perhaps, you know family planning that type of thing. (p7, immediate, w7)

Healthcare settings were considered to lend greater credibility than web-based sources.

I think there's so many scaremongers and bad sites on the Internet – there are a lot of good as well, but I don't think you are going to get bogus things in the chemist or a surgery. You may do, and if you do it's unfortunate, but I think on the Internet you are more inclined to get these bogus sites. (p7, immediate, w7)

However, many women then went on to discuss how having information resources in these places may not be effective due to embarrassment about picking them up in public places.

> *I think they would be much better in the doctor's room, yeah when you go in… , 'cause then no one could see you, and I think the leaflets should be with them, not outside. (p5, over 3 weeks, w5)*

Paper based tools were preferred, in part due to the desire to take something along to consultations, and partly due to fear of searching for information on the Internet.

> *I think I'd prefer to have the paper one because I'd be inclined to think I'm not one of these Internet nerds. (p7, immediate, w7)*

5.5 Discussion

A qualitative study has been presented that built on the quantitative findings of the study in Chapter 4 through exploration of the impact of perceived threat on anticipated symptomatic presentation in women at increased genetic risk. This study has also further explored implications for developing an ovarian cancer symptom awareness tool with specific content for this risk population. Personal experience of ovarian cancer as a result of familial diagnosis was integral to shaping participants' health beliefs and anticipated presentation.

5.5.1 The influence of risk status on anticipated symptomatic presentation

Personal risk status was a prominent driving force behind many of the beliefs and presentation expectations held by the participants. Women's perceptions of ovarian cancer were coloured by their personal and familial experiences of the disease. These experiences were discussed in terms of both facilitators and barriers to ovarian cancer knowledge, anticipated presentation, and information seeking. Symptoms of ovarian cancer were commonly mentioned, with experiences of symptoms that were unusual acting as a trigger in many cases. Emphasis on new and unusual bodily sensations was often paired with keeping fit and slim, suggesting that women are trying to undertake

risk management strategies that are within their personal control. This behaviour could also be deemed as a compensatory mechanism to attempt to control worrying thoughts about ovarian cancer risk (Andersen et al. 2002, Schwartz et al. 1995b).

Participants discussed the importance of presenting with symptoms regardless of whether it turns out to be ovarian cancer. Similar findings were reported by Low et al. (2013a), where participants felt that even if symptoms were not likely to be cancer it was considered beneficial to present as it could lead to the detection of other conditions. The anticipated willingness to present could be viewed positively since women are anticipating engagement with the healthcare system; however, for women at increased genetic risk, this could lead to over-presentation and could reflect inappropriate help seeking (Andersen et al. 2002, Fallowfield et al. 2010, Kash et al. 1992, Lerman et al. 1994). The present qualitative findings reinforce those reported in Chapter 4 which suggested that the affective component of perceived threat needs to be managed in women at increased genetic risk in order to avoid hyper-vigilance and possible over burden on the healthcare service (Evans et al. 2014).

Experience with familial ovarian cancer diagnosis was an important facilitator to presentation. Women felt they would act quickly should they suspect anything wrong. This often stemmed from experiences where family members had delayed presentation, or had not monitored bodily changes. Quotes emphasised women's feelings that nothing would stop them seeking medical help if they thought something was wrong. The participants discussed how they would not act in the same way as their family members, and would instead be proactive and decisive in the event of noticing changes they attributed to possible ovarian cancer. The experiences were also mentioned as helping to increase confidence in decisions regarding ovarian cancer, because women felt knowledgeable as a result of their experiences. This reflects the survey findings in which having personal experience with ovarian cancer was associated with greater self-efficacy (Chapter 4). This association was only found for women at increased genetic risk and not those from the general population sample, suggesting that seeing a family member with ovarian cancer makes some women more

determined to avoid the same experience themselves (Absetz et al. 2003, Fallowfield et al. 2010).

There are positive and negative implications of the views on symptoms that were elicited in the current study. If women are experiencing symptoms indicative of ovarian cancer, early presentation is important; however, if presenting for any bodily changes it could lead to overburdening of the healthcare system. Hyper-vigilance may also be harmful to the psychological wellbeing of the individual (Norman and Brain 2005). This reinforces the need for provision of clear and concise information about how to recognise and act upon the symptoms of ovarian cancer. A symptom awareness tool could include this type of information, and could also include statements which encourage women to visit their GP and manage their expectations about what is likely to happen in the consultations. The fear of diagnosis expressed by participants highlights the prominence of the affective component of threat. It suggests that worry is influencing women's behaviour and beliefs, with their personal experience with ovarian cancer influencing their fears. This fear in the presence of potential symptoms also highlights the need for psycho-educational support.

Increasing knowledge about symptoms and their nature could mitigate against women associating any symptom experience with the inevitability of ovarian cancer. Symptom education could therefore help women manage their worry levels and reduce the likelihood of over presenting. Specifically, tools could focus on promoting the benefits of presentation and dispelling the barriers. This could be achieved by providing women with clear and concise information about the symptoms of ovarian cancer, their frequency, and what to do if they are experienced. Such tools could also facilitate the interaction between patient and doctor, and help women to feel more empowered about their decision to seek medical advice.

Confidence was discussed as being a driving force by participants who felt they had to be confident in order to interact with health professionals (Smith et al. 2005b). Some

women talked about personal experiences where health professionals had been dismissive of their concerns about ovarian cancer. Some women also reported that they would read up on ovarian cancer information prior to going to see their GP, to ensure that they were fully prepared to voice their concerns. A symptom awareness tool may therefore be used as an act of preparation for GP consultations (Murray et al. 2003). Information on what to do before a GP visit may therefore be well received if incorporated into such a tool. The tool could suggest that women prepare by writing down symptoms experienced, or a list of things they would like to be discussed in the consultations. This may help to increase confidence about the visit and facilitate the doctor-patient interaction. As women found it an emotional burden to reiterate their risk status it may be useful to prime them in an awareness tool for such an event so that they can be prepared. This may help women feel more confident in presenting and if the tool is paper based, it will enable women to take the tool with them to aid discussion in the consultation (Murray et al. 2003, Smith et al. 2005b). The need for this type of information supports the need for specific content for women at increased genetic risk in an ovarian cancer awareness tool.

5.5.2 Ovarian cancer information needs

Information about ovarian cancer was perceived both positively and negatively and could therefore be viewed as a double edged sword. Some women felt empowered by reading information and wanted to be up to date with all information about ovarian cancer. This was considered by many as a good act of preparation. Others felt that information could be overwhelming and would lead to increased worry. Women felt that facts and statistics relating to ovarian cancer was a source of concern when looking for information about the disease, with it discouraging them from searching for information. This was also mentioned when participants were discussing the content of symptom awareness tools. The notion of such information deterring women from presenting could reflect helplessness because if women read statistics of survival and feel the outcomes are poor they may feel there is no point in doing anything about it. These are important considerations for tool development because the tool should aim to avoid increasing worry or feelings of helplessness.

When probed about symptom monitoring behaviour, women expressed different personal preferences as to how they would go about this. When it came to reviewing the awareness tools, those who were shown the symptom diary expressed that they felt this was not useful due to the time frames being too long. It may therefore prove useful to explain to women that they need to monitor their symptoms for a certain amount of time in order for GPs to consider a diagnosis of ovarian cancer. If women present with symptoms too early this could lead to GPs dismissing their concerns. Clinical information needs to be considered in order to determine what time frames should be advocated to women.

The Internet was commonly mentioned as an information source, and concerns were expressed about the vast amounts and varying quality of information that can be accessed in this way. Even those who endorsed the Internet as an information resource questioned the credibility of some of the information on the Internet. This suggests that some women may not be getting the information that they desire about ovarian cancer as a result of being concerned about information quality. It also highlights issues surrounding how best to disseminate information to women. Provision of evidence-based information from credible sources, or signposting to such resources could therefore help reassure women that they are accessing accurate and trustworthy information.

5.5.3 The need for education

Women reported that reassurance was gained through participation in ovarian cancer research and screening studies and the close contact with health professionals that this provides. In such cases it was felt that anything troublesome or problematic would be detected through participation in such schemes. Utilising medical tests as a source of reassurance and hope is potentially worrying due to the uncertainty surrounding the clinical effectiveness of ovarian cancer screening (Menon et al. 2009, Rosenthal and Jacobs 2006). This trust in ovarian cancer screening was similarly reported by Lancastle et al. (2011), where women felt reassured and less distressed as a result of putting faith in the effectiveness of screening. The trust that women are placing on screening tests

could suggest that women need to be educated about the current opportunities available to them. If women are unclear of the opportunities available to them they should be encouraged to go and visit their GP or genetic counsellor to discuss their personal situation and options.

5.5.4 Study limitations

The small sample size in the present study could have led to the possibility that not all themes were captured relative to the interview questions. Small samples are a common feature of qualitative research, with samples vastly smaller than those used in quantitative research. However, it was felt that the recurring nature of themes identified in the interviews reflects the quality of data. In addition, the data analysis method used here is designed to be performed on small samples sizes (Smith 2004).

Study participants were selected based on anticipated presentation times, worry and geographical location. If a different sampling technique had been used, such as self-efficacy or age a broader range of participants may have been included. However, it was felt that the sampling used here was adequate and sufficient. The spread of anticipated presentation time was chosen to reflect the different presentation beliefs of the sample, with this reflecting the outcome of interest.

5.5.5 Implications and future research

This study has enabled a further exploration of the role of perceived threat for women at increased genetic risk of ovarian cancer, and has provided information regarding tailored content of an ovarian cancer symptom awareness tool. Work now needs to be done in order to gain consensus on what symptom information should be given to women. This information is crucial and could help manage expectations and maintain psychological wellbeing. Once this symptom information has been gathered it can be added to the current findings to develop a draft tool. Once created the awareness tools should be presented to a sample of potential users and providers in order to gain user feedback.

5.5.6 Summary

The present study has further explored the concept of perceived threat and how perceived susceptibility and worry may influence decisions to seek medical help for possible ovarian cancer symptoms in women at increased genetic risk of ovarian cancer. Women's perceptions of ovarian cancer and behavioural intentions relating to the disease have largely been shaped by their familial experiences with the disease and women may be cautious about searching for information independently. This stems from concerns over the quality of the information available and the content of some informational resources being overwhelming.

Women at increased genetic risk of ovarian cancer are receptive to ovarian cancer awareness tools and expressed a desire for simple and clear information to be available. The next steps of the project will involve a systematic search of the literature to identify symptoms indicative of ovarian cancer. These symptoms will then be presented to a group of clinical experts in order to consolidate symptom information. This symptom information can then be included in a symptom awareness tool with tailored content for women at increased genetic risk of developing ovarian cancer.

6 Identification and validation of empirical literature on ovarian cancer symptoms

6.1 Introduction

Previous chapters have highlighted that a symptom awareness tool which addresses the specific health beliefs of women at increased genetic risk of ovarian cancer is needed. Chapter 4 identified the salient health beliefs that influenced anticipated symptomatic presentation for women at increased genetic risk of ovarian cancer and women from the general population. The aim of the current chapter is to build on this knowledge by identifying the symptom information that should be included in an awareness tool.

Symptom information should be embedded within information that attempts to maintain the psychological wellbeing of the individual. This is particularly important for women at increased genetic risk since evidence suggests that encouraging regular self-monitoring in this population may lead to anxiety and hyper-vigilant early detection behaviour (Brain et al. 1999, Fallowfield et al. 2010, Norman and Brain 2005). A key theme emerging from the qualitative interviews with women at increased genetic risk (Chapter 5) related to anticipated fear in the presence of potential ovarian cancer symptoms. Concern over the quality and credibility of information resources was also expressed, particularly in relation to information found on the internet. Provision of credible and scientifically sourced symptom information is therefore especially important for these women. Information resources may help women manage their worry levels, and could facilitate informed decisions to seek medical help. This is true for all women, but is particularly salient for women at increased genetic risk.

6.1.1 The need for symptom consensus

Despite clinical guidelines providing information on ovarian cancer symptoms, disparity exists in the terminology used to describe these symptoms. The systematic search in Chapter 3 demonstrated that a wide variety of symptoms are included in existing ovarian cancer awareness tools, with an average of eight symptoms in the

identified tools. The disparity between the symptoms identified in guidelines (Department of Health 2009, National Institute for Health and Clinical Excellence 2011) and symptoms in awareness tools suggests that providers of awareness tools do not always take into account clinical guidelines. This could lead to confusion among the public over what the symptoms of ovarian cancer are. Consensus on these symptoms would therefore be beneficial for medical professionals and women wishing to find out about the symptoms of ovarian cancer. This point holds for all women wishing to be aware of symptoms, not just those at increased genetic risk of developing ovarian cancer, as the symptoms of ovarian cancer are the same regardless of risk status.

Evidence suggests that symptoms are present for both early and late stage ovarian cancer (Cass and Karlan 2010, Goff et al. 2007, Rossing et al. 2010). Detection of ovarian cancer symptoms is difficult for women and health professionals due to the high frequency of symptoms that are not unique to the condition (Austoker 2009, Hamilton et al. 2009, Kirwan et al. 2002). The language used to describe ovarian cancer symptoms is also problematic due to varying terminology used by patients and health professionals. Women have been reported to use the term “bloating” to describe both persistent and intermittent changes, creating confusion with the term “distension”, which is used by health professionals to differentiate persistent changes (Austoker 2009, Bankhead et al. 2008, Bankhead et al. 2005, Hamilton et al. 2009). This use of different wording highlights the need for clarification of the terminology used to describe symptoms.

Practically, it may also prove useful to provide brief descriptive information on symptoms which could help women to understand the symptoms terms, identify symptoms, and potentially disentangle them from other everyday experiences. In addition to identifying the symptoms of ovarian cancer, it is important to consider thresholds at which the symptoms may be indicative of ovarian cancer. Judgments need to be made based on the best available clinical evidence in order to provide women with information that will help them determine whether and when to act on symptoms they are experiencing. One challenge in ovarian cancer is to encourage

women to be more aware of the symptoms and increase their understanding in order for them to recognise and appraise the symptoms as possible cancer symptoms. Increasing the understanding of symptoms could also facilitate the doctor-patient interaction, as it may enable women to more accurately express their symptom experience (Bankhead et al. 2008).

6.1.2 Aims of the present study

The present study focused on the symptom content of the ovarian cancer symptom awareness tool (OvSTAT). This was achieved by 1) conducting a systematic search of the empirical literature to identify symptoms indicative of ovarian cancer, with a critical appraisal of study quality and analysis of symptom effect sizes, 2) gaining clinical opinion on the symptoms from a group of experts in the form of a virtual reference group, and 3) conducting surveys with GPs and women at increased genetic risk of ovarian cancer to gain a fuller understanding of symptom experience expectations. The three evidence strands were then synthesised to identify the content of symptom information to be provided within the symptom awareness tool. This allowed the incorporation of symptom information and guidance that was based on best available clinical evidence, expert opinion, and the views of likely users and providers.

6.2 Methods

In order to guide the symptom content of the tool, a variety of methods were used to ensure that decisions were guided by best available evidence. The methods and results for each of the strands of research are presented separately.

6.3 Study 1a. Systematic search of ovarian cancer symptoms in ovarian cancer cases and cancer free controls

First, a systematic search was carried out in order to identify symptoms that are associated with ovarian cancer. Information identified from case control studies that compared symptom experience in women diagnosed with ovarian cancer and a cancer

free control group was then synthesised. Identified papers provided empirical evidence on symptoms indicative of ovarian cancer. The PRISMA guidelines were used to aid the reporting of the systematic search (Liberati et al. 2009).

6.3.1 Method

The database PubMed was searched to identify papers that included symptoms of ovarian cancer. The Department of Health (2009) and National Institute for Health and Clinical Excellence (2011) guidelines were used to guide the content of the systematic search. These guidelines identify a total of 10 possible individual symptoms (bloating, pelvic pain, abdominal pain, full, appetite, distension, fatigue, back pain, bowel and urinary symptoms). The symptoms from these guidelines were entered separately into PubMed with “AND ovarian cancer” in order to identify papers which included the symptoms. The search strategy is provided in Appendix 23.

6.3.2 Inclusion criteria

Case-control studies of symptoms experienced in women diagnosed with ovarian cancer and cancer-free women were included.

6.3.3 Exclusion criteria

Studies were excluded if they concerned symptoms relating to the treatment of ovarian cancer, the tumour pathology of ovarian cancer, if secondary data were used, or if the studies were concerned with awareness rather than experience of symptoms in cancer cases and cancer-free controls.

6.3.4 Data extraction

All identified articles were assessed for eligibility, with titles and abstracts reviewed prior to full article review (Liberati et al. 2009). All symptoms that were indicative of ovarian cancer in the included papers were extracted, not just the symptom which allowed the study to be detected in the search. This ensured that all symptoms indicative of ovarian cancer were examined. Reasons for exclusion were noted for

excluded articles. The references of included articles were also searched in order to ensure that all relevant articles were identified. Data extracted included the symptoms that were associated with ovarian cancer, study population information, study design, symptom frequency, odds ratios and study limitations. Data were extracted using a standard protocol (see Appendix 24) which was pilot tested and discussed with the supervisory team until satisfactory for this review.

6.3.5 Quality assessment

The quality of included studies was assessed using the Newcastle-Ottawa quality assessment scale for case control studies (Wells et al. 2011) (see Appendix 25). The scale assesses study quality in terms of seven items across three categories: *selection*, *comparability* and *exposure* (Wells et al. 2011). Points were awarded for the *selection* category if: (1) the cases were adequately defined with independent validation of ovarian cancer diagnosis; (2) the cases were representative; (3) the selection of controls was such that they were community controls, derived from the same population as the cases; (4) controls were well defined, with explicit statements of absence of ovarian cancer. Points were awarded for *comparability* if (5) the study groups were comparable on potential confounders such as age, medical facility, co-morbidity (maximum of two points). Points were awarded for *exposure* if: (6) data collection of the outcomes was achieved by secure record or structured interviews where researchers were blinded to case/control status; and (7) the same method of data collection was used for both cases and controls. The overall quality assessment was the sum of met criteria (range 0-8). Overall quality ratings were graded as low (1-3), average (4-6) or high (7-8). A total of 23% of the quality assessments were double coded, with 100% agreement reached.

6.3.6 Data analysis

ReviewManager (Version 5.2) was used for estimation of effect sizes for each symptom. This was achieved by pooling the data on each symptom that was gathered from included papers identified in the systematic search. The number of ovarian

cancer cases and cancer-free controls experiencing each symptom in each study was extracted in order to estimate odds ratios for each symptom. Odds ratios for each symptom were then pooled across studies using the inverse variance method. A random effects model was used based on the heterogeneity of the included studies.

6.4 Results

6.4.1 Studies identified in systematic search

Thirteen case control studies were identified from the systematic search. The search yielded 5,866 records, but 5,853 studies did not meet the inclusion criteria and were excluded (see Figure 6.1). The main reason for exclusion was that the study was not relevant (n=5,699). Characteristics of the 13 included studies can be seen in Table 6.1. Over half of the studies were from the USA (54%), the average sample size for cases was 357, and 990 for controls. The median age of participants was >40 in all studies, except for one (Behtash et al. 2008). The average number of symptoms examined was 8 (sd 4, range 2-14). Data on symptoms was extracted from medical records or insurance claims (n=6), and studies which used interview or survey methods collected symptom data through the use of set symptom lists (n=7).

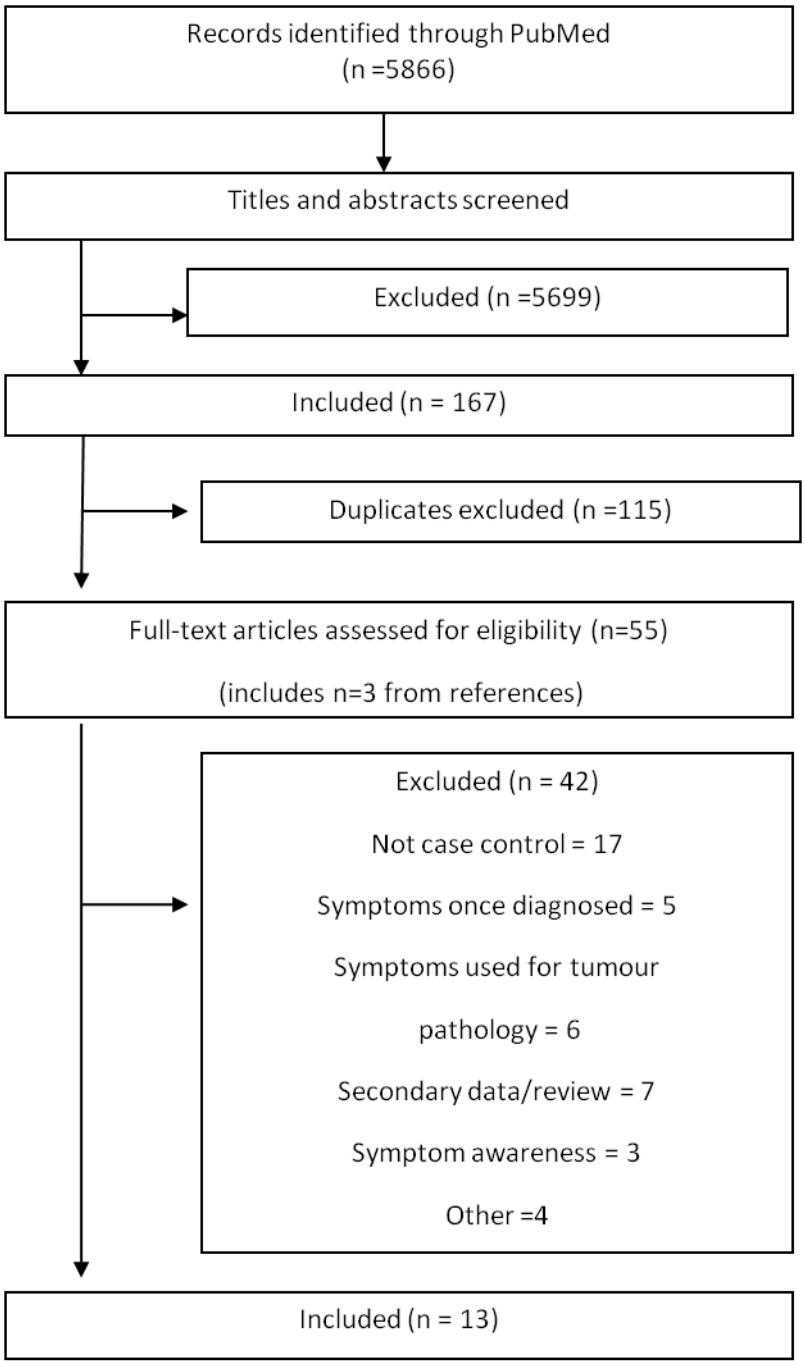


Figure 6.1. Flow diagram of study selection for systematic search to identify symptoms indicative of ovarian cancer

Table 6.1. *Country of origin, sample information, symptoms and method of included studies*

	Country	Cases (n)	Controls (n)	Cases median age	Controls median age	Symptoms	Method
Behtash et at 2008	Iran	100	100	24 (15-35)	24 (15-35)	Abdominal pain, bloating, bowel, fatigue, gastrointestinal, nausea/vomiting, urinary, vaginal bleeding	Medical records
Devlin et al 2010	USA	82	230	_____	_____	Abdominal pain, bloating, urinary	Health insurance claims
Friedman et al 2005	USA	69	69	59 (30-87)	59 (30-87)	Abdominal pain, appetite, back pain, bloating, bowel, fatigue, nausea/vomiting, pelvic pain, urinary, weight change	Medical records
Goff et al 2004	USA	44	1011	55	45 (15-90)	Abdominal mass, abdominal pain, appetite, back pain, bloating, bowel, distension, fatigue, indigestion, nausea/vomiting, pelvic pain, urinary, vaginal bleeding, weight change	Survey (symptom list)
Hamilton et al 2009	UK	212	1060	67 (59-78)	67 (59-78)	Abdominal mass, abdominal pain, appetite, bowel, bloating, distension, urinary, vaginal bleeding	Medical records
Kim et al 2009	Korea	116	135	54(18-77)	51(28-71)	Abdominal pain, bloating, full, pelvic pain, urinary	Survey (symptom list)
Lim et al 2012	UK	191	268	65* (50-79)	65* (52-78)	Abdominal pain, back pain, bloating, bowel, distension, fatigue, full, indigestion, nausea/vomiting, pelvic pain, urinary, vaginal bleeding, weight change	Survey (symptom list)
Lurie et al 2009	UK	432	491	55.6* (19-88)	56.7* (19-88)	Abdominal mass, abdominal pain, back pain, bowel distension, fatigue, nausea/vomiting, urinary, vaginal bleeding, weight change	Interviews (symptom list)
Olson et al 2001	USA	168	251	--	---	Abdominal pain, appetite, bloating, bowel, fatigue, nausea/vomiting, urinary	Interviews (symptom list)
Pitta et al 2013	Brazil	60	150	51*	44*	Abdominal mass, abdominal pain, appetite, back pain, bloating, bowel, distension, full, fatigue, indigestion nausea/vomiting, pelvic pain, urinary, weight change	Survey (symptom list)
Smith et al 2005	USA	1985	6024	77 (68-101)	78 (68-101)	Abdominal pain, bloating, gastrointestinal, pelvic pain	Health insurance claims
Vine et al 2003	USA	267	317	-------(20-74)	------(20-74)	Abdominal pain, bloating, bowel, distension, fatigue, indigestion, pelvic pain, urinary, vaginal bleeding, weight change	Interviews (symptom list)
Wynn et al 2007	USA	920	2760	59	59	Abdominal pain, back pain	Health insurance claims

*mean age is presented due to non-reporting of median

6.4.2 Quality of included studies

The ratings from the modified Newcastle-Ottawa scale are presented in Table 6.2. Four studies were rated overall as low quality, seven as average quality, and two as high quality.

Table 6.2. *Quality assessment rating of included studies*

	Selection (max 4)	Comparability (max 2)	Exposure (max 2)	Overall quality rating*
Behtash et al 2008	1	2	1	Average
Devlin et al 2010	2	0	1	Low
Friedman et al 2005	3	2	1	Average
Goff et al 2004	3	1	1	Average
Hamilton et al 2009	4	2	1	High
Kim et al 2009	1	0	1	Low
Lim et al 2012	3	1	1	Average
Lurie et al 2009	4	2	1	High
Olson et al 2001	1	1	1	Low
Pitta et al 2013	2	0	1	Low
Smith et al 2005	4	1	1	Average
Vine et al 2003	3	2	1	Average
Wynn et al 2007	3	2	1	Average

*overall quality rating scores were low (1-3), average (4-6) or high (7-8)

6.4.3 Symptoms indicative of ovarian cancer identified in included studies

In addition to the ten symptom terms that were used in the search strategy, a further six symptoms were identified and extracted from included articles (vaginal bleeding, gastrointestinal symptoms, abdominal mass, nausea/vomiting, weight change and indigestion). The thirteen identified studies therefore included a total of 16 symptoms indicative of ovarian cancer. The symptoms were abdominal mass, abdominal pain, appetite loss, back pain, bloating, bowel changes, distension, fatigue, feeling full, gastrointestinal symptoms, indigestion, nausea/vomiting, pelvic pain, urinary, vaginal bleeding and weight change. The symptoms identified in each article can be seen in Table 6.1. Three articles (Kim et al. 2009, Lim et al. 2012, Vine et al. 2003) provided data for the symptom 'pelvic and abdominal pain', whereas all other articles that had data for *pelvic pain* or *abdominal pain* included such data as separate symptoms. Therefore the data extracted from these three articles for 'pelvic and abdominal pain'

were entered for both *pelvic pain* and *abdominal pain* in order to reflect the presence of the two symptoms.

6.4.4 Estimation of effect size for each symptom

Estimated effect sizes are presented in order of size of the odds ratio (OR) in Table 6.3. Forest plots for each symptom are provided in Appendix 26.

Table 6.3. *Number of studies, sample sizes, odds ratios and 95% confidence intervals for symptoms pooled across studies (pooled by inverse variance method)*

Symptom	Number of studies	Cases N	Controls N	ORs (95% CI)
Abdominal mass	3	704	1701	81.95 (6.49-1034.58)
Feeling full	3	367	553	30.92 (12.27-77.93)
Distension	6	1206	3297	27.88 (12.96-59.98)
Bloating	11	3294	9615	21.49 (10.47-44.11)
Appetite loss	5	591	1760	14.37 (7.50-27.54)
Pelvic pain	7	2732	7974	10.69 (4.87-23.44)
Abdominal pain	13	4646	12866	8.10 (6.26-10.48)
Indigestion	4	562	1746	6.41 (1.72-23.91)
Gastrointestinal	2	2085	6124	4.47 (3.54-5.65)
Urinary	11	1757	3221	3.88 (2.69-5.60)
Fatigue	8	1331	2657	3.49 (2.29-5.32)
Vaginal bleeding	6	1246	3247	3.41 (1.57-7.42)
Weight change	5	1019	1295	3.20 (0.94-10.92)
Bowel changes	14	2218	6457	2.99 (1.82-4.91)
Nausea/vomiting	7	1064	2340	2.14 (0.96-4.79)
Back pain	6	1716	4749	1.81 (0.66-4.94)

6.5 Study 1b. Virtual reference group

A virtual reference group of experts in ovarian cancer was convened to provide clinical opinion on the symptom information identified from the systematic search. The empirically identified symptoms, along with the pooled effect sizes, were presented to

the experts to gain opinion on the relevance of the symptom in relation to ovarian cancer detection.

6.5.1 Participants

Academics and clinicians in the field of ovarian cancer were identified via discussion with the supervisory team. Ten experts were identified and sent an invitation via email. Seven experts had clinical backgrounds (including gynaecology oncology, ovarian cancer early diagnosis and academic primary care with ovarian cancer speciality) and two had academic careers focused on ovarian cancer early diagnosis.

6.5.2 Procedure

Ethical approval for the study was received from Cardiff University School of Medicine Research Ethics Committee (see Appendix 27). The email invitation included an embedded link to a short online survey. After reading the study information, the participants were invited to complete the online consent form before progressing to the survey. At the start of the survey, participants were informed: *"Please consider a woman at risk for ovarian cancer who needs to decide whether or not to consult a doctor about her symptoms. ("At risk" refers to a woman with a positive family history of ovarian cancer.)".*

6.5.3 Measures

Questions included relevance of each symptom to ovarian cancer (responses: 1=never, 2=seldom, 3=quite often, 4=very often, 5=always), ranking of importance (rank from 1-16 assigned to symptoms), expected frequency (responses: 1=daily, 2=most days, 3=some days, 4=on one occasion) and duration of symptoms (responses: 1=up to one week, 2= 1-2 weeks, 3=2-3 weeks, 4=3-4 weeks, 5=more than a month) for ovarian cancer suspicion to be aroused and what symptoms should be retained for a symptom list for women at increased risk of ovarian cancer. Participants were also asked in open ended questions if they would label any of the symptoms differently, and whether they would group any of the symptoms in to similar clusters.

6.5.4 Data analysis

SPSS v20 was used to conduct descriptive and non-parametric data analyses. Averages were calculated for symptom duration, frequency and symptom relevance. The Friedman Test was used to rank the symptoms in order of importance. This test calculates a rank for each of the symptoms individually, and then considers the values of the ranks for each symptom in order to calculate an overall rank for all symptoms.

6.6 Results

Of the ten experts invited to take part, seven completed the online survey, of whom two provided partial data. The seven participants consisted of five experts from clinical backgrounds and two experts from academic backgrounds.

6.6.1 Relevance of symptoms to ovarian cancer

Table 6.4 presents the symptoms in rank order of importance for ovarian cancer. Abdominal mass was ranked highest, followed by bloating and distension. The remaining 13 symptoms were deemed as "seldom" being indicators of ovarian cancer. When asked whether each of the symptoms should be retained for inclusion in an ovarian cancer symptom awareness list for women at increased genetic risk, seven symptoms were endorsed by all respondents: abdominal mass, bloating, distension, feeling full, pelvic pain, abdominal pain and appetite loss. These seven symptoms were also the highest ranked symptoms and had the largest odds ratios (see Table 6.4). The remaining nine symptoms (bowel changes, urinary, fatigue, gastrointestinal, indigestion, vaginal bleeding, weight change, back pain and nausea/vomiting) received the lowest ranks, had the smallest odds ratios, and were endorsed by a minority of experts. *Gastrointestinal symptoms* and *nausea/vomiting* received no endorsement, with the remaining seven symptoms endorsed by very few of the experts (Table 6.4).

Table 6.4. *Rank, relevance and endorsement of ovarian symptoms according to virtual reference group*

Symptom	Rank	Relevance of symptom (mode)	Number endorsing symptom retention (n=5)	ORs (95% CI)[a]
Abdominal mass	1.2	3	5	81.95 (6.49-1034.58)
Bloating	4.1	3	5	21.49 (10.47-44.11)
Distension	4.7	3	5	27.88 (12.96-59.98)
Feeling full	6.1	2	5	30.92 (12.27-77.93)
Pelvic pain	6.3	2	5	10.69 (4.87-23.44)
Abdominal pain	7.5	2	5	8.10 (6.26-10.48)
Appetite loss	8.7	2	5	14.37 (7.50-27.54)
Bowel changes	8.8	2	1	2.99 (1.82-4.91)
Urinary	9.1	2	1	3.88 (2.69-5.60)
Fatigue	9.9	2	1	3.49 (2.29-5.32)
Gastrointestinal	11.4	2	0	4.47 (3.54-5.65)
Indigestion	11.4	2	1	6.41 (1.72-23.91)
Vaginal Bleeding	11.4	2	1	3.41 (1.57-7.42)
Weight change	11.5	2	2	3.20 (0.94-10.92)
Back pain	11.9	2	1	1.81 (0.66-4.94)
Nausea/vomiting	12.0	2	0	2.14 (0.96-4.79)

[a]Pooled effect sizes from systematic search

6.6.2 Guidance on symptom duration and wording

The symptom guidance from the virtual reference group is summarised in Table 6.5. The experts thought that the majority of symptoms should be experienced on most days for 2-3 weeks before a woman at increased genetic risk of ovarian cancer should seek medical advice. *Abdominal mass*, *distension* and *nausea/vomiting* were thought to warrant medical advice sooner than this, and the symptoms *fatigue* and *weight change* were thought to warrant medical advice after a longer duration.

Table 6.5. *Summary of symptom duration and frequency information gathered via the virtual reference group*

Symptom	Duration mode	Frequency mode
Abdominal mass	Up to 1 week	On one occasion
Abdominal pain	2-3 weeks	Most days
Appetite loss	2-3 weeks	Most days
Back pain	2-3 weeks	Most days*
Bloating	2-3 weeks	Most days
Bowel changes	2-3 weeks*	Some days
Distension	1-2 weeks	Most days
Fatigue	More than a month*	Most days
Feeling full	2-3 weeks*	Most days
Gastrointestinal	3-4 weeks	Most days
Indigestion	2-3 weeks*	Most days
Nausea/vomiting	1-2 weeks*	Most days
Pelvic pain	2-3 weeks*	Most days
Urinary	2-3 weeks*	Most days
Vaginal bleeding	2-3 weeks	Most days*
Weight change	More than a month	Most days

*multiple modes exist. Median score is presented instead.

6.6.3 Feedback on symptom duration and frequency

Four participants provided feedback about wording of symptoms (Table 6. 6), and five participants provided feedback about possible clustering of symptoms (Table 6.7). It can be seen in Table 6.6 and Table 6.7 that some experts felt that the symptoms had overlap or could be correlated with each other. The difficulty that arises when describing symptoms is evident in responses (e.g. “bloating is a really problematic term”), as is the ambiguity surrounding some of the symptom terms (e.g., “Bloating/feeling full/indigestion are in my view poorly differentiated by patients and doctors”).

Table 6.6. *Opinions on symptom labelling expressed by the virtual reference group*

Symptom labelling responses
'Bloating' is a really problematic term. I use it to mean 'up and down' and distension to mean 'up and up' but women use it idiosyncratically (and that's OK). You would also have to consider if the vaginal bleeding is post-menopausal bleeding or other variants in pre-menopausal women. Weight change has to be weight loss and weight gain separately
Indigestion is an unhelpful term and would be better labelled as dyspepsia (i.e. "heartburn") to avoid confusion with bloating. If targeted at patients, then perhaps re-label it as "heartburn".
Abdo/pelvic pains/bowels change = something wrong with your tummy, appetite loss / weight change = not well in self, feeling full / distension / bloating = ?
I've used the term "difficulty eating" and I guess that's the same as appetite loss but it could include some of the other gastrointestinal, indigestion, and nausea issues for some women. Mostly I see it important to distinguish frequent (near daily) experiences of this from those who have these symptoms "sometimes".

Table 6.6 presents the experts' opinions on how they would label symptoms, with labels given to some symptoms in such a way that multiple symptom terms are encompassed, for example "I've used the term "difficulty eating" and "I guess that's the same as appetite loss but it could include some of the other gastrointestinal, indigestion, and nausea issues for some women". Expert opinions on potential clustering of symptoms can be seen in Table 6.7. Symptoms related to *pain* and symptoms relating to *bloating* and *distension* were suggested to be grouped together as they are not easily differentiated (Table 6.7).

Table 6.7. *Opinions on symptom clustering expressed by the virtual reference group*

Symptom clustering responses
I wouldn't group them together, because they can occur independently
I'd duck the GI symptoms
Bloating/feeling full/indigestion are in my view poorly differentiated by patients and doctors - I would group these together as bloating/indigestion. GI symptoms overlaps with many others e.g. indigestion, nausea and vomiting, bowel changes. You could lump these together under GI symptoms, but then the patient needs to be told what actually constitute GI - and I'd leave out bowel changes from the list of GI symptoms, given the low OR in the list above
Mass / distension / bloating
I group Pelvic and abdominal pain together because many women don't appear to differentiate them and they are highly correlated. Similarly I put bloating and distention together both because they tend to be correlated but it also seems to draw women's attention to bloating that is not episodic but more consistent day to day which is the sort of more concern in my eyes. I also put difficulty eating and feeling full quickly together but I don't feel as strongly about.

6.7 Study 1c. Critical thresholds identified by GPs and women at increased genetic risk

Two sets of survey data were used to gain a fuller understanding of symptom experience expectations in a sample of women at increased genetic risk and a sample of GPs. The women's survey provided opinion from potential users on the thresholds of symptoms they would expect before seeking medical help for ovarian cancer concerns. The GP survey provided professional opinion on thresholds of symptoms they would expect to see before considering ovarian cancer. Ethical approval for the study was received from Cardiff University School of Medicine Research Ethics Committee (see Appendix 7).

6.7.1 GP survey method

Recruitment

GPs were identified via a database held within the Cochrane Institute of Primary Care and Public Health at Cardiff University which contained contact details for 349 GPs. These GPs had previously taken part in research within the department and agreed to have their contact details stored on the database for future research purposes.

Inclusion criteria

Inclusion criteria were the ability to give informed consent. There was no age or gender restriction on participation.

Procedure

Invitation emails were sent to all GPs on the database. Fourteen emails (4%) were automatically returned due to incorrect or defunct email addresses, bringing the total number of possible GP responders to 335. Those who wished to participate completed an online consent form and then completed the online survey.

Measures

Symptom frequency was assessed with the question: "How <u>often</u> would you expect this symptom to be experienced before a woman should seek medical advice?"

Response options were: up to 1 week, 1-2 weeks, 2-3 weeks, 3-4 weeks, more than a month. Symptom duration was assessed with the question: "How long would you expect this symptom to be experienced before a woman should seek medical advice?". Response options were: on one occasion, some days, most days, daily.

6.7.2 Women at increased genetic risk of ovarian cancer survey method

As part of the survey reported in Chapter 4, two questions on symptom frequency and duration contributed to the present phase of the research.

Procedure

A total of 475 women were sent the survey, as described in Chapter 4. Women were provided with a stamped addressed envelope to return the paper version of the survey, and were also provided with a website address if they wished to complete the survey online (Chapter 4).

Measures

Symptom frequency and duration was assessed with similar questions to those used in the GP survey. Frequency was assessed with the question: "How often would you expect the symptom to occur during this time before going to get advice?". Duration was assessed with the question: "How long would you wait after noticing the symptom before going to get advice?". The response options for both of these questions were the same as the options described for the GP survey.

6.7.3 Data analysis

Survey data were analysed using SPSS v20. Average responses for symptom frequency and duration were calculated separately for each sample to determine symptom frequency and duration for each symptom. The Mann Whitney U test was used to compare the responses between the groups.

6.8 Results

6.8.1 Sample characteristics

As described in Chapter 4, 164 women (35%) did not return the form and 28 (6%) were excluded due to having undergone a procedure to remove their ovaries. The final sample was 283 (63%). Four participants completed the survey online. The average age

of the women was 53 years (sd=10). The majority of women were married or cohabiting and were educated beyond age 16 (Chapter 4, p81). The GP survey was completed by 108 GPs (33%). The average age of GPs was 48 years (sd= 8), 61 (56%) were male and 47 (44%) were female.

6.8.2 Opinion on symptom frequency and duration

The symptom duration and frequencies that women and GPs thought would warrant medical advice are presented in Table 6.8.

Table 6.8. *Critical thresholds for symptoms from a sample of women at increased genetic risk and a sample of GPs (medians for frequency and duration)*

Symptom	Women	GPs	Statistic
Abdominal pain	F: Most days (3)	F: Most days (3)	U=12134, z=-2.12, p=0.34
	D 1-2 weeks (2)	D: 3-4 weeks (4)	U= 4651, z=-10.37,p<0.001
Appetite	F: Most days (3.0)	F: Most days (3.0)	U=13090,z=-0.44, p=0.66
	D: 1-2 weeks (2)	D: 3-4 weeks (4)	U=7651, z=-6.75,p<0.001
Back pain	F: Most days (3)	F: Most days (3)	U=12519, z=-1.37,p=0.17
	D: 2-3 weeks (3)	D: More than a month (5)	U=6485, z=-8.26,p<0.001
Bloating	F: Most days (3)	F: Most days (3)	U=13285, z=-0.31,p=0.75
	D: 1-2 weeks (2)	D: 3-4 weeks (4)	U=6300,z=-8.48,p<0.001
Bowel	F: Most days (3)	F: Most days (3)	U=13320, z=-0.04, p=0.97
	D: 2-3 weeks (3)	D: 3-4 weeks (4)	U=6157, z=-8.48, p<0.001
Distension	F: Most days (3)	F: Most days (3)	U=13420,z=-0.42,p=0.68
	D: 1-2 weeks (2)	D: 3-4 weeks (4)	U=6528, z=-8.30, p<0.001
Fatigue	F: Most days (3.1)	F: Most days (3.2)	U=12489, z=-1.17, p=0.24
	D: 2-3 weeks (3)	D: 3-4 weeks (4)	U=8027, z=-6.43, p<0.001
Full	F: Most days (3)	F: Most days (3)	U=13395,z=-0.11,p=0.91
	D: 2-3 weeks (2)	D: 3-4 weeks (4)	U=7657,z=-6.71,p<0.001
Pelvic pain	F: Most days (3)	F: Most days (3)	U=12119, z=-1.98,p=0.054
	D: 1-2 weeks (2)	D: 2-3 weeks (3)	U=5324, z=-9.45, p<0.001
Urinary	F: Most days (3)	F: Most days (3)	U=12852, z=-0.61, p=0.54
	D: 2-3 weeks (3)	D: 3-4 weeks (4)	U=8446, z=-5.88,p<0.001
Vaginal bleeding	F: Most days (3)	F: On one occasion (1)	U=4315, z=-9.89,p<0.001
	D: 1-2 weeks (2)	D: Up to 1 week (1)	U=9083,z=-4.98,p=<0.001

*F= frequency, D= duration

Overall, women anticipated shorter times for symptomatic presentation compared to GPs, with these differences statistically significant for all symptoms ($p < 0.001$). With

the exception of the symptoms *vaginal bleeding* and *back pain*, GPs felt that medical advice should be sought when symptoms are experienced on most days for 3-4 weeks. However, women felt they would seek help sooner, with expected durations of 1-2 weeks or 2-3 weeks for all symptoms. The only statistically significant difference for symptom frequency was seen for *vaginal bleeding*, where women reported an expected frequency of 'most days' before presenting, compared to the less frequent "on one occasion" reported by GPs ($p < 0.001$).

6.9 Discussion

The results of the current study have demonstrated that it is possible to identify symptoms that are associated with ovarian cancer. The use of different methods led to a consistent opinion on symptoms and critical thresholds for ovarian cancer symptoms. The systematic search identified symptoms that were indicative of ovarian cancer and experts then used their prior experience and the data summarised from the systematic search to make decisions on the most important symptoms of ovarian cancer. Expectations of symptom experience were also gained from a sample of GPs and women at increased genetic risk. The current study has presented a set of symptoms that can be used in a symptom awareness tool which has specific content for women at increased genetic risk of ovarian cancer.

Of the 16 symptoms presented to the virtual reference group, the majority were perceived as having low relevance for ovarian cancer. Only three symptoms (abdominal mass, bloating and distension) were viewed as "quite often" being indicators of ovarian cancer. All of the other symptoms were viewed as "seldom" being indicators, suggesting that the symptoms may have problems with specificity, i.e. they could be attributed to conditions other than ovarian cancer. This reflects the vague nature of the symptoms and the difficulty that both women and health professionals face when trying to attribute symptoms to possible ovarian cancer (Evans et al. 2007). The feedback on symptom labelling and clustering also supports this, suggesting that

more than just the symptom term needs to be provided in order for women to understand what the symptom term means.

6.9.1 What symptoms should be included in OvSTAT?

The seven symptoms with the highest rankings in the virtual reference group were also the seven symptoms that received endorsement for retention in a symptom list by all experts in the virtual reference group. This finding paired with the odds ratios from the systematic search suggests that these symptoms should be considered for inclusion in the symptom awareness tool. Of these seven symptoms, *abdominal mass* appeared to be a stand-alone symptom. When the guidance on symptom duration and frequency is considered, *abdominal mass* is also highlighted as an individual symptom. The experts in the virtual reference group expected this symptom to be experienced on one occasion for up to a week before medical advice should be sought, whereas all other symptoms had longer durations and higher frequencies. However, the inclusion of this symptom still needs to be considered, as the findings may reflect the relevance of the symptom for other forms of cancer, with ovarian cancer one such possibility. Abdominal mass may therefore not be suitable for inclusion in an ovarian cancer symptom awareness tool because it is not an ovarian specific symptom. Support for this is seen in the absence of this symptom from the National Institute for Health and Clinical Excellence (2011) and Department of Health (2009) guidelines. The likelihood of a woman being able to detect the symptoms highlighted in the awareness tool also needs to be considered. In many cases, abdominal masses are hard to feel or notice externally, and are instead often revealed via scans or surgery (Prat 2014). Noticeable abdominal masses also tend to present in later stage disease (Prat 2014), and therefore may not be suitable to include in a tool which aims to bring about earlier detection.

The remaining six symptoms were considered to be indicative of ovarian cancer and therefore should be included in an awareness tool. Based on the findings from the virtual reference group, these six symptoms could be grouped into three symptom

pairs. *Bloating* and *distension* could be grouped, with this evident in the ovarian cancer literature where these terms have been used interchangeably (Kim et al. 2009, Lim et al. 2012, Vine et al. 2003). *Pelvic pain* and *abdominal pain* could also be combined, with this grouping observed in some of the identified studies in the systematic search in the current study (Bankhead et al. 2008, Bankhead et al. 2005, Hamilton 2009) and in the systematic search of ovarian cancer symptom awareness tools (Chapter3). *Feeling full* and *appetite loss* could also be grouped, as these symptoms relate to issues surrounding difficulty with eating. These potential groupings are also endorsed in the symptom labelling and clustering responses from the virtual reference group.

6.9.2 What symptoms should not be included in OvSTAT?

The remaining nine symptoms received much less support from all strands of the current research. These nine symptoms were ranked lowest and did not receive unanimous endorsement for retention in a symptom list. These symptoms also had the smallest odds ratios, with the odds ratio for *weight change*, *back pain* and *nausea/vomiting* particularly supporting exclusion due to the confidence intervals crossing one. The group of nine symptoms appear to be more non-specific in nature and the results of the current study suggest that these symptoms should not be included in the symptom awareness tool. This could be due to the other symptoms being stronger indicators of ovarian cancer, which may also be easier for women to identify and understand.

6.9.3 Symptom guidance information

Symptom time frames

GPs and experts in the virtual reference group expected symptoms to be experienced for a longer duration compared to women at increased genetic risk of ovarian cancer. This suggests that women's expectations in relation to symptoms need to be managed, and could reflect women's anticipated anxiety in the presence of possible ovarian cancer symptoms. This was similarly mentioned during qualitative interviews in Chapter 5, where women felt that they would not wait to complete a four-week

symptom diary, and would instead act sooner because they felt that early presentation is important. This view on presentation could be viewed positively, with women anticipating prompt action rather than adopting a “wait and see” approach. Conversely, this could be problematic in terms of potential impact on the healthcare systems. This echoes the notion of hyper-vigilance that was highlighted in Chapter 4, where there was an association between higher perceived threat and earlier anticipated presentation in women at increased genetic risk, due to the influence of the affective component of perceived threat.

The finding that GPs expected symptoms to be experienced for a longer time frame compared to women suggests that women at increased genetic risk may need to experience symptoms for longer than they currently expect in order for the GP to consider ovarian cancer. This is an important piece of guidance that could be provided to women in OvSTAT. The difference in expected symptom durations could also explain some of the frustration that women feel when they present to the GP with concerns about possible ovarian cancer symptoms. It is possible that women are presenting at too early a time point in the symptom experience and are therefore frustrated at the lack of action taken. Educating women about time frames in which to act could help maintain their psychological wellbeing, as well as increase the possibility that GPs will consider the symptoms as possible indicators of ovarian cancer. The current findings suggest that a symptom time frame of ‘most days’ for ‘three weeks or more’ takes into account the expectations of experts and GPs, and could be used in OvSTAT. Information on time frames could enable women to understand when is the best time to act, as well as when to present again if symptoms persist.

Symptom wording

The virtual reference group also provided useful ideas about the wording of symptoms for OvSTAT. These ideas could be incorporated to help explain what is meant by the symptom term. Explanations of symptoms could be useful as women previously expressed that they felt they did not always understand the symptom content of

symptom awareness tools (Chapter 5). Explanations could also help reduce misunderstandings between women and healthcare professionals, as they have previously been reported to use different terminology and descriptions for symptoms (Bankhead et al. 2008, Bankhead et al. 2005, Hamilton et al. 2009).

6.9.4 Limitations of the systematic search

The 13 identified studies varied in quality, with this possibly influencing the odds ratios for the symptoms. However, when sensitivity analysis was conducted to exclude the low quality studies it did not greatly change the estimated effect sizes. For the 16 identified symptoms, a wide variety of effect sizes were observed, possibly reflecting methodological problems such as sample size, study timing and stage of disease. Different methodologies were used by included studies, with interviews, medical records and questionnaires utilised. These variations in data collection methods could have influenced findings reported by the studies, and estimation of effect sizes in the current study. Interviews allow for detailed responses, and can allow for more expansion on points as opposed to questionnaires (Keeble et al. 2014). However, interview analysis can be subjective, with low generalisabilty due to smaller samples. Questionnaires allow for data to be gathered from a large number of participants in a systematic way; however, findings can be limited by recall bias, as participants may retrospectively try to remember symptoms. Medical records avoid recall bias, involve large amounts of data and often cover a long time frame. However, medical records have data quality issues, due to dependence on the accuracy of the data recording process (Bankhead et al. 2005, Keeble et al. 2014).

The heterogeneity of studies identified in the systematic search is problematic. The observed heterogeneity could be due in part to the low rates of symptoms experienced in the control groups. A random effects model was used, which assumed that other sources of variation occurred. It can therefore be said that the estimated effect sizes represents a truth about the population effect size, but there may be other factors as a result of the heterogeneity in the studies. A fixed effects model would

have been preferential, as this would allow for more confidence in the estimated effect sizes of symptoms that are indicative of ovarian cancer.

Three studies provided data for 'pelvic and abdominal pain' combined, whereas all other studies that included information for these symptoms did so separately. It was decided in order to include the data from the three studies that pooled these symptoms together that the data would be entered for both 'pelvic pain' and 'abdominal pain'. This may be problematic as it may have not accurately reflected the symptom that was experienced. However, it was not possible to disentangle this information and it was deemed best to reflect the symptom in both symptom codes.

6.9.5 Limitations of virtual reference group

The virtual reference group method could be a limitation, as the virtual nature of participation could be restrictive. Other methods, such as a Delphi round (Hasson et al. 2000), may be more beneficial in bringing experts together to talk through questions. The Delphi technique is also useful as it allows for decisions to be made on the day. However, the various locations of experts and associated costs precluded using this method.

One participant felt that they were unable to answer all of the virtual reference group questions accurately due to wishing to know specific patient information in order to make informed decisions. Use of vignettes may therefore have been better. However, as the virtual reference group aimed to gain opinion on symptom information that could be provided to all women at increased genetic risk in an awareness tool, it was envisaged that vignettes would make responses too specific. It was also thought that focusing the participants to the research context by asking them to consider the information needs of a woman at increased genetic risk who was deciding whether to act on her symptoms was sufficient for stating the research purpose.

6.9.6 Limitations of GP and women at increased genetic risk surveys

The GP sample was potentially not representative as they were recruited from a database of GPs who had previously participated in research within the department. These GPs may therefore have a particularly interest in participating in research studies and the results may therefore not be representative of GPs. The generalisability of the results from this GP sample could therefore be questioned. One way to overcome this in future research would be to recruit GPs directly from practices and not from an existing research database in order to have a representative sample, however due to the time consuming nature of this type of recruitment it was outside of the scope of this PhD. The GP survey was conducted online, whilst the women at increased genetic risk mainly responded via postal surveys. This variation in data collection method could again raise questions about sample representativeness. The GP data collection was done via email and an online survey as it was envisaged that this would lead to the optimal response rate from this population. Specifically, it was felt that sending GPs a paper based questionnaires would have required more time and would have led to lower response rates.

The GP and women's survey included questions on expected frequency and duration of 11 ovarian cancer symptoms. These symptoms are those used in the ovarian cancer awareness measure (O-CAM) (Simon et al. 2012a). The virtual reference group however, asked experts about the frequency and duration of 16 symptoms. This was due to the symptoms for the virtual reference group being guided by the symptoms identified in the symptom systematic search. This resulted in the virtual reference group providing opinion on some symptoms that were not presented to the GP/Women samples. However, as the aim of the virtual reference group was to gain clinical opinion on the empirically identified symptoms, it was necessary to ask them about all 16 symptoms. All of the 11 symptoms in the GP/Women surveys were also in the virtual reference group questions, so it still allowed for comparisons of opinions to be carried out.

6.9.7 Future research and implications

Validation of the symptoms identified in this study is a crucial next step for the research area. Evaluation of the predictive ability of symptoms indicative of ovarian cancer should be undertaken, both for individual and combined symptoms. The symptoms identified as indicative of ovarian cancer in the current study can now be used for educating women about what symptoms are indicative of ovarian cancer. Future research which aims to validate the symptoms could do so in the content of different disease stages in order to further explore symptom experience in early and late stage.

The symptom information identified in the current study could be provided to all women, not just those at increased genetic risk of ovarian cancer. This is because it is the ovarian cancer information that the symptoms are embedded within that varies according to risk status (as highlighted by the different patterns of health beliefs in Chapter 4), and not the actual symptoms. Whilst the symptom information will be useful to women from the general population, it is especially important for women at increased genetic risk that accurate symptom information, such as specific time frames is provided. The current findings suggest that women at increased genetic risk may be more concerned in the presence of symptoms than women from the general population and may be presenting too early in the symptom experience for ovarian cancer to be considered. The symptoms identified in this study can be incorporated into OvSTAT with the confidence that they are based on best available clinical evidence and expert opinion.

6.9.8 Summary

The work presented in the current chapter has sought consensus on symptoms, thresholds and guidance for the symptom content of OvSTAT. Three potential symptom clusters have been identified that can be included in the awareness tool. The next chapter will report the creation of the draft OvSTAT, with decisions for tool content made based on the findings of the previous studies. The draft tool will also be

presented to a sample of potential users and providers in order to gain feedback on the content. This will lead to the development of a final version of OvSTAT that is based on clinical and empirical evidence, and which has had user feedback throughout the development process.

7 Creation of draft OvSTAT and user feedback

7.1 Introduction

The findings from previous chapters were used to create a draft ovarian cancer symptom awareness tool (OvSTAT). Common health beliefs were identified for the two risk populations as well as unique health beliefs for women at increased genetic risk. This led to the creation of a tool that has core elements that address the shared and unique health beliefs of these two populations.

The purpose of the OvSTAT was to provide core information regarding the key symptoms of ovarian cancer and the critical threshold for when to act on these symptoms and seek medical advice (Chapter 7). The OvSTAT also aims to address psychological barriers to anticipated symptomatic presentation identified in Chapters 4 and 5. Evidence from Chapter 4 suggested that the relationship between symptom awareness and anticipated presentation was not direct. Therefore the tool also aimed to address indirect paths by increasing self-efficacy and reducing barriers, and in women at increased genetic risk, to manage ovarian cancer worry. In the following chapter, each section of the draft tool will be linked to key empirical findings and theoretical concepts from previous chapters of the PhD.

User testing is an important step in the development of complex interventions (Craig et al. 2008b). The usability and understanding of the draft tool was therefore explored in order to understand how the tool will be received by potential users and providers. Testing usability and acceptability determines whether the tool is easy to understand, contains the relevant information and is likely to achieve its purpose. Involving potential users and providers in this process allows for feedback to be gained from people who are likely to come into contact with the tool, and allows for changes to be suggested and implemented, improving the design of the tool prior to evaluation.

7.1.1 Aims

This chapter aims to 1) describe the creation of the first draft of OvSTAT, 2) assess usability of OvSTAT and 3) present changes made to create the final version of OvSTAT.

7.2 Development of the draft OvSTAT

The previous phases of work which were guided by the MRC complex intervention guidelines (Craig et al. 2008b) were drawn upon to create the draft tool, along with relevant components of The Discern tool (Charnock et al. 1999). Discern was designed to guide the evaluation of written consumer health information on treatment options (Charnock et al. 1999). As per section one of the DISCERN evaluation Handbook which outline requirements for good quality health information the OvSTAT was designed to include: 1) a clear statement of the aims, 2) achieving these aims, 3) relevance of the publication, 4) information sources, 5) production date, 6) balance of information, 7) additional sources of support, and 8) information and areas of uncertainty (Charnock et al. 1999). Evidence for the fulfilment of these requirements is shown in the description of the tool content in the following section.

7.3 Embedding key findings in the draft tool

Based on the findings of previous phases the following topic areas were included in the tool.

7.3.1 Front page

The OvSTAT logo was developed based on a previous study conducted by Dr Jana Witt within Cardiff University School of Medicine: OvDEX (oophorectomy decision explorer). OvDex is a tool that helps women find out more about the options available to them to reduce their risk of developing ovarian cancer. The tool allows women to tailor information to their personal situation to help them make an informed decision about whether to opt for oophorectomy (http://www.ovdex.co.uk/index.html). A sentence on the front page details the purpose and intended audience of the tool. The target audience of women at increased genetic risk of ovarian cancer and women from the general population reflects the findings of the previous phases of the present PhD. As the PhD progressed, it became clear that the specific information needs for women at

increased genetic risk could be embedded within core information that could be provided for women regardless of risk status.

Figure 7.1. Design and content of front page of OvSTAT

7.3.2 *"What is this leaflet for?"*

This section explicitly outlines the aims of the tools and explains to the user what information they can expect from the tool. This section also states the importance of ovarian cancer symptom awareness and the benefits of presenting early with symptoms. The information within this section helps identify the main benefits of ovarian cancer symptomatic presentation (i.e., ease of treatment), which reflects the HBM (Rosenstock et al. 1988) and the SEM findings (Chapter 4), where perceiving more benefits than barriers was associated with presentation.

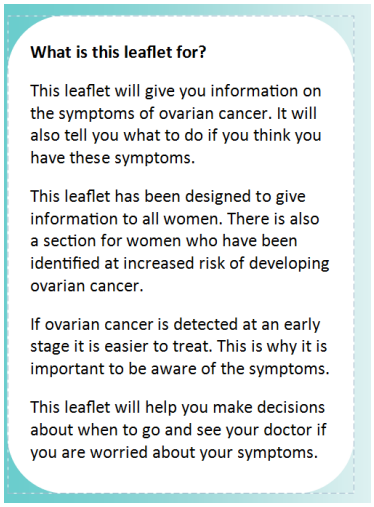


Figure 7.2. Design and content of *what is this leaflet for?* section

7.3.3 *"Ovarian cancer truths"*

The survey findings (Chapter 4) and qualitative interview phase (Chapter 5) showed that some women at increased genetic risk of ovarian cancer had misconceptions regarding ovarian cancer, primarily concerning the purpose of smear testing. Some women believed that the smear test could detect ovarian cancer. This misconception was reflected in the inclusion of 'myth busting' sections in some of the tools identified during the systematic search of symptom awareness tools (Chapter 3). Information to dispel this misconception was therefore included in OvSTAT. Previous research phases also highlighted the emphasis and trust that women at increased genetic risk were placing on familial ovarian cancer screening, even though the effectiveness of ovarian cancer screening is not currently known. Text explaining that ovarian cancer screening is not currently offered by the NHS was therefore included to reinforce the importance of symptom awareness in the absence of other detection strategies.

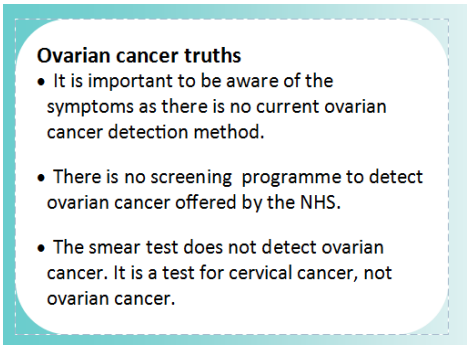


Figure 7.3. Design and content of *Ovarian cancer truths* section

7.3.4 *"What are the symptoms of ovarian cancer?"*

Symptoms and symptom guidance was based on the findings of Chapter 7. Three symptom clusters were identified based on the systematic search and virtual reference group data. The guidance for experiencing symptoms 'on most days for 3 weeks or more' reflects the critical thresholds identified by the synthesis of the symptom data in Chapter 7. This specific guidance is important to include as it informs readers about appropriate presentation times. Positive feedback regarding the use of a female body image in tools was well received in qualitative interviews (Chapter 5), in line with previous research which has demonstrated the effective use of visual aids in imparting

health information (Edwards et al. 2002, Lipkus 2007). An illustration of a female body was therefore included to illustrate where the identified symptoms would be experienced. The body was used to emphasise the non-gynaecological nature of the symptoms of ovarian cancer. Due to the issues identified in Chapter 7 regarding symptom terminology and the interchangeable use of many symptom terms, a brief explanation for each of the symptoms was also included. It was envisaged that these explanations would help to increase understanding of the symptom clusters, thereby improving awareness and appraisal of potential ovarian cancer symptoms despite variability in terminology. The symptom explanations could also help to increase self-efficacy (confidence in noticing a symptom), as women could feel more confident in explaining their symptom experience if they recognised their symptoms in OvSTAT. Self-efficacy was shown in Chapter 4 to be directly associated with symptom knowledge and was indirectly associated with presentation through perceiving more benefits than barriers to presentation in both risk populations. In women at increased genetic risk, self-efficacy was also indirectly associated through perceived threat (Chapter 4). Increasing self-efficacy could therefore be beneficial for multiple reasons.

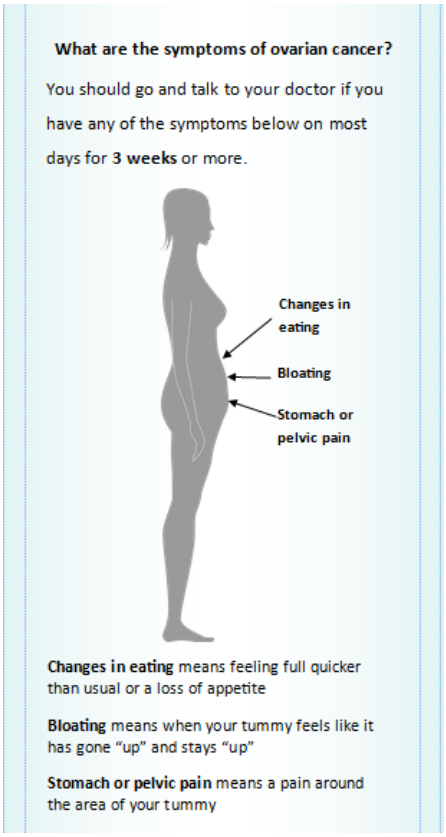


Figure 7. 4. Design and content of *What are the symptoms of ovarian cancer?* section

7.3.5 *"When should I go and see the doctor?"*

Previous phases highlighted the importance of presenting action-oriented information as well as awareness raising information in relation to ovarian cancer symptoms. Many women anticipated presenting immediately in the presence of possible ovarian cancer symptoms (Chapter 4). Women's understanding of critical thresholds and expectations therefore need to be managed, and women need to be informed that they may need to experience symptoms for longer time periods in order for doctors to be able to correctly assess the relevance of symptoms as indicative of ovarian cancer. Importantly, this section also emphasises that women experience these symptoms from time to time, and the experience of them does not necessarily indicate that ovarian cancer is present. This is crucial information for managing worry levels, which is particularly relevant for women at increased genetic risk, for whom the SEM of HBM constructs revealed that higher perceived threat (which included worry) was associated with immediate anticipated presentation (Chapter 4). Attempts to manage perceived threat are therefore especially important for this population and could help avoid over-presentation.

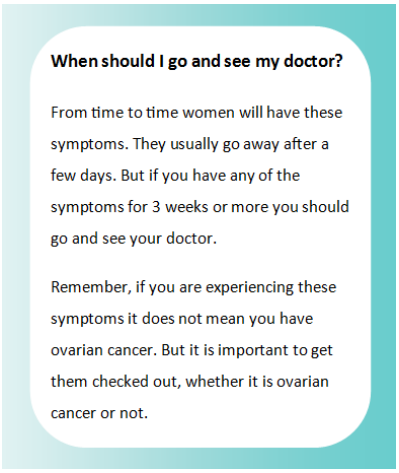


Figure 7.5. Design and content of *When should I go and see my doctor?* section

7.3.6 *"What to expect at the doctors"*

This section of OvSTAT provides information about what women might expect if they present with concerns about ovarian cancer symptoms. Again, this section attempts to manage expectations, and also aims to put women at ease about the consultation

process and reduce barriers to presentation (Chapter 4/5). This section also encourages women to take OvSTAT with them to the visit in order to prompt them and facilitate the doctor-patient discussion. OvSTAT could therefore be a way of helping women feel more confident in their decision to present and could also help manage expectations of what will happen when they present.

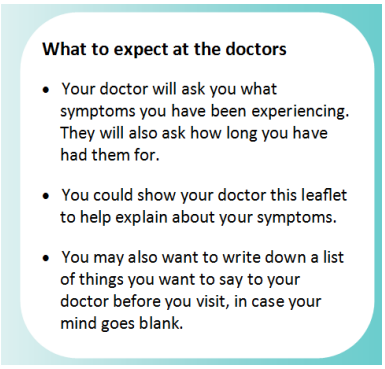


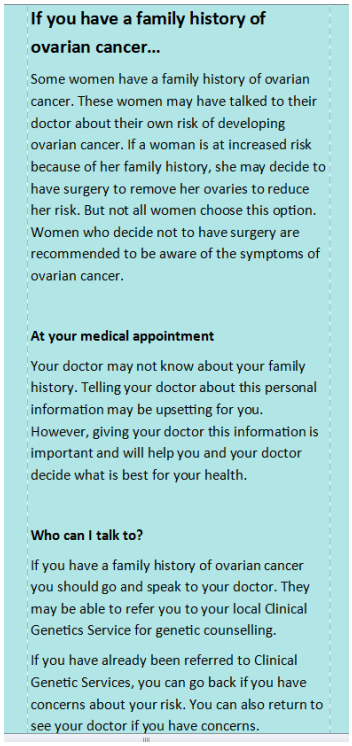
Figure 7.6. Design and content of *What to expect at the doctors* section

7.3.7 *"If you have a family history of ovarian cancer"*

This section of OvSTAT contains specific content for women at increased genetic risk of ovarian cancer and aims to address some of the specific information needs of these women as outlined in the previous phases. The first paragraph highlights the importance of symptom awareness for women who do not choose RRSO. The next paragraph in this section helps prepare women at increased genetic risk for their medical appointment. The importance of disclosing family history to the doctor is emphasised, and women are encouraged to prepare themselves emotionally to share this information. Many women in the interviews in Chapter 5 described this as an emotional burden, and were disgruntled at their doctor's lack of knowledge of their family history. In reality, doctors may not be aware of all of their patients' personal circumstances, hence it is important for women to raise their family history if they are presenting with ovarian cancer symptom concerns.

The final paragraph provides information about who to talk to. This information highlights the importance of talking to the doctor about family history and that there are specific services available to those who have been identified as being at increased

genetic risk. Encouraging women to utilise the Clinical Genetics Service could help manage their perceived threat levels (Chapter 4), as specific support and genetic counselling can be provided depending on the needs of the individual.



If you have a family history of ovarian cancer...

Some women have a family history of ovarian cancer. These women may have talked to their doctor about their own risk of developing ovarian cancer. If a woman is at increased risk because of her family history, she may decide to have surgery to remove her ovaries to reduce her risk. But not all women choose this option. Women who decide not to have surgery are recommended to be aware of the symptoms of ovarian cancer.

At your medical appointment

Your doctor may not know about your family history. Telling your doctor about this personal information may be upsetting for you. However, giving your doctor this information is important and will help you and your doctor decide what is best for your health.

Who can I talk to?

If you have a family history of ovarian cancer you should go and speak to your doctor. They may be able to refer you to your local Clinical Genetics Service for genetic counselling.

If you have already been referred to Clinical Genetic Services, you can go back if you have concerns about your risk. You can also return to see your doctor if you have concerns.

Figure 7.7. Design and content of *If you have a family history of ovarian cancer* section

7.3.8 *"What to do now"*

This section reminds women to seek medical advice if they experience symptoms on most days for three weeks or more. It also encourages women to go back to their doctors if the symptoms persist or return. This encourages women to be confident in re-attending if their concerns continue, and again links to the self-efficacy and benefits/barriers findings for the SEM of HBM constructs (Chapter 4). Women are also suggested to keep the leaflet so that they can refer to it again if they need it. Keeping the leaflet would allow women to take the leaflet to the consultation with them, which may facilitate discussion with the doctor.

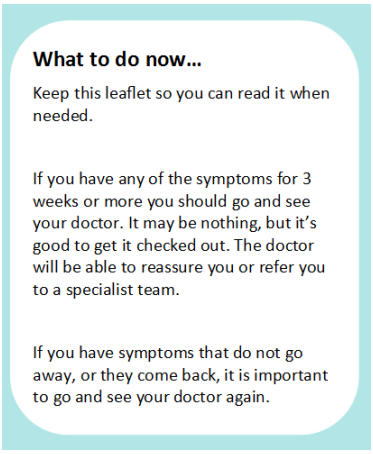


Figure 7.8. Design and content of *What to do now…* section

7.3.9 *"For further information and support"*

The ovarian cancer charity Target Ovarian Cancer agreed to be included in the tool as a source of further information and support for women. Therefore if women have any particular questions or concerns, they have a dedicated charity with multiple resources available to them. This section also details that the tool was created at Cardiff University, which highlights that the tool was created in the UK. The funders for the project were also detailed here, along with a version number and date which ensures readers can see when the information was created.

Figure 7.9. Design and content of *For further information and support* section

7.4 Methods

The present study examined the users' and providers' understanding of the OvSTAT tool and their opinions on content. The methodology used was the cognitive

interviewing technique, which enables an evaluation of the purpose, layout and content of health technologies, with a view to designing a version of OvSTAT that is 'fit for purpose'. Ethical approval for the study was received from Cardiff University School of Medicine Research Ethics Committee (see Appendix 27).

7.4.1 Cognitive interviews

User testing involved a sample of users and providers giving feedback and opinion on the draft OvSTAT. Verbal probing is a cognitive interviewing technique that can be used for user testing (Collins 2003, Willis 2005). Verbal probing is commonly used for testing questionnaires, but can also be applied to other materials (Willis 2005). Verbal probing involves the participant looking at the material, followed by the interviewer asking target questions which are then followed up by probing for specifics relating to the question or answer given (Collins 2003, Willis 2005). Verbal probing allows for further information to be gathered and encourages the participants to expand and explain their answers. The content of the interviews was informed by a topic guide with responses probed in order to fully explore the cognitive processes underlying the response (Willis 2005).

The main topics were usefulness/understanding of the tool, content and layout, improvements and inclusion of a section for women at increased genetic risk (see Appendix 28). Other topics that arose during interview were explored though the use of probes and prompts. The main probes covered comprehension, paraphrasing and improvements (see Appendix 28).

7.4.2 Recruitment

The study aimed to recruit 8-10 participants, representing a variety of potential users and providers. Ten women at increased genetic risk were identified from the pool of women who agreed to take part in future research studies when they completed the survey in Chapter 4. These women were selected to reflect a range of age (above 50 and below 50 to reflect cancer risk increasing in older age), anticipated presentation

time and ovarian cancer worry levels of potential users. Two women from the general population and two GPs were identified from within the Department of Primary Care and Public Health, and a clinical genetics specialist was identified from Cardiff and Vale University Health Board. Ovarian cancer charity Target Ovarian Cancer was also approached to identify a participant with experience of providing information materials for women with ovarian cancer concerns.

7.4.3 Procedure

Women at increased genetic risk were sent an information sheet, consent form, and a postage paid pre-addressed envelope. On receipt of the signed consent form the participant was contacted and a time and date for the interview was arranged. Once the interview had been arranged, the draft OvSTAT (see Appendix 29) was posted to the participant. A representative from Target Ovarian Cancer was identified via email, and upon receipt of signed consent the draft OvSTAT was posted. Due to geographical distance, telephone interviews were conducted with women at increased genetic risk and the charity representative. The two women from the general population, two GPs and the genetic specialists were interviewed face to face. Participants were consented and then given the draft OvSTAT (see Appendix 29) to read at the start of the interview prior to the interview commencing. All interviews were audio recorded and transcribed verbatim.

7.4.4 Data analysis

Thematic analysis (Braun and Clarke 2006, Green and Thorogood 2013) was conducted using NVivo 8 (QSR International Pty Ltd 2008). The transcripts were read and re-read in order to achieve familiarisation with the data. Initial codes were identified and applied to the transcripts. Themes representative of the codes were then identified based on the codes (Green and Thorogood 2013). Quotes presented in the following section represent examples of the identified themes. Insertions to clarify topic content are denoted by square brackets. The removal of irrelevant information within the quotes is denoted by "…".

The characteristics of each participant are presented in parentheses after each quote in the following order: hp1 = health professional one, hp2= health professional two, hp3= health professional three, ir1= increased risk participant one, ir2= increased risk participant two, ir3= increased risk participant three, g1= general population participant one, g2= general population participant two, cr1= charity representative participant.

7.4.5 Amendments to OvSTAT

Amendments to OvSTAT were considered and changes that would result in improvements to the tool were made on the basis of the cognitive interview findings.

7.5 Results

7.5.1 Sample characteristics

Five women (50%) at increased genetic risk of ovarian cancer agreed to take part in the study. Contact could not be made with one participant to arrange an interview, and another participant was unavailable for interview during the study period. A total of three telephone interviews were arranged and completed with women at increased genetic risk of ovarian cancer. Characteristics of these are shown in Table 7.1.

Table 7.1. *Age, education level, anticipated presentation time and ovarian cancer worry for the three women at increased genetic risk of ovarian cancer*

Participant	Age	Education	Presentation	Worry
1	52	Secondary	As soon as I notice	6
2	64	Up to 16	+4 weeks	7
3	70	Secondary	Over 1 up to 2 weeks	3

Cognitive interviews were also completed with two women from the general population, two GPs (one male, one female), one clinical geneticist (female) and one ovarian cancer charity representative (female). The cognitive interviews had an average length of 17 minutes (range 11- 30 minutes).

7.5.2 Cognitive interview findings

Themes that arose from the cognitive interviews included positive feedback, negative feedback and recommendations for improvement.

7.6 Positive aspects of OvSTAT

7.6.1 Tool purpose

Overall, the tool was well received. The aims of increasing awareness of ovarian cancer symptoms, and providing information about what to do if symptoms were experienced were identified and understood by participants.

> *I think it's a great idea and I think it's really good, I think it's been a long time coming, there isn't a lot out there for people like me who are looking for information, apart from websites.' (ir3)*

> *'it doesn't overload you with stuff, it just gives you simple things to look out for and then like simple steps like if you see this go see a doctor, and like saying not to panic and everything.' (g2)*

The section on ovarian cancer truths was viewed positively, with the dispelling of the common misconception of the smear test detecting ovarian cancer singled out as being particularly useful by health professionals.

> *'I think it's quite good to clarify…that the smear doesn't check it, because there's an amazing amount of people who think that the smear does.*' (hp2)

The tool was viewed as containing information that would be expected to be included in similar health education leaflets. It was also said that this information was presented in a logical way, which aided the flow and readability of the tool.

> *'Well as the questions were springing to my mind, actually they were addressed, so I think it was a nice logical order so that prompted me to read on.' (g1)*

> *'it's nice and logically laid out in it's almost like a timeline isn't it? So what's it for, these are the symptoms, what you should do next, and what should you expect at the doctors. I think that flows quite nicely.' (hp2)*

The length of the tool and the layout of the information in different sections was also praised.

'people get bored don't they of reading, whereas actually I thought it was quite good the way it was all laid out, who it's for, broken down into nice bits.' (ir2)

'I liked the colour of the brochure, I thought the typeface and the wording was easy to read, and it was clear.' (ir3)

The language used in the tool was reviewed positively and was regarded as making the tool accessible for women with different literacy levels.

'it reads like that sort of you know, level of pitch in terms of what you do reading women's magazines and whatever, so I think that's probably appropriate, because women certainly pick up on that information and bring it in.' (hp1)

The basic language and lack of medical terminology was discussed as a specific positive attribute to the tool.

'It doesn't feel too medicalised… I think it's good and I think talking in the first person, if you are experiencing this, I think it's pitched just right to be honest.'(g1)

'I thought it was very easy to read and informative. Not going into too much, some leaflets I've seen go into a bit too much blah, blah sciency type things, I thought this was very, not simple in a bad way, simple in a good way.' (ir2)

The logo on the front page of the tool was also praised 'And I liked the front cover, I liked the OvSTAT symbol. That shows the ovaries presumably?' *(ir3)*

7.6.2 Symptom information

The symptom information was viewed as clear and well-focused.

'It's quite good that there's not too many symptoms, because that could become a bit overwhelming.' (hp2)

'It's easier to remember those three changes in eating, bloating stomach or pelvic pain. Becoming too detailed in medical jargon I think it can just cloud that.' (g1)

The symptom message was perceived to be enhanced by the use of a female body illustration. This was praised for breaking up the space, drawing the reader's attention to the symptoms, and for highlighting that the symptoms are not focused around the area of the ovaries.

> *'it probably is quite helpful… I think getting away from those sort of diagrams of ovaries that show like, this is your ovary here, and this is… probably better because it (ovarian cancer) is going to present in a non-specific way, and so you need to be… perhaps representing that.' (hp1)*

> *'Good picture, I liked the picture, actually showing the bloating and you know pointing out where to look.'(ir2)*

The placing of the picture also received positive feedback, with it viewed as a core feature of the tool.

> *'you sort of pick up the leaflet don't you and open it, and that bit you look at you sort of see that first because you've got the diagram, and really out of all of it, that is the most important bit isn't it?' (ir2)*

The specific time frames that were provided with the symptoms were described as providing a clear message that could be easily understood.

> *'I think lots of people would probably take note of that (3 week timeframe).' (ir1)*

> *'Yeah, I liked the bubbles splitting things up and I liked the fact that you had the headings in bold and the important things like the three weeks in bold.' (g2)*

The frequency of experiencing symptoms on 'most days' was viewed positively, and was described as providing guidance without being too specific. This was noted as important as providing specific symptom frequencies may lead to inappropriate help seeking. The section that informs that these symptoms may be experienced without

them being ovarian cancer was similarly viewed as being useful for managing potential concerns.

'you have to be careful not to be too specific because if you're too specific then they'll say well I only had it three times in three weeks and it says I have to have it at least four times.' (hp3)

' it was nice that you've said a lot of people have these symptoms… and often they go away, but, if you have them a long time you should go and be seen, and that it doesn't mean… that there is a cancer.. it can be caused by other things.' (hp1)

The explanation of symptoms underneath the female body illustration was described as aiding understanding of the symptoms. These sentences that expand on the symptom terms were viewed as a useful inclusion.

'with all types of symptoms, different people mean different things by them. That happens time and time again in consultations so you just get the wrong end of the stick from patients and they get the wrong end of the stick from you. So it's good to clarify what you mean by them.' (hp2)

'you had more information underneath [the body image] just giving a bit more…especially in things like changes in eating, I would have had a question about that if you hadn't have said at the bottom that means fuller quicker because I would have been like, what sort of changes because it could have been anything if you didn't have the explanation.' (g2)

7.6.3 Encouraging doctor patient interaction

The section about what to expect at the doctors was praised ''I think all the stuff about what to expect at the doctors you know, makes sense, and is quite clear' (hp1). The suggestion to take the leaflet to the consultations was also deemed useful.

''I think it is a good point to say about… taking the leaflet or being explicit about the fact that that's why you've come about your symptoms, because often people will come with these symptoms, and it may not necessarily cross your mind that they think they've got ovarian cancer.' (hp1)

Many of the participants felt that the tool would be useful at encouraging doctor-patient discussion and could be used in consultations.

> *'I think it's quite reassuring to take something along to the doctor's consultation, just to help… my description of any symptoms that I'd been experiencing, just as a back up to my concern really.' (g1)*

It was felt that the tool could help make the concerns of the patients more explicit, and could also help the health professional to focus on the patient's primary concern. One health professional described how patients raising the concern of ovarian cancer could make them consider ovarian cancer quicker than they may have done without the specific concern being flagged.

> *'if somebody brought something like this, you'd be thinking, oh, actually, I ought to be quite sure in my own mind… I may have seen the patient and I may have been very confident that this was their IBS, but if they say to you, oh doctor, do you think I could have ovarian cancer, you start to think, oh well, actually, yeah, perhaps I do need to pay a bit more attention to that as a possible symptom and perhaps I ought to think more about it…because… as much as you try maybe you don't always get to the bottom of the reason that they've come or the symptoms that is really bothering them.' (hp1)*

7.6.4 Content for women at increased genetic risk of ovarian cancer

The concept of one tool that is applicable to all women, with specific content for women at increased genetic risk, was well received.

> *'I think it should be included all in the one leaflet. I didn't think as someone who hasn't got a family member suffering… it didn't irritate me at all or put me off the leaflet by being there. But I can also empathise that if you did have a family history, that's going to be an extra layer of concern, and it might be irresponsible for the leaflet not to address it.' (g1)*

> *'The family history section goes well…it's good that everyone's included in the same leaflets, so it's not sort of like you're segregating different people like you need a different leaflet… it's nice that everyone's all grouped together, it's more inclusive, so, yeah, I'd prefer that if they had a separate one.'(g2)*

However, whilst deemed relevant for all, it was expressed that the tool could fulfil a specific role for women at increased risk, with OvSTAT considered as potentially useful to women who have sought medical advice about their genetic risk status.

'I think it's good to have a leaflet. And I think it's difficult because it's always non-specific what you're trying to explain so having a leaflet means that you give them something to take away, so I think it's good.' (hp3)

The content within the increased genetic risk section was regarded as being informative and containing adequate levels of information.

'I think it's good to talk about that possibly having your ovaries removed as well, because that's been in the news hasn't it as well, with Angelina Jolie, so I think that's quite good as well.' (ir2)

'the bit about genetics is sufficient because the idea of this is, when do I need to be worried that I might have cancer. That's what this this leaflet is for. It's not when do I need to worry if my family history is significant.' (hp3)

The section promoting the importance of disclosing their risk status to their doctor was also positively received.

'they'd know information about their own risk level, but I think again, to flag up that actually it's not always going to be obvious when you go to the doctor that you've had testing for your genetic risk…making it clear… to flag up that this is the reason that you are presenting'. (hp1)

7.7 Negatives aspects of OvSTAT

When probed about any irrelevant information within the tool, the length of the introductory section was discussed by some participants.

'if you were going to cut anything out, I think, knowing what this leaflet is for, it's sort of the thing where you always put in isn't it, but really, if somebody picks up a leaflet, like they know it's an information leaflet, and they've picked it up to read about ovarian cancer in simple terms, because that's what it says on the front.' (hp1)

7.7.1 Clarification of content

The first bullet point in the *ovarian cancer truths* section created confusion with participants. It was interpreted by some to mean that there was no method of detecting ovarian cancer, whereas it was intended to mean that there is no routinely available detection method.

> *'I guess I just thought it was a little bit confusing.' (hp1)*
>
> *'To me I read that and thought, so how are they going to know whether I've got it or not when I go to the doctor. And people might think, well I won't bother going.' (hp2)*
>
> *'is there a blood test?' (ir3)*

This confusion was compounded by the second bullet point making a very similar point.

> *'Because… then you have said, there's no screening programme offered for it.' (hp1)*
>
> *'They obviously can detect it, it's just you can't screen for it, and you kind of say that at the bottom, in the next line.' (hp3)*

The final bullet point in the *ovarian cancer truths* section also drew criticism from a health professional who felt it is was important to clarify that the purpose of the smear test is to detect pre-cancerous cells.

> *'if I was going to be nit-picky I would say it's not a test for cervical cancer, it's a test for pre-cancerous cells that could in years to come become cervical cancer.' (hp1)*

Questions also arose concerning the explanation of the symptom *bloating*. Some participants felt that this was not explained in a clear way that would be understood by all readers.

> *'bloating ,I personally didn't like that explanation that your tummy feels like it's gone up and stays up. I wonder whether you should more say that it's, because it's more a blown out, isn't it? It's sort of like a, because it's like you're pregnant.' (ir2)*
>
> *'I'm not sure what gone up means.' (hp2)*

The different layout of the family history section compared to other sections was discussed. This subtle formatting difference was viewed positively as highlighting the different content. Language and font differences in comparison to the other sections were positively noted.

'I like the way it (family history section) wasn't highlighted so strongly in terms of the formatting to the centre sections, because it's not going to be relevant for everyone.' (g1)

'I think it's maybe that the headings seem smaller than all your other headings.' (g2)

'you go from 'you' and 'your' in the kind of the general population bit to 'some women', in the increased risk.' (cr1)

7.7.2 Missing information

When participants were asked about the *what to expect at the doctors* section, questions arose as to what tests may be done if the doctor suspects ovarian cancer.

'on the 'what to expect at the doctors' bit, I just wonder whether there should be something about you know, the doctor might give you a ca 125 test or scan or something.' (cr1)

However, when probed about their reasoning for this, many felt that it may be detrimental to include this information.

'if you tell them… your doctor might then do a scan and a blood test and if the doctor doesn't do a scan and a blood test and so on, then you're raising expectations of things… All you as a patient need is to decide if I need to go to the doctor and then you leave it to the doctor to decide.' (hp3)

7.8 Recommendations

It was suggested that the font on the front page could be changed to emphasise the letters that make up 'OvSTAT'.

'just highlight or switch the font sizes.' (cr1)

Suggestions were made to clarify the first bullet point in *ovarian cancer truths*. These included amending the sentence to clarify the meaning, and also removing the sentence entirely.

' I guess maybe if you added routine, like a screening or… it's not routinely looked for, maybe it would be a bit sort of clearer for people.' (hp1)

'I don't know whether they should just be combined (bullet points 1 and 2.).' (cr1)

A suggestion for how to clarify the role of the smear test was also made.

'…say to people that it's not, your ovaries are not being looked at, it's a cervical test, the cervical smear test is of your cervix only, and nothing else.' (hp1)

One participant expressed a desire for more information regarding the prevalence of ovarian cancer. However, probing this suggestion led the participant to explain how they also felt the tool provided adequate guidance to additional information resources where this information could be found.

'if I was going to add one bullet point to anywhere it would be one sentence on prevalence of ovarian cancer in the general female population… But I know that's something that I could go and find out anyway, quite easily on the internet, so it doesn't trouble me.' (g1)

The inclusion of information regarding the inherited link with breast cancer was also raised.

'there is this kind of possible link between breast cancer and ovarian…and if you've got that BRCA gene, I know you can't really mention that because obviously people reading this won't necessarily know what that is.' (ir2)

'the only other thing you might want to put in there is if you have a family history of breast and/or ovarian cancer. Just you know, obviously some people will have only breast cancer but they may then get ovarian cancer.' (hp4)

Possible explanations to enhance the explanation of *bloating* were also discussed.

'I wonder whether you can say things like, you know, things like whether you've noticed that your trousers are tighter, or your clothes are tighter.' (hp2)

'I think you need to say more… out rather up… or blown out.' (ir2)

Improvements to the information specifically for women at increased genetic risk were also made.

'how would a woman know that she's been identified, would she, you know, if she was reading that, would it be sort of better to say… I don't know, or if you're perhaps worried about your family history or something.' (cr1)

'it might be better(to order the section) if you have a family history, who would you talk to? See your GP and they might refer you to genetics and then what might happen next.' (cr1)

Suggestions were also made for more coherent ordering of the information in the increased genetic risk section.

'I wonder whether that sentence, 'they may be able to refer you to your local clinic or genetic service'. You know rather than saying 'genetic counselling' you might say 'to discuss options'. (cr1)

7.8.1 Amendments made to OvSTAT following cognitive interviews

Amendments to improve OvSTAT that were suggested by participants were considered by the supervisory team. Table 7.2 shows the amendments that were made to OvSTAT following the cognitive interviews, with the final version of OvSTAT in Appendix 30. The readability of OvSTAT was assessed with the Flesch-Kincaid Grade test (Friedman and Hoffman-Goetz 2006), with the reading age of the final tool of Grade 6 (11-12 years old).

Table 7.2. *Summary of changes made to OvSTAT following cognitive interviews*

Section	**Amendment**
Front page	Highlight the letters in 'ovarian cancer symptom awareness tool' that make up 'OvSTAT'
What is this leaflet for?	Reworded 'identified at increased risk of ovarian cancer' to 'women with a family history of ovarian cancer'
Ovarian cancer truths	Removed first bullet point
Ovarian cancer truths	Third bullet point reworded to 'it is a cervical cancer screening test, not ovarian cancer'
What are the symptoms?	Reworded bloating explanation to 'feels like it has gone 'out' and stays 'out''
When should I go and see my doctor?	Added 'on most days' to be consistent with symptom guidance
Family history	Added 'the doctor will assess your family history, and if you are eligible may refer you'
Family history	Changed font size of headings to be consistent with the rest of the document
Family history	Changed the tense to match the rest of the document, now 'you' instead of 'some women'
Family history	Changed 'for genetic counselling' to 'to discuss your personal risk'
Family history	Changed order of subheadings, moved 'at your medical appointment' below 'who can I talk to'
Family history	Added 'family history of ovarian or breast cancer'

7.9 Discussion

The feedback gained from cognitive interviews with a sample of potential users and providers has led to the development of a final version of OvSTAT. The tool was well received by a range of users (women at increased genetic risk and women from the general population) and providers (GPs, a clinical geneticists and a representative from an ovarian cancer charity). Overall, the content and layout of the tool was viewed favourably, with the aim of the tool easily identified and the information within the tool perceived to be useful and easy to understand. Criticisms were also reported, with most suggestions for improvement relating to consistency or clarification. These suggestions were incorporated in the final version of OvSTAT. Future research should

now evaluate the acceptability and feasibility of OvSTAT as well as its potential to influence the determinants of presentation behaviour.

7.9.1 Positive feedback on the draft OvSTAT

Participants liked how the tool provided information relating to ovarian cancer symptom awareness in a clear and simple manner. The tool was praised for the flow of information, which covered the background, the symptoms, what to do if the symptoms are experienced, what to expect in the medical appointment, and signposting to additional information. The tool was also regarded as being useful in dispelling common misconceptions surrounding ovarian cancer, namely, that the smear test does not detect ovarian cancer. The inclusion of the *ovarian cancer truths section* was particularly well received by tool providers. This information can help educate women about ovarian cancer and emphasises the importance of symptom awareness in the absence of routine ovarian cancer screening. The use of a female body illustration was noted as aiding visualisation of the symptom origins, and was praised for emphasising that the symptoms are non-gynaecological in origin. The image placement also received positive feedback, as participants felt that it was the focal point of the tool and helped to impart the symptom message. Understanding was further enhanced by corresponding symptom descriptions.

The dual audience of the tool was well received and the inclusion of an embedded section specifically for women at increased genetic risk of ovarian cancer was endorsed. Participants described the all-inclusive nature of this approach, and felt that the separate section for women at increased geneticrisk was not detrimental to women who were not at increased risk. This finding suggests that a combined tool could be acceptable. An inclusive approach may help to manage the psychological well-being of women at increased genetic risk, as a separate tool aimed at this population could lead to feelings of segregation. Embedding the specific information for women at increased genetic risk within a tool for a wider audience may mean that symptom information can be processed in a less threatening way.

The potential usefulness of OvSTAT in consultations was discussed. Both providers and users noted the potential of the tool for enhancing doctor-patient interaction. This was also mentioned in relation to information within the increased risk section of the tool. The importance of disclosing family history was echoed by the health professionals. Health professionals described how in consultations the patient's main concern for presenting was not always clear and that disclosing this information could allow the health professional to understand what matters most to the patient (Murray et al. 2003, Smith et al. 2005b). This highlights the importance of the attempt to empower women to disclose potentially emotive information when presenting with ovarian cancer concerns within OvSTAT. It also emphasises the importance of this section in psychologically preparing women to share this information.

7.9.2 Suggested changes

Amendments mainly centred on minor clarifications of content (see Table 7.2). However, other recommendations were not acted upon. The lack of specific information about tests at medical appointments was identified by some participants, but when thoughts around the inclusion of this information were probed, it was expressed that including such information may raise expectations about what will happen at the medical appointment. The implications of having this type of information in writing was discussed by the health professionals, who thought that patients having test information in black and white could cause confusion and possibly create friction if the doctor does not think the tests are applicable to the patient. The omission of this information therefore helps with managing expectations about interaction with healthcare professionals, which is particularly important for women at increased genetic risk.

Some participants also felt the introductory section was lengthy, and in the instance of needing to condense information, this section could be streamlined. However, it was decided to keep the section unchanged as those who suggested changes to this section only did so after probing for areas of improvements and none of the participants felt

strongly that the change should be made. The Discern tool also details how good quality tools have clear aims that tell the reader what is about, what it covers and who it is for (Charnock et al. 1999). This paired with the perceived usefulness of the current content of this section by the other participants, guided the decision to keep this section unchanged. The use of DISCERN evaluation Handbook enabled decisions to be made in order for a good quality health information leaflet to be created (Charnock et al. 1999).

7.9.3 Study limitations

The verbal probing technique could lead to an artificial interview process in comparison to standard interview techniques (Willis 1999). However, the purpose of the interview needs to be considered here, with verbal probing concerning the analysis of specific content (OvSTAT), whereas traditional semi-structured interviews are concerned with collecting of data relating to what participants disclose (Willis 2005). Verbal probing was therefore a useful technique for exploring and understanding users' and providers' thoughts about the tool. Effort was also made to ensure that probes were non-leading, in order to minimise potential bias.

The sample consisted of a variety of potential tool users and providers. Whilst a larger sample may have enabled more people from each of the subgroups to be represented, the current numbers were considered sufficient for carrying out preliminary usability and acceptability testing. It should also be acknowledged that the women at increased genetic risk of ovarian cancer had already participated in the survey in Chapter 4 of the thesis and were derived from the UKFOCSS (Jacobs et al. 1999) and PsyFOCS (Brain et al. 2012) studies. As a result of their prior research involvement, these women may not be representative of women at increased genetic risk of ovarian cancer and may have been potentially biased in favour of the tool.

The use of different interview techniques to collect data needs to be considered. Data from the women at increased genetic risk and the charity representative were

gathered via telephone, whilst the remaining interviews were conducted face to face. Telephone interviews were utilised as they allowed for participants based around the UK to be included. This method may have led to loss of information, such as non-verbal cues or responses. However, the importance of non-verbal information in interpreting data has been questioned, and the absence is not thought to impede data quality (Novick 2008). The use of different data collection methods may raise questions over the comparability of the findings; however, interview responses were considered to be comparable due to the use of a standard topic guide.

Information about other risk factors for ovarian cancer, such as gene mutations, age, oral contraceptive use and BMI (Andersen et al. 2002, Lockwood-Rayermann et al. 2009), were not included in OvSTAT. This was based on the aim of the tool. OvSTAT was not designed as a risk assessment tool, but instead aims to provide women with information on ovarian cancer symptoms and guidance on when to seek help for such symptoms. The previous chapters have highlighted the potential for heightened perceived threat to be experienced by women at increased genetic risk in response to reading ovarian cancer materials. Including risk information was therefore considered to be potentially detrimental, as this type of information may cause worry and apprehension, and discourage presentation (Beeken et al. 2011). Importantly, risk information should be discussed with the appropriate medical professionals, and therefore could be discussed when individuals present with ovarian cancer concerns.

7.9.4 Implications and future research

An ovarian cancer symptom awareness tool (OvSTAT) was created based on the previous phases of research. User testing provided evidence which forms an important part in the development of complex interventions (Craig et al. 2008b). Overall, OvSTAT was viewed positively, with information on the symptoms of ovarian cancer considered to be presented in a clear and understandable way. Areas for change were identified, leading to tool amendments that aimed to increase its acceptability and usability. Further research is needed to assess the acceptability and usability of

OvSTAT. The next steps should also validate the tool as being capable of influencing the (i) determinants of presentation behaviour and (ii) presentation behaviour itself. The results of the current study suggest that OvSTAT was perceived as useful and informative, and could therefore potentially be a mechanism through which ovarian cancer symptom awareness is improved and timely presentation promoted.

8 General discussion

8.1 Introduction

The research presented in this thesis set out to identify the determinants of anticipated presentation with ovarian cancer symptoms in women at increased genetic risk of ovarian cancer. The studies undertaken to understand these determinants led to the development of OvSTAT. In this chapter, the findings of these phases of work are summarised and synthesised with existing evidence. Methodological strengths and weaknesses, as well as wider evaluation and implementation issues, are discussed.

8.2 The need for OvSTAT

The present research set out to address the question of whether an ovarian cancer symptom awareness tool was needed for women at increased genetic risk of ovarian cancer. Through the different phases of work that were completed, an understanding of the health beliefs and determinants of anticipated presentation in women at increased genetic risk was gained. Importantly, analysis of the health beliefs of a sample of women from the general population was also undertaken, and allowed similarities and differences between the two risk populations to be identified. Initially it was envisaged that a symptom awareness tool specifically for women at increased genetic risk would be developed. However, as the project progressed it became clear that the specific information needs for women at increased genetic risk could be embedded within core information applicable to the general population. This decision was aided by the mixed-method approach of the PhD, where phases of research were guided by the knowledge base identified in preceding phases. Modelling of theory relevant to the intervention led to the decision to create a tool with core components for all women, and a flexible component that can provide relevant information specifically for women at increased genetic risk. This highlights the continuous process of developing complex interventions as described in the MRC complex intervention guidelines, whereby the different phases of work influence and shape iterations of the intervention (Craig et al. 2008b). The findings of the PhD have revealed the determinants of anticipated presentation and support needs of women at increased

genetic risk of ovarian cancer, which led to the development of a tool that attempts to meet these needs. Embedding this information within a tool that has ovarian cancer symptom information for all women maximises the potential exposure and impact of the tool.

The systematic search (Chapter 3) highlighted that even though a number of symptom awareness tools were currently in circulation, there was no theoretically driven awareness tool for women at increased genetic risk of ovarian cancer. This gap suggested that it would be worthwhile pursuing the development of a symptom awareness tool for this population. The systematic search was also useful in identifying examples of tools that could be used in the interviews (Chapter 5), and for identifying components of symptom awareness. A wide variety of formats, content and design of tools were revealed that were considered when OvSTAT was being developed (Chapter 7). Components of symptom awareness were further explored in Chapter 6, where the symptoms of ovarian cancer and thresholds for when to act on symptoms were identified.

Chapters 4 and 5 examined the health beliefs of women at increased genetic risk, identifying the impact that perceived threat has on this population and the determinants of early anticipated presentation. These two chapters highlighted the need for OvSTAT as an information resource for women at increased genetic risk, as well as a potential mechanism for managing worry levels. As discussed, women from the general population were included as a comparator in the study in Chapter 4, allowing an understanding of health beliefs and determinants of anticipated presentation in women from the general population. This study was not only useful in identifying the unique determinants of awareness and anticipated presentation in the increased genetic risk sample, but also for increasing understanding of the ovarian cancer health beliefs in a general population sample using a statistical method that has not previously been applied in this context. Findings identified common health beliefs for the two risk populations (self-efficacy, knowledge and perceived benefits and barriers), as well as unique health beliefs for women at increased genetic risk (the

make-up of perceived threat and the association with earlier anticipated presentation). These findings reinforce the idea that a tool should be created that has core elements which address the health beliefs of both populations, as well as tailored content that addresses the specific health beliefs of women at increased genetic risk.

A prototype of the symptom awareness tool was generated and tested. Usability and acceptability (Chapter 7) was explored with a sample of potential users and providers and revealed that OvSTAT could potentially be useful for educating women about the symptoms of ovarian cancer, encouraging presentation and facilitating the doctor-patient interaction in consultations. The multiple phases of work meant that the development process for OvSTAT included GPs, oncologists, women at increased genetic risk of ovarian cancer and women from the general population. Involvement from a variety of people representing potential users and providers highlights the rigorous development process of the tool.

8.3 Methodological strengths and weakness

8.3.1 Health Belief Model

The HBM was central to the thesis and provided guidance for many aspects of the research from questionnaire development to the tool content. The MRC complex intervention guidelines describe how an understanding of the research context and applicable theories is an important process in intervention development (Craig et al. 2008a). The use of the HBM throughout the development process has led to an understanding of the determinants of anticipated presentation with ovarian cancer symptoms, which led to a strong theoretical understanding of the components that make up OvSTAT (Craig et al. 2008a, Smith et al. 2012). This understanding is crucial for the future of OvSTAT as it allows potential weaknesses in the tool to be identified and improved, in addition to providing guidance on what variables should be measured before and after use in order to assess the changes brought about by the tool (Craig et al. 2008b, Jones et al. 2013).

8.3.2 Is the HBM useful in the current context?

Using the HBM in the current research has highlighted that it is not sufficient to simply provide women with the symptoms of ovarian cancer in order to bring about symptomatic presentation. Ovarian cancer symptom awareness is embedded within other health beliefs, such as perceived threat, self-efficacy, and perceived benefits and barriers to presentation. This supports the notion that while improving awareness alone will not lead to behaviour change, prompting behaviour change in the absence of awareness is even less likely (Redeker et al. 2009).

The use of the HBM indicated that symptom awareness may not be directly linked to presentation for ovarian cancer. The lack of a direct association between ovarian cancer symptom awareness and anticipated presentation was also reported by Low et al. (2013b), and suggests that different mechanisms underpin these processes which may be specific to ovarian cancer. Modelling using the HBM in Chapter 4 demonstrated that ovarian cancer awareness influenced anticipated presentation through mechanisms including perceived threat, self-efficacy and perceived benefits and barriers. The current research was the first to compare data on levels of worry and perceived susceptibility in a general population and increased genetic risk sample, and to examine how worry and perceived susceptibility interact with help-seeking intentions. The findings of the SEM based on the HBM also contribute to the literature in supporting the inclusion of both cognitive and affective measures of perceived threat in future research studies, particularly those which involve at risk populations.

The SEMs in Chapter 4 revealed that the HBM accounted for 3-14% of variance in anticipated presentation, suggesting that there are other factors influencing anticipated presentation that were not measured and that other theories may have better explained the determinants of anticipated presentation. The role of intentions and subjective norms may have been overlooked in the current study, whereas intentions are integral in other theories such as the Theory of Planned Behaviour (Ajzen 1991, Gollwitzer and Sheeran 2006) and are important determinants of behaviour (Jones et al. 2013). However, since emotional and cognitive representations

of risk were thought to be influential for women at increased genetic risk of ovarian cancer, the TPB was not applied in the current context. A further shortcoming of the HBM is that it focuses on one decision to seek medical help, when in fact this is often a multi-stage process (Wyke et al. 2013). It is also important to consider that not everyone will present to primary care in the presence of symptoms, instead favouring other options such as looking for advice on the internet, or simply managing the symptoms that are being experienced (Corner and Brindle 2010). This scenario highlights the potential benefits of considering more than one behavioural outcome. However, presenting to primary care with symptoms is the gateway to ovarian cancer diagnosis, and therefore was chosen as the outcome of interest in the studies presented in the thesis.

Andersen's model of patient delay (Andersen et al. 1995) could be a useful conceptualisation of anticipated ovarian cancer symptomatic presentation; however, the multiple stages outlined in this model may be best applied to research which follows individuals through all stages of the symptom experience, from first appraisal through to treatment. The fixed and linear nature of the Andersen model reduces its relevance to multiple symptomatic presentations and other modifying influences on anticipated presentation, such as those outlined by the HBM. It was therefore felt that the holistic applicability of the HBM was preferential for understanding the determinants of anticipated symptomatic presentation in the current research context. Although Walter et al. (2011) further developed the Model of Pathways to Treatment to incorporate a more fluid explanation of presentation behaviour, neither model addresses the role of emotions which were considered to be important in the current context.

Other theories that could be applied to anticipated presentation are those which focus on the social contexts of the individual, such as the Network Episodic Model (Pescosolido and Boyer 1999), or those which focus on the individual's problem solving capabilities, such as the Common Sense Model (Leventhal and Diefenbach 1991). However, these theories have been described as focusing more on observation instead

of action (Smith et al. 2012), have been less widely applied to intervention development, and do not focus on the potential emotional considerations of ovarian cancer symptomatic presentation. Overall, it was deemed that the HBM was an adequate model to use, especially due to its applicability for women at increased genetic risk and its frequent application for health promotion purposes (Jones et al. 2013). It is unlikely that one theory will fully explain anticipated symptomatic presentation, highlighted in the multitude of overlapping health behaviour theories in existence. However, the present research showed that some of the key components do include threat representation and theories that take this into account are likely to be more successful at predicting help-seeking behaviour.

8.4 Mixed methods

This section will discuss what was gained by the mixed method approach, and the strengths and weaknesses of the various methodological approaches that were used throughout this thesis.

8.4.1 Qualitative exploration of quantitative findings

The use of interviews to elaborate and further explore the quantitative findings was a worthwhile process which added to the research findings (Emery et al. 2013). In the SEMs in Chapter 4, the influence of personal experience with ovarian cancer was not readily understood and was observed to be less of an influence for women at increased genetic risk than expected. However, when interviews (Chapter 5) were conducted to expand and explore the SEM findings, it was evident that experience with ovarian cancer was embedded in many aspects of women's beliefs about ovarian cancer. The interviews allowed a deeper understanding of how risk status and experience with the disease influences perceptions about the disease and its symptoms.

8.4.2 Symptom awareness

The mixed method approach enabled ovarian cancer symptom awareness to be examined from multiple angles, including perspectives gained by evaluating existing tools, women from different risk populations and GPs. The identification and evaluation of existing tools identified that a wide variety of symptoms were included in tools and were often not consistent with the current guidelines on ovarian cancer symptoms (Chapter 3). These findings highlighted the importance of focussing on key symptoms and providing symptom frequency and duration information in OvSTAT, which formed the focus of Chapter 6. The survey data from women at increased genetic risk and women from the general population highlighted that symptom awareness could be improved in both populations (Chapter 4) and further emphasised the importance of educating women on the symptoms of ovarian cancer.

The data on symptom frequency and duration from women at increased genetic risk and GPs allowed for analysis to be conducted that identified the average symptom duration and frequency in the two populations (Chapter 6). These findings revealed that women at increased genetic risk anticipated presenting in a shorter time frame compared to GPs' views on when they should present. This finding complimented and further endorsed the findings from Chapter 4 where women were anticipating presenting immediately after symptoms were experienced. The combined findings suggested that women may over-present and that their expectations need to be managed in relation to symptomatic presentation. This hyper-vigilance in women at increased genetic risk echoes findings from ovarian screening and BSE literature, where high levels of worry and perceived risk were associated with hyper-vigilant behaviour (Brain et al. 2011, Hay et al. 2006, Norman and Brain 2005, Schwartz, Lerman et al. 1995).

8.4.3 Identification of symptoms and critical thresholds to include in OvSTAT

Work on developing the core symptom content of OvSTAT was done in Chapter 6, which identified the symptom information to be included in the tool. The synthesis of

the findings from different methodologies arrived at a consistent opinion on symptoms and critical thresholds and ensured that the symptoms included in OvSTAT were based on empirical data and expert clinical opinion. This was particularly important in the current absence of medical consensus on what is an appropriate presentation interval for ovarian cancer symptomatic presentation. The methods utilised in Chapter 6 therefore enabled symptom frequency and duration information to be included in OvSTAT, with this a key piece of information for women who are trying to make decisions about seeking medical advice. Temporal information was often missing in the tools identified in the systematic search (Chapter 3), or was based on arbitrary time frames rather than empirical evidence.

Symptom duration and frequency information was particularly important in light of the findings from Chapter 4, where many women were anticipating presenting immediately after experiencing symptoms. OvSTAT encourages women to present if they experience symptoms on most days for three weeks or more. When the findings of this thesis are taken in to account this is considered an appropriate interval because it aims to manage presentation expectations and maintain the psychological wellbeing of the women who use OvSTAT. The reality is that women may need to experience symptoms for longer in order for possible ovarian cancer to be considered by health professionals. Including time frame information in ovarian cancer materials could be considered best practice in light of the symptoms commonly being experienced without them being indicative of ovarian cancer (Austoker 2009, Hamilton 2009). This is particularly pertinent for women at increased genetic risk who may have heightened levels of worry and are often basing their symptom knowledge on relatives' symptom experiences (Chapter 5).

8.4.4 User and provider involvement

The target audience and potential tool providers were recruited in many phases of the work allowing key stakeholders to be influential in the tool development process. The development process of OvSTAT would not have been as strong if such a thorough

approach had not been taken. The cognitive interviews allowed for in depth understanding of the usability and favourability of the tool and led to issues with the tool to be identified and rectified prior to the final version being developed. Importantly, this feedback was gained from different angles due to the different potential users and providers who were included. Participants from the general population provided insight on how a tool with a specific section for women at increased genetic risk was perceived by those who are not at increased risk. Conversely, women at increased genetic risk provided feedback on a tool for all women with a specific section for women at increased genetic risk.

GPs were important to include in the development as they could potentially be distributing OvSTAT, or exposed to OvSTAT in consultations if patients present with it. The genetic counsellor led to feedback to be gained about the tool in relation to women at increased genetic risk and the use of an ovarian cancer charity representative provided insight from someone with experience in providing information resources for women with ovarian cancer concerns. The cognitive interviews with different healthcare professionals and a charity representative could also be considered to contribute to early feasibility work for OvSTAT. The GPs felt that the tool would be useful for aiding their understanding of the patients' main concern and the genetic counsellor felt that the tool could play an important role in providing women who consult to the genetic services with a resource to take home after consultations (Chapter 7).

8.4.5 Sample limitations

Sample limitations associated with opportunistic methods of recruiting women at increased genetic risk are acknowledged. Women at increased genetic risk were recruited from a pool of women who had participated in UKFOCSS and its psychological partner study, and were therefore a well-studied population who may not be representative of the population from which they were drawn. Women who have chosen to participate in multiple research studies may also have different health

beliefs compared to those who did not participate, or may have different health beliefs as a result of study participation. Research suggests that women at increased genetic risk who are recruited into studies through screening programmes have higher levels of worry (Robinson et al. 1997, Trask et al. 2001), whereas those recruited from the general population have been reported to have lower levels of worry (Andersen et al. 2002, Drescher et al. 2000).

Although the general population sample was population representative, these data were derived from the ICBP Welsh population (Brain et al. 2014), and for cohort studies it is preferable for samples to be drawn from the same (i.e. UK wide) population (Mann 2003). In addition, it was not possible to verify the personal risk status of individual ICBP participants. Finally, temporal differences in data collection methods for the two samples mean that they may not be entirely comparable.

8.4.6 Different risk populations

OvSTAT contains information for women from the general population and women at increased genetic risk. It may therefore have been advantageous to explore the health beliefs and information needs of women from the general population in more detail alongside the increased genetic risk population. This is because much of the information that can be provided to women at increased genetic risk is relevant to women from the general population, and vice versa. This is reflected in OvSTAT containing core information for all women and a specific section incorporated for women at increased genetic risk. It may therefore have been beneficial to include women from the general population in other phases of the research, such as qualitative interviews, to further explore their ovarian cancer health beliefs. However, as previously discussed, it was originally anticipated that a tool solely for women at increased genetic risk would be created, and as the thesis progressed it became apparent that a tool with a dual audience should be created. The decision to tailor tool content according to risk means that one leaflet can be provided for all women, rather

than segregation by, and potential reinforcement of worry associated with, increased genetic risk status.

8.4.7 Cross-sectional nature of the current research

Only prospective research can confirm the validity of study findings with regard to association between health beliefs and determinants of symptomatic presentation. Whilst cross-sectional research is useful in identifying correlates, as was the case in the present study, it poses difficulty for inferring causality. However, the large samples, time frames and associated costs of prospective research made this an unachievable method within the scope of the PhD. It should also be noted that questions concerning recognition of symptoms may elicit different responses compared to questions which ask participants to recall symptoms. Recognition could lead to increased symptom reporting as a result of guessing, whereas recall may elicit truer responses (Stubbings et al. 2009, Waller et al. 2004, Yawn et al. 2004).

8.5 Potential limitations of OvSTAT content

Although some existing symptom awareness tools include information on potential risk factors for ovarian cancer, OvSTAT did not include such information. OvSTAT is not designed to identify personal risk; rather, it aims to increase symptom knowledge and encourage women to go and see their doctor if they have symptom concerns. It is at this point that personal risk factors and other sensitive information can be addressed with a health professional. The previous phases of research also highlighted the heightened perceived threat and potential worry and apprehension women at increased genetic risk feel when reading ovarian cancer materials. It was therefore felt that including risk information may have detrimental consequences for women's psychological wellbeing and presentation behaviour. The omission of specific risk factors such as specific gene mutations, age, oral contraceptive use and BMI (Andersen et al. 2002, Lockwood-Rayermann et al. 2009) highlights that OvSTAT is not in itself a solution for all educational needs relating to ovarian cancer; instead, OvSTAT is a first

response tool and should initiate thoughts and discussion about ovarian cancer with relevant medical professionals.

The symptom awareness tool was created in the form of a leaflet, reflecting the most common format of existing ovarian cancer symptom awareness tools as identified in the systematic search (Chapter 3). However, what distinguishes OvSTAT from those already in existence is the dual audience and the strong theoretical background to content development. The acceptability of a leaflet was explored in interviews (Chapter 5), where women were asked, unprompted, about their thoughts on awareness tools, and were then shown a variety of awareness materials and asked to discuss their opinion of them. The responses from the interviews helped shape ideas about tool format, with a leaflet created based on the efficiency with which information can be imparted, and the potential ease of implementation. The acceptability of the leaflet was further explored in cognitive interviews with a variety of potential users and providers and was therefore deemed to be an acceptable format (Chapter 7). A short, written intervention could prove useful as leaflets have been reported to be effective at improving awareness (Austoker et al. 2009, Grunfeld et al. 2002).

8.6 The future of OvSTAT

The current research has demonstrated the need to provide women with information about ovarian cancer that educates them about the symptoms, when to present if these symptoms are experienced, and the importance of symptom awareness in the absence of routine screening. It has also demonstrated that the psychological wellbeing of women at increased genetic risk needs to be maintained because worry (i.e. the affective component of perceived threat) is particularly prominent in this population. As outlined in the MRC complex intervention guidelines (Craig et al. 2008b), the current research has generated an evidence base which led to the preliminary development of an ovarian cancer symptom awareness tool (OvSTAT).

Follow-on research to evaluate the clinical utility and actual implementation of the tool now needs to be considered.

8.6.1 Feasibility testing

Potential user and provider attitudes to OvSTAT could be explored with a questionnaire study and would allow further insight into usability of the tool. This could involve giving OvSTAT to participants and asking questions about content, format and implementation. The interviews with women at increased genetic risk (Chapter 5) and the cognitive interviews with healthcare professionals (Chapter 7) provided a snapshot of the feasibility of OvSTAT. However, studies investigating feasibility should also assess whether the tool improves the desired outcomes on an individual level, i.e. reduced worry, increased symptom awareness and confidence in symptom detection/disclosure, and whether these impact the primary outcome of presentation. Importantly, this would also provide an opportunity to address the theoretical issue of an appropriate presentation interval. Based on the findings in Chapter 6, OvSTAT encourages women to present if they experience symptoms for three weeks or more. Field testing could allow for this interval to be tested, exploring whether it is appropriate in a clinical setting. Whilst the proposed interval of three weeks was based on empirical and clinical findings (Chapter 6), the acceptability of this time frame to doctors and patients in clinical settings needs to be explored and understood in order for the tool to be successfully implemented. Field testing could therefore be conducted with potential users and providers and would be a useful precursor to potential larger scale controlled studies, allowing information to be gathered on the feasibility of study procedures, measurement, recruitment and retention.

8.6.2 Observation

Consultations in which OvSTAT is used could also be observed in order to assess organisational implementation issues, such as how it is used in practice and whether it helps patients talk about their ovarian cancer concerns with a health professional.

These processes could lead to improvements being made to OvSTAT and are important steps in checking that the intervention can be used as intended before progressing to a larger trial (Craig et al. 2008a, Hardeman et al. 2005). Alongside ideas for implementation, it is important to consider ways of measuring the impact of OvSTAT. This is important as once tools are implemented it is often hard to assess their potential impact. Impact could also be measured through observing the use of the tool in consultations and assessing the influence it had on the clinician and patient.

8.6.3 Controlled evaluation

Ultimately, a randomised control trial (RCT) of OvSTAT compared to standard care could be carried out in women at increased genetic risk and women from the general population. A cluster RCT should be considered in this context, as individual outcomes may be dependent on other processes such as GP and practice influences (Craig et al. 2008a). An RCT would enable exploration of the determinants of presentation behaviour (as outlined in this thesis) to be measured and explored. It would also allow for an evaluation of the mode of action which will facilitate symptomatic presentation (as outlined in the different sections of OvSTAT), such as increasing knowledge about benefits of early presentation, teaching critical thresholds, increasing self-efficacy and dispelling myths. A possible RCT could therefore involve participants completing psychometric measures at baseline and post intervention to assess the impact of OvSTAT on health beliefs. Direct behavioural measures of GP visits could also be collected. This would enable assessment of whether the tool influences the determinants of presentation behaviour and presentation behaviour itself. However, cost effectiveness should be considered, as RCTs involve large numbers of participants in order to see effect sizes, and have associated time and financial considerations.

8.6.4 Experimental study of the emotional impact of OvSTAT

An assessment of the attentional and emotional impact of the tool could be carried out using the modified stroop task (mStroop). The mStroop has been used to evaluate processing biases in other contexts, using Mogg and Bradley (1998) cognitive motivational model of anxiety. According to this model, individuals demonstrate

selective processing bias towards stimuli that are congruent with their current worries. Recruiting women at increased genetic risk of developing ovarian cancer and women from the general population would allow comparisons to be made between the different risk populations. Analysis would assess the emotional or intuitive responses that women experience in response to the tool, allowing information-processing responses to the tool to be measured, and as a function of risk status. In particular, this experimental study could also allow for further exploration of the affective and cognitive representations of risk perceptions that were highlighted in Chapter 4. Understanding of the different representations could be expanded and further explored in terms of the Dual Process Theory (Epstein 1994), which suggests that people have two responses to information processing. System One refers to fast responses, and could relate to affective representations of risk perception, whereas System Two is more deliberative and could explain the cognitive representation of risk perception (Epstein 1994). In the context of cancer, people could initially respond to a symptom with an emotional response, with System One initially evoking a fear response, but System Two will then over-ride this response as a result of reflecting on the situation, leading to considerations to act on the symptom and to dispel negative beliefs about cancer (Robb et al. 2014). The mStroop task could allow for deeper exploration of the affective and cognitive responses to ovarian cancer information as a function of risk status, which would allow for the idea of dual processing in this context to be explored.

An evaluation of the psychological impact of OvSTAT could prove particularly useful in light of the current interest surrounding stratified medicine, which involves targeting resources and screening programmes at those who are most at risk or predisposed to the condition (Dent et al. 2013). If such an approach was implemented, advances in testing for gene mutations would mean that increased numbers of women could have risk assessments regardless of their known family history (Meisel et al. 2013). In this context, it will be even more important to have information readily available to help women manage their increased risk status.

8.6.5 Implementation considerations and challenges

For women at increased genetic risk of ovarian cancer, support groups and charities should be considered as dissemination opportunities. Other healthcare professionals could also disseminate OvSTAT, with health education leaflets commonly found in GP waiting rooms. This could be a useful way of providing the leaflet to women from the general population. Interviews in Chapter 5 revealed suggestions from participants as to potential places to access awareness tools. GP surgeries were a common suggestion, with the GP waiting room, or the consultation itself viewed as potential access points. However, this approach depends on individual GP and organisational "buy-in" to the intervention. Evans et al. (2014) investigated the attitudes towards raising public awareness of gynaecological cancers in 621 GPs. Positively, most of the GPs (77%) viewed raising awareness of gynaecological cancers as important, however, when asked whether they would distribute a leaflet about this in their practices, only half said they would. Increased demand on resources and the emotional impact on the patient were salient barriers to implementation (Evans et al. (2014). GPs felt that mailing out the leaflet to patients would be costly, with other methods, such as having the leaflet in the practice, posters and hosting it on the practice website viewed as more favourable options(Evans et al. 2014). These finding suggests that in order for leaflets to be endorsed and distributed within a primary care setting the distribution preferences, costs and benefits of implementation need to be considered and presented to practices (Evans et al. 2014). This further supports the previously discussed preliminary studies of OvSTAT and also suggests that in such studies an evaluation of the cost of implementation should also be assessed.

8.7 Conclusion

In the absence of routine ovarian screening, the psychological wellbeing of women at increased genetic risk for ovarian cancer needs to be maintained, since evidence presented in this thesis indicates that the affective component may predominate over the cognitive component of perceived threat in these women. The creation of OvSTAT could be a mechanism through which ovarian cancer symptom awareness and presentation is improved, as well as a mechanism through which women manage their

levels of worry and self-manage their risk status. Further research is needed to evaluate the acceptability of OvSTAT and its impact on ovarian cancer awareness, worry and presentation behaviour.

9 References

Abraham C, Southby L, Quandte S, Krahé B and van der Sluijs W (2007) What's in a leaflet? Identifying research-based persuasive messages in European alcohol-education leaflets. *Psychology and Health* 22 (1) 31-60.

Absetz P, Aro A R and Sutton S R (2003) Experience with breast cancer, pre-screening perceived susceptibility and the psychological impact of screening. *Psycho-Oncology* 12 (4) 305-318.

Ajzen I (1991) The theory of planned behavior. *Organizational behavior and human decision processes* 50 (2) 179-211.

Allgar V and Neal R (2005a) General practictioners' management of cancer in England: secondary analysis of data from the National Survey of NHS Patients–Cancer. *European journal of cancer care* 14 (5) 409-416.

Allgar V L and Neal R D (2005b) Delays in the diagnosis of six cancers: analysis of data from the National Survey of NHS Patients: Cancer. *British journal of cancer* 92 (11) 1959-1970.

Andersen B L, Cacioppo J T and Roberts D C (1995) Delay in seeking a cancer diagnosis: delay stages and psychophysiological comparison processes. *British Journal of Social Psychology* 34 (1) 33-52.

Andersen M R, Bowen D, Yasui Y and McTiernan A (2003a) Awareness and concern about ovarian cancer among women at risk because of a family history of breast or ovarian cancer. *American Journal of Obstetrics and Gynecology* 189 (4) S42-S47.

Andersen M R, Drescher C W, Zheng Y, Bowen D J, Wilson S, Young A, McIntosh M, Mahony B S, Lowe K A and Urban N (2007) Changes in cancer worry associated with participation in ovarian cancer screening. *Psycho-Oncology* 16 (9) 814-820.

Andersen M R, Nelson J, Peacock S, Giedzinska A, Dresher C, Bowen D and Urban N (2004) Worry about ovarian cancer risk and use of screening by high-risk women: How you recruit affects what you find. *American Journal of Medical Genetics Part A* 129 (2) 130-135.

Andersen M R, Peacock S, Nelson J, Wilson S, McIntosh M, Drescher C and Urban N (2002) Worry about ovarian cancer risk and use of ovarian cancer screening by women at risk for ovarian cancer. *Gynecologic oncology* 85 (1) 3-8.

Andersen M R, Smith R, Meischke H, Bowen D and Urban N (2003b) Breast cancer worry and mammography use by women with and without a family history in a population-based sample. *Cancer Epidemiology Biomarkers & Prevention* 12 (4) 314-320.

Andersen R, Vedsted P, Olesen F, Bro F and Søndergaard J (2009) Patient delay in cancer studies: a discussion of methods and measures. *BMC health services research* 9 (1) 189-196.

Antoniou A, Pharoah P, Narod S, Risch H, Eyfjord J, Hopper J, Loman N, Olsson H, Johannsson O and Borg Å (2003) Average Risks of Breast and Ovarian Cancer Associated with BRCA1 or BRCA2 Mutations Detected in Case Series Unselected for Family History: A Combined Analysis of 22 Studies. *The American Journal of Human Genetics* 72 (5) 1117-1130.

Appleton J V and Cowley S (1997) Analysing clinical practice guidelines. A method of documentary analysis. *Journal of Advanced Nursing* 25 (5) 1008-1017

Armitage C J and Conner M (2000) Social cognition models and health behaviour: A structured review. *Psychology and Health* 15 (2) 173-189.

Armitage C J and Conner M (2001) Efficacy of the theory of planned behaviour: A meta-analytic review. *British journal of social psychology* 40 (4) 471-499.

Austoker J (2009) Diagnosis of ovarian cancer in primary care. *BMJ* 339 583-589.

Austoker J, Bankhead C, Forbes L J L, Atkins L, Martin F, Robb K, Wardle J and Ramirez A J (2009) Interventions to promote cancer awareness and early presentation: systematic review. *British journal of cancer* 101 S31-S39.

Bandura A (2000) Cultivate self-efficacy for personal and organizational effectiveness. *Handbook of principles of organization behavior* 120-136.

Bandura A (2004) Health promotion by social cognitive means. *Health education & behavior* 31 (2) 143-164.

Bankhead C R, Collins C, Stokes-Lampard H, Rose P, Wilson S, Clements A, Mant D, Kehoe S T and Austoker J (2008) Identifying symptoms of ovarian cancer: a qualitative and quantitative study. *BJOG: An International Journal of Obstetrics & Gynaecology* 115 (8) 1008-1014.

Bankhead C R, Kehoe S T and Austoker J (2005) Symptoms associated with diagnosis of ovarian cancer: a systematic review. *BJOG : an international journal of obstetrics and gynaecology* 112 (7) 857-865.

Baumeister R F and Newman L S (1994) How stories make sense of personal experiences: Motives that shape autobiographical narratives. *Personality and Social Psychology Bulletin* 20 (6) 676-690.

Becker M H (1974) The Health Belief Model and Sick Role Behavior. *Health Education & Behavior* 2 (4) 409-419.

Beeken R J, Simon A E, von Wagner C, Whitaker K L and Wardle J (2011) Cancer fatalism: deterring early presentation and increasing social inequalities? *Cancer Epidemiology Biomarkers & Prevention* 20 (10) 2127-2131.

Behtash N, Ghayouri Azar E and Fakhrejahani F (2008) Symptoms of ovarian cancer in young patients 2 years before diagnosis, a case-control study. *Eur J Cancer Care (Engl)* 17 (5) 483-487.

Bennett P (2009) How can we reduce the distress associated with health screening? From psychological theory to clinical practice. *Social and Personality Psychology Compass* 3 (6) 939-948.

Bish A, Ramirez A, Burgess C and Hunter M (2005) Understanding why women delay in seeking help for breast cancer symptoms. *Journal of psychosomatic research* 58 (4) 321-326.

Black N (1994) Why we need qualitative research. *Journal of Epidemiology and Community Health* 48 (5) 425.

Brain K, Norman P, Gray J and Mansel R (1999) Anxiety and adherence to breast self-examination in women with a family history of breast cancer. *Psychosomatic medicine* 61 (2) 181-187.

Brain K, Parsons E, Bennett P, Cannings-John R and Hood K (2011) The evolution of worry after breast cancer risk assessment: 6-year follow-up of the TRACE study cohort. *Psycho-Oncology* 20 (9) 984-991.

Brain K E, Lifford K J, Fraser L, Rosenthal A N, Rogers M T, Lancastle D, Phelps C, Watson E K, Clements A and Menon U (2012) Psychological Outcomes of Familial Ovarian Cancer Screening: No Evidence of Long-Term Harm. *Gynecologic Oncology* 127 (3) 556-563.

Brain K E, Smits S, Simon A E, Forbes L J, Roberts C, Robbé I J, Steward J, White C, Neal R D and Hanson J (2014) Ovarian cancer symptom awareness and anticipated delayed presentation in a population sample. *BMC cancer* 14 (1) 171-181.

Braun V and Clarke V (2006) Using thematic analysis in psychology. *Qualitative research in psychology* 3 (2) 77-101.

Brocki J M and Wearden A J (2006) A critical evaluation of the use of interpretative phenomenological analysis (IPA) in health psychology. *Psychology and health* 21 (1) 87-108.

Brubaker R G and Wickersham D (1990) Encouraging the practice of testicular self-examination: a field application of the theory of reasoned action. *Health Psychology* 9 (2) 154-163.

Burak L J and Meyer M (1997) Using the Health Belief Model to examine and predict college women's cervical cancer screening beliefs and behavior. *Health Care for Women International* 18 (3) 251-262.

Byrne B M (2009) *Structural equation modeling with AMOS: Basic concepts, applications, and programming*. CRC Press.

Cancer Research UK (2011) Cancer Research UK Ovarian Cancer UK Statistics [accessed January 2013] (available at: http://publications.cancerresearchuk.org/downloads/Product/cs_pdf_ovarian_march_2011.pdf).

Carpenter C J (2010) A meta-analysis of the effectiveness of health belief model variables in predicting behavior. *Health communication* 25 (8) 661-669.

Cass I and Karlan B Y (2010) ovarian Cancer symptoms speak out—But What are they really saying? *Journal of the National Cancer Institute* 102 (4) 211-212.

Charnock D, Shepperd S, Needham G and Gann R (1999) DISCERN: an instrument for judging the quality of written consumer health information on treatment choices. *Journal of epidemiology and community health* 53 (2) 105-111.

Chen S and Parmigiani G (2007) Meta-analysis of BRCA1 and BRCA2 penetrance. *Journal of Clinical Oncology* 25 (11) 1329-1333.

Chung V, Horowitz A M, Canto M T and Siriphant P (2007) Oral cancer educational materials for the general public: 1998. *Journal of Public Health Dentistry* 60 (1) 49-52.

Cohen M (2006) Breast cancer early detection, health beliefs, and cancer worries in randomly selected women with and without a family history of breast cancer. *Psycho-Oncology* 15 (10) 873-883.

Collins D (2003) Pretesting survey instruments: an overview of cognitive methods. *Quality of Life Research* 12 (3) 229-238.

Conner M and Norman P (2005) *Predicting health behaviour*. McGraw-Hill International.

Cooper C P, Polonec L and Gelb C A (2011) Women's Knowledge and Awareness of Gynecologic Cancer: A Multisite Qualitative Study in the United States. *Journal of Womens Health* 20 (4) 517-524.

Cooper C P, Polonec L, Stewart S L and Gelb C A (2012) Gynaecologic cancer symptom awareness, concern and care seeking among US women: a multi-site qualitative study. *Family Practice* 30 (1) 96-104.

Corner J L and Brindle L A (2010) Socio-cultural influences on the help-seeking behavior of patients with cancer. *Journal of Epidemiology and Community Health* 65 (6).

Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I and Petticrew M (2008a) Developing and evaluating complex interventions: new guidance.

Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I and Petticrew M (2008b) Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 337 (1) a1655-a1655.

Dent T, Jbilou J, Rafi I, Segnan N, Törnberg S, Chowdhury S, Hall A, Lyratzopoulos G, Eeles R and Eccles D (2013) Stratified cancer screening: the practicalities of implementation. *Public health genomics* 16 (3) 94-99.

Department of Health (2007) Cancer reform strategy. [accessed January 2013] (available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_081007.pdf).

Department of Health (2009) Department of Health key messages for ovarian cancer for health professionals. [accessed January 2013] (available at: http://www.ovarian.org.uk/media/8815/ovarian_cancer_kms_final.pdf).

Devlin S M, Diehr P H, Andersen M R, Goff B A, Tyree P T and Lafferty W E (2010) Identification of ovarian cancer symptoms in health insurance claims data. *J Womens Health (Larchmt)* 19 (3) 381-389.

Diefenbach M A, Miller S M and Daly M B (1999) Specific worry about breast cancer predicts mammography use in women at risk for breast and ovarian cancer. *Health psychology* 18 (5) 532.

Drescher C, Holt S K, Andersen M R, Anderson G and Urban N (2000) Reported ovarian cancer screening among a population-based sample in Washington State. *Obstetrics & Gynecology* 96 (1) 70-74.

Eadie D and MacAskill S (2008) Symptom awareness and cancer prevention: exploratory findings from an at-risk population. *Health Education* 108 (4) 332-345.

Edwards A, Elwyn G and Mulley A (2002) Explaining risks: turning numerical data into meaningful pictures. *BMJ* 324 (7341) 827-831.

Edwards A G K, Naik G, Ahmed H, Elwyn G J, Pickles T, Hood K and Playle R (2013) Personalised risk communication for informed decision making about taking screening tests. *Cochrane Database of Systematic Reviews* (2).

Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, Thomson R, Barratt A, Barry M, Bernstein S, Butow P, Clarke A, Entwistle V, Feldman-Stewart D, Holmes-Rovner M, Llewellyn-Thomas H, Moumjid N, Mulley A, Ruland C, Sepucha K, Sykes A and Whelan T (2006) Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ* 333 (7565) 417-419.

Emery J D, Walter F M, Gray V, Sinclair C, Howting D, Bulsara M, Bulsara C, Webster A, Auret K and Saunders C (2013) Diagnosing cancer in the bush: a mixed-methods study of symptom appraisal and help-seeking behaviour in people with cancer from rural Western Australia. *Family practice* 30 (3) 294-301.

Epstein S (1994) Integration of the cognitive and the psychodynamic unconscious. *American psychologist* 49 (8) 709-724.

Epstein S A, Hsiang Lin T, Audrain J, Stefanek M, Rimer B and Lerman C (1997) Excessive breast self-examination among first-degree relatives of newly diagnosed breast cancer patients. *Psychosomatics* 38 (3) 253-261.

Evans J, Ziebland S and McPherson A (2007) Minimizing delays in ovarian cancer diagnosis: an expansion of Andersen's model of 'total patient delay'. *Family Practice* 24 (1) 48-55.

Evans R E, Morris M, Sekhon M, Buszewicz M, Walter F M, Waller J and Simon A E (2014) Increasing awareness of gynaecological cancer symptoms: a GP perspective. *British Journal of General Practice* 64 (623) e372-e380.

Fallowfield L, Fleissig A, Barrett J, Menon U, Jacobs I, Kilkerr J, Farewell V and Trialists U (2010) Awareness of ovarian cancer risk factors, beliefs and attitudes towards screening: baseline survey of 21 715 women participating in the UK Collaborative Trial of Ovarian Cancer Screening. *British journal of cancer* 103 (4) 454-461.

Fitch M, Deane K, Howell D and Gray R E (2002) Women's experiences with ovarian cancer: reflections on being diagnosed. *Canadian oncology nursing journal= Revue canadienne de nursing oncologique* 12 (3) 152-168.

Forbes L J L, Linsell L, Atkins L, Burgess C, Tucker L, Omar L and Ramirez A J (2011) A promoting early presentation intervention increases breast cancer awareness in older women after 2 years: a randomised controlled trial. *British journal of cancer* 105 (1) 18-21.

Forbes L J L, Simon A E, Warburton F, Boniface D, Brain K E, Dessaix A, Donnelly C, Haynes K, Hvidberg L and Lagerlund M (2013) Differences in cancer awareness and beliefs between Australia, Canada, Denmark, Norway, Sweden and the UK (the International Cancer Benchmarking Partnership): do they contribute to differences in cancer survival&quest. *British journal of cancer* 108 (2) 292-300.

Forster A S, Forbes L J L, Abraham C, Warburton F G, Douglas E and Ramirez A-J (2013) Promoting early presentation of breast cancer: a preliminary evaluation of a written intervention. *Chronic illness* 10 (1) 18-30.

Friedman D B and Hoffman-Goetz L (2006) A systematic review of readability and comprehension instruments used for print and web-based cancer information. *Health Education & Behavior* 33 (3) 352-373.

Friedman G D, Skilling J S, Udaltsova N V and Smith L H (2005) Early symptoms of ovarian cancer: a case-control study without recall bias. *Family practice* 22 (5) 548-553.

Gajjar K, Ogden G, Mujahid M I and Razvi K (2012) Symptoms and Risk Factors of Ovarian Cancer: A Survey in Primary Care. *ISRN Obstetrics and Gynecology* 2012.

Gayther S A and Pharoah P D P (2010) The inherited genetics of ovarian and endometrial cancer. *Current opinion in genetics & development* 20 (3) 231-238.

Gilbert L, Basso O, Sampalis J, Karp I, Martins C, Feng J, Piedimonte S, Quintal L, Ramanakumar A V and Takefman J (2012) Assessment of symptomatic women for early diagnosis of ovarian cancer: results from the prospective DOvE pilot project. *The Lancet Oncology* 13 (3) 285-291.

Glanz K, Rimer B K and Viswanath K (2008) *Health behavior and health education: theory, research, and practice*. John Wiley & Sons.

Goff B A, Mandel L, Muntz H G and Melancon C H (2000) Ovarian carcinoma diagnosis. *Cancer* 89 (10) 2068-2075.

Goff B A, Mandel L S, Drescher C W, Urban N, Gough S, Schurman K M, Patras J, Mahony B S and Andersen M R (2007) Development of an ovarian cancer symptom index - Possibilities for earlier detection. *Cancer* 109 (2) 221-227.

Goff B A, Mandel L S, Melancon C H and Muntz H G (2004) Frequency of symptoms of ovarian cancer in women presenting to primary care clinics. *JAMA* 291 (22) 2705-2712.

Gollwitzer P M and Sheeran P (2006) Implementation intentions and goal achievement: A meta-analysis of effects and processes. *Advances in experimental social psychology* 38 69-119.

Green J and Thorogood N (2013) *Qualitative methods for health research*. Sage.

Grunfeld E A, Ramirez A J, Hunter M S and Richards M A (2002) Women's knowledge and beliefs regarding breast cancer. *British journal of cancer* 86 (9) 1373-1378.

Hallowell N (1998) 'You don't want to lose your ovaries because you think 'I might become a man''. Women's perceptions of prophylactic surgery as a cancer risk management option. *Psycho-Oncology* 7 (3) 263-275.

Hamilton W (2009) The CAPER studies: five case-control studies aimed at identifying and quantifying the risk of cancer in symptomatic primary care patients. *British journal of cancer* 101 S80-S86.

Hamilton W, Peters T J, Bankhead C and Sharp D (2009) Risk of ovarian cancer in women with symptoms in primary care: population based case-control study. *BMJ* 339 b2998-b2998.

Hardeman W, Sutton S, Griffin S, Johnston M, White A, Wareham N J and Kinmonth A L (2005) A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. *Health education research* 20 (6) 676-687.

Hasson F, Keeney S and McKenna H (2000) Research guidelines for the Delphi survey technique. *Journal of advanced nursing* 32 (4) 1008-1015.

Hay J L, Buckley T R and Ostroff J S (2005) The role of cancer worry in cancer screening: a theoretical and empirical review of the literature. *Psycho-Oncology* 14 (7) 517-534.

Hay J L, McCaul K D and Magnan R E (2006) Does worry about breast cancer predict screening behaviors? A meta-analysis of the prospective evidence. *Preventive medicine* 42 (6) 401-408.

Hensley M L, Robson M E, Kauff N D, Korytowsky B, Castiel M, Ostroff J, Hurley K, Hann L E, Colon J and Spriggs D (2003) Pre-and postmenopausal high-risk women undergoing screening for ovarian cancer: anxiety, risk perceptions, and quality of life. *Gynecologic oncology* 89 (3) 440-446.

Hippisley-Cox J, Coupland C, Vinogradova Y, Robson J, May M and Brindle P (2007) Derivation and validation of QRISK, a new cardiovascular disease risk score for the United Kingdom: prospective open cohort study. *BMJ* 335 (7611) 136-148.

Hitwise (2012) Hitwise UK Search Update. Data Centre. [accessed 29 May 2012] (AVAILABLE AT: http://www.experian.com/hitwise/online-trends-search-engine.html).

Howard A F, Balneaves L G and Bottorff J L (2009) Women's decision making about risk-reducing strategies in the context of hereditary breast and ovarian cancer: a systematic review. *Journal of genetic counseling* 18 (6) 578-597.

Hu L t and Bentler P M (1999) Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Structural Equation Modeling: A Multidisciplinary Journal* 6 (1) 1-55.

Hurley K E, Miller S M, Costalas J W, Gillespie D and Daly M B (2001) Anxiety/uncertainty reduction as a motivation for interest in prophylactic oophorectomy in women with a family history of ovarian cancer. *Journal of women's health & gender-based medicine* 10 (2) 189-199.

Jacobs I, Skates S, MacDonald N, Menon U, Rosenthal A, Davies A, Woolas R, Jeyarajah A, Sibley K and Lowe D (1999a) Screening for ovarian cancer: a pilot randomised controlled trial. *LANCET* 353 (9160) 1207-1210.

Johnson R B and Onwuegbuzie A J (2004) Mixed methods research: A research paradigm whose time has come. *Educational researcher* 33 (7) 14-26.

Jones C J, Smith H and Llewellyn C (2013) Evaluating the effectiveness of health belief model interventions in improving adherence: a systematic review. *Health Psychology Review* (ahead-of-print) 1-17.

Jones S C, Magee C A, Francis J, Luxford K, Gregory P, Zorbas H and Iverson D C (2010) Australian women's awareness of ovarian cancer symptoms, risk and protective factors, and estimates of own risk. *Cancer Causes and Control* 21 (12) 2231-2239.

Kash K M, Holland J C, Halper M S and Miller D G (1992) Psychological distress and surveillance behaviors of women with a family history of breast cancer. *Journal of the National Cancer Institute* 84 (1) 24-30.

Keeble S, Abel G A, Saunders C L, McPhail S, Walter F M, Neal R D, Rubin G P and Lyratzopoulos G (2014) Variation in promptness of presentation among 10,297 patients subsequently diagnosed with one of 18 cancers: Evidence from a National Audit of Cancer Diagnosis in Primary Care. *International Journal of Cancer* 135 (5) 1220-1228.

Kim M K, Kim K, Kim S M, Kim J W, Park N H, Song Y S and Kang S B (2009) A hospital-based case-control study of identifying ovarian cancer using symptom index. *J Gynecol Oncol* 20 (4) 238-242.

Kirwan J M, Tincello D G, Herod J J, Frost O and Kingston R E (2002) Effect of delays in primary care referral on survival of women with epithelial ovarian cancer: retrospective audit. *Bmj* 324 (7330) 148-151.

Kline R B (2011) *Principles and practice of structural equation modeling*. Guilford press.

Lancastle D, Brain K and Phelps C (2011) Illness representations and distress in women undergoing screening for familial ovarian cancer. *Psychology & Health* 26 (12) 1659-1677.

Lashley M E (1987) Predictors of breast self-examination practice among elderly women. *Advances in Nursing Science* 9 (4) 25-34.

Lerman C, Daly M, Masny A and Balshem A (1994) *Attitudes about genetic testing for breast-ovarian cancer susceptibility*. Journal of Clinical Oncology. 12 (4) 843-850.

Lerman C, Trock B, Rimer B K, Jepson C, Brody D and Boyce A (1991) Psychological side effects of breast cancer screening. *Health Psychology* 10 (4) 259-267.

Leventhal H and Diefenbach M (1991) The active side of illness cognition. *Mental representation in health and illness* 247-272.

Liberati A, Altman D G, Tetzlaff J, Mulrow C, Gøtzsche P C, Ioannidis J P A, Clarke M, Devereaux P J, Kleijnen J and Moher D (2009) The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Medicine* 6 (7) e1000100.

Lifford K J, Clements A, Fraser L, Lancastle D and Brain K (2013a) Catalysts to withdrawal from familial ovarian cancer screening for surgery and reactions to discontinued screening: a qualitative study. *Familial cancer* 12 (1) 19-26.

Lifford K J, Clements A, Fraser L, Lancastle D and Brain K (2013b) A qualitative study of women's experiences of familial ovarian cancer screening. *Psycho-Oncology* 22 (11) 2576-2584.

Lim A W, Mesher D, Gentry-Maharaj A, Balogun N, Jacobs I, Menon U and Sasieni P (2012) Predictive value of symptoms for ovarian cancer: comparison of symptoms reported by questionnaire, interview, and general practitioner notes. *J Natl Cancer Inst* 104 (2) 114-124.

Lipkus I M (2007) Numeric, verbal, and visual formats of conveying health risks: suggested best practices and future recommendations. *Medical decision making : an international journal of the Society for Medical Decision Making* 27 (5) 696-713.

Lockwood-Rayermann S, Donovan H S, Rambo D and Kuo C W J (2009) Original Research: Women's Awareness of Ovarian Cancer Risks and Symptoms. *AJN The American Journal of Nursing* 109 (9) 36-45.

Low E L, Simon A E, Waller J, Wardle J and Menon U (2013a) Experience of symptoms indicative of gynaecological cancers in UK women. *British journal of cancer* 109 (4) 882-887.

Low E L, Waller J, Menon U, Jones A, Reid F and Simon A E (2013b) Ovarian cancer symptom awareness and anticipated time to help-seeking for symptoms among UK women. *Journal of Family Planning and Reproductive Health Care* 39 (3) 163-171.

Lurie G, Thompson P J, McDuffie K E, Carney M E and Goodman M T (2009) Prediagnostic symptoms of ovarian carcinoma: a case-control study. *Gynecol Oncol* 114 (2) 231-236.

Macleod U, Mitchell E D, Burgess C, Macdonald S and Ramirez A J (2009) Risk factors for delayed presentation and referral of symptomatic cancer: evidence for common cancers. *British journal of cancer* 101 S92-S101.

Mahon S M (1996) Educating women about early detection of gynecologic cancers using a brochure. 23 (3) 529-531.

Mann C (2003) Observational research methods. Research design II: cohort, cross sectional, and case-control studies. *Emergency Medicine Journal* 20 (1) 54-60.

Meisel S, Side L, Fraser L, Gessler S, Wardle J and Lanceley A (2013) Population-Based, Risk-Stratified Genetic Testing for Ovarian Cancer Risk: A Focus Group Study. *Public health genomics* 16 (4) 184-191.

Meiser B, Butow P, Barratt A, Friedlander M, Gattas M, Kirk J, Suthers G, Walpole I and Tucker K (1999) Attitudes toward prophylactic oophorectomy and screening utilization in women at increased risk of developing hereditary breast/ovarian cancer. *Gynecologic oncology* 75 (1) 122-129.

Menon U, Gentry-Maharaj A, Hallett R, Ryan A, Burnell M, Sharma A, Lewis S, Davies S, Philpott S and Lopes A (2009) Sensitivity and specificity of multimodal and ultrasound screening for ovarian cancer, and stage distribution of detected cancers: results of the prevalence screen of the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS). *The Lancet Oncology* 10 (4) 327-340.

Michie S, Johnston M, Abraham C, Lawton R, Parker D and Walker A (2005) Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality and Safety in Health Care* 14 (1) 26-33.

Miller S M, Roussi P, Daly M B and Scarpato J (5094) New strategies in ovarian cancer: uptake and experience of women at high risk of ovarian cancer who are considering risk-reducing salpingo-oophorectomy. [Review]. *Clinical Cancer Research* 16 (21) 5094-5106.

Milne S, Orbell S and Sheeran P (2002) Combining motivational and volitional interventions to promote exercise participation: Protection motivation theory and implementation intentions. *British journal of health psychology* 7 (2) 163-184.

Mogg K and Bradley B P (1998) A cognitive-motivational analysis of anxiety. *Behaviour research and therapy* 36 (9) 809-848.

Murray E, Lo B, Pollack L, Donelan K, Catania J, White M, Zapert K and Turner R (2003) The impact of health information on the internet on the physician-patient relationship: patient perceptions. *Archives of Internal Medicine* 163 (14) 1727-1734.

National Institute for Health and Clinical Excellence (2011) CG122 Ovarian cancer: The recognition and initial management of ovarian cancer. *NICE guideline* [accessed January 2013] (available at: www.nice.org.uk/nicemedia/ live/13464/54194/54194.pdf).

Neal R (2009) Do diagnostic delays in cancer matter? *British Journal of Cancer* 101 (Suppl 2) 9-12.

Norman P and Brain K (2005) An application of an extended health belief model to the prediction of breast self-examination among women with a family history of breast cancer. *British journal of health psychology* 10 (Pt 1) 1-16.

Novick G (2008) Is there a bias against telephone interviews in qualitative research? *Research in nursing & health* 31 (4) 391-398.

Ogden J (2003) Some problems with social cognition models: a pragmatic and conceptual analysis. *Health Psychology* 22 (4) 424-428.

Olson S H, Mignone L, Nakraseive C, Caputo T A, Barakat R R and Harlap S (2001) Symptoms of ovarian cancer. *Obstetrics and Gynecology* 98 (2) 212-217.

Pescosolido B A and Boyer C A (1999) How do people come to use mental health services? current knowledge and changing perspectives. *A handbook for the study of mental health: Social contexts, theories, and systems*. Cambridge University Press.

Pitta D D, Sarian L O, Barreta A, Campos E A, Andrade L L, Fachini A M, Campbell L M and Derchain S (2013) Symptoms, CA125 and HE4 for the preoperative prediction of ovarian malignancy in Brazilian women with ovarian masses. *BMC Cancer* 13 (1) 423-434.

Prat J (2014) Staging classification for cancer of the ovary, fallopian tube, and peritoneum. *International Journal of Gynecology & Obstetrics* 124 (1) 1-5.

QSR International Pty Ltd (2008) Nvivo 8. Warrington, UK.

Quaife S, Forbes L, Ramirez A, Brain K, Donnelly C, Simon A and Wardle J (2013) Recognition of cancer warning signs and anticipated delay in help-seeking in a population sample of adults in the UK. *British journal of cancer* 110 (1) 12-18.

Quaye L, Gayther S A, Ramus S J, Di Cioccio R A, McGuire V, Hogdall E, Hogdall C, Blaakr J, Easton D F and Ponder B A J (2008) The effects of common genetic variants in oncogenes on ovarian cancer survival. *Clinical Cancer Research* 14 (18) 5833-5839.

Ramirez A J, Westcombe A M, Burgess C C, Sutton S, Littlejohns P and Richards M A (1999) Factors predicting delayed presentation of symptomatic breast cancer: a systematic review. *Lancet* 353 (9159) 1127-1131.

Rebbeck T R, Kauff N D and Domchek S M (2009) Meta-analysis of risk reduction estimates associated with risk-reducing salpingo-oophorectomy in BRCA1 or BRCA2 mutation carriers. *Journal of the National Cancer Institute* 101 (2) 80-87.

Redeker C, Wardle J, Wilder D, Hiom S and Miles A (2009) The launch of Cancer Research UK's Reduce the Risk'campaign: Baseline measurements of public awareness of cancer risk factors in 2004. *European Journal of Cancer* 45 (5) 827-836.

Richards M A (2009a) The national awareness and early diagnosis initiative in England: assembling the evidence. *British journal of cancer* 101 S1-S4.

Richards M A (2009b) The size of the prize for earlier diagnosis of cancer in England. *British journal of cancer* 101 S125-S129.

Rim S H, Polonec L, Stewart S L and Gelb C A (2011) A National Initiative for Women and Healthcare Providers: CDC's Inside Knowledge: Get the Facts About Gynecologic Cancer Campaign. *Journal of Women's Health* 20 (11) 1579-1585.

Risch H A, McLaughlin J R, Cole D E, Rosen B, Bradley L, Kwan E, Jack E, Vesprini D J, Kuperstein G and Abrahamson J L (2001) Prevalence and penetrance of germline BRCA1 and BRCA2 mutations in a population Series of 649 women with ovarian cancer. *The American Journal of Human Genetics* 68 (3) 700-710.

Rizzo L, Brick J M and Park I (2004) A minimally intrusive method for sampling persons in random digit dial surveys. *Public Opinion Quarterly* 68 (2) 267-274.

Robb K, Stubbings S, Ramirez A, Macleod U, Austoker J, Waller J, Hiom S and Wardle J (2009) Public awareness of cancer in Britain: a population-based survey of adults. *British journal of cancer* 101 S18-S23.

Robb K A, Simon A E, Miles A and Wardle J (2014) Public perceptions of cancer: a qualitative study of the balance of positive and negative beliefs. *BMJ open* 4 (7) e005434.

Robinson G E, Rosen B P, Bradley L N, Rockert W G, Carr M L, Cole D E C and Murphy K J (1997) Psychological impact of screening for familial ovarian cancer: reactions to initial assessment. *Gynecologic oncology* 65 (2) 197-205.

Rogers R W (1975) A protection motivation theory of fear appeals and attitude change. *The Journal of Psychology* 91 (1) 93-114.

Rosenstock I, Strecher V and Becker M (1988) Social learning theory and the health belief model. *Health Education & Behavior* 15 (2) 175-183.

Rosenstock I, Strecher V and Champion V (1997) The Health Belief Model and Health Behavior: Handbook of Health Behavior Research Personal and Social Determinants. New York: Plenum.

Rosenthal A and Jacobs I (2006) Familial ovarian cancer screening. 20 (2) 321-338.

Rossing M A, Wicklund K G, Cushing-Haugen K L and Weiss N S (2010) Predictive value of symptoms for early detection of ovarian cancer. *Journal of the National Cancer Institute* 102 (4) 222-229.

Rufford B D, Jacobs I J and Menon U (2007) Feasibility of screening for ovarian cancer using symptoms as selection criteria. *BJOG: An International Journal of Obstetrics & Gynaecology* 114 (1) 59-64.

Ruiter R A, Verplanken B, Kok G and Werrij M Q (2003) The role of coping appraisal in reactions to fear appeals: do we need threat information? *Journal of health psychology* 8 (4) 465-474.

Rutter D (2000) Attendance and reattendance for breast cancer screening: A prospective 3-year test of the Theory of Planned Behaviour. *British Journal of Health Psychology* 5 (1) 1-13.

Ryan A, Wilson S, Greenfield S, Clifford S, McManus R J and Pattison H M (2006) Range of self-tests available to buy in the United Kingdom: an Internet survey. *Journal of Public Health* 28 (4) 370-374.

Schwartz M, Lerman C, Daly M, Audrain J, Masny A and Griffith K (1995a) Utilization of ovarian cancer screening by women at increased risk. *Cancer Epidemiology Biomarkers & Prevention* 4 (3) 269-273.

Schwartz M D, Lerman C, Miller S M, Daly M and Masny A (1995b) Coping disposition, perceived risk, and psychological distress among women at increased risk for ovarian cancer. *Health Psychology* 14 (3) 232-235.

Sheeran P (2002) Intention—behavior relations: A conceptual and empirical review. *European review of social psychology* 12 (1) 1-36.

Simon A E, Forbes L J L, Boniface D, Warburton F, Brain K E, Dessaix A, Donnelly M, Haynes K, Hvidberg L and Lagerlund M (2012a) An international measure of awareness and beliefs about cancer: development and testing of the ABC. *BMJ open* 2 (6) e001758

Simon A E, Waller J, Robb K and Wardle J (2010) Patient Delay in Presentation of Possible Cancer Symptoms: The Contribution of Knowledge and Attitudes in a Population Sample from the United Kingdom. *Cancer Epidemiology Biomarkers & Prevention* 19 (9) 2272-2277.

Simon A E, Wardle J, Grimmett C, Power E, Corker E, Menon U, Matheson L and Waller J (2012b) Ovarian and cervical cancer awareness: development of two validated measurement tools. *Journal of Family Planning and Reproductive Health Care* 38 (3) 167-174.

Sixsmith J and Murray C D (2001) Ethical issues in the documentary data analysis of Internet posts and archives. *Qualitative Health Research* 11 (3) 423-432

Smith J A (1996) Beyond the divide between cognition and discourse: Using interpretative phenomenological analysis in health psychology. *Psychology and health* 11 (2) 261-271.

Smith J A (2004) Reflecting on the development of interpretative phenomenological analysis and its contribution to qualitative research in psychology. *Qualitative research in psychology* 1 (1) 39-54.

Smith J A (2007) *Qualitative psychology: A practical guide to research methods*. Sage.

Smith L H, Morris C R, Yasmeen S, Parikh-Patel A, Cress R D and Romano P S (2005a) Ovarian cancer: can we make the clinical diagnosis earlier? *Cancer* 104 (7) 1398-1407.

Smith L K, Pope C and Botha J L (2005b) Patients' help-seeking experiences and delay in cancer presentation: a qualitative synthesis. *The Lancet* 366 (9488) 825-831.

Smith S M, Murchie P, Devereux G, Johnston M, Lee A J, Macleod U, Nicolson M C, Powell R, Ritchie L D and Wyke S (2012) Developing a complex intervention to reduce time to presentation with symptoms of lung cancer. *British Journal of General Practice* 62 (602) e605-e615.

Soames Job R F (1988) Effective and ineffective use of fear in health promotion campaigns. *American Journal of Public Health* 78 (2) 163-167.

Sohl S J and Moyer A (2007) Tailored interventions to promote mammography screening: A meta-analytic review. *Preventive medicine* 45 (4) 252-261.

Stratton J F, Pharoah P, Smith S K, Easton D and Ponder B A (1998) A systematic review and meta-analysis of family history and risk of ovarian cancer. *BJOG: An International Journal of Obstetrics & Gynaecology* 105 (5) 493-499.

Stubbings S, Robb K, Waller J, Ramirez A, Austoker J, Macleod U, Hiom S and Wardle J (2009) Development of a measurement tool to assess public awareness of cancer. *British journal of cancer* 101 S13-S17.

Tiller K, Meiser B, Gould L, Tucker K, Dudding T, Franklin J, Friedlander M and Andrews L (2005) Knowledge of risk management strategies, and information and risk management preferences of women at increased risk for ovarian cancer. *Psycho-Oncology* 14 (4) 249-261.

Trask P C, Paterson A G, Wang C, Hayasaka S, Milliron K J, Blumberg L R, Gonzalez R, Murray S and Merajver S D (2001) Cancer-specific worry interference in women attending a breast and ovarian cancer risk evaluation program: impact on emotional distress and health functioning. *Psycho-Oncology* 10 (5) 349-360.

Trivers K F, Rodriguez J L, Hawkins N A, Cooper C P, Polonec L and Gelb C A (2011) Intention to seek care for symptoms associated with gynecologic cancers, HealthStyles survey, 2008. *Prev Chronic Dis* 8 (6) A144.

Twombly R (2007) Cancer killer may be "Silent" no more. *Journal of the National Cancer Institute* 99 (18) 1359-1361.

Tyndel S, Austoker J, Henderson B J, Brain K, Bankhead C, Clements A and Watson E K (2007) What is the psychological impact of mammographic screening on younger women with a family history of breast cancer? Findings from a prospective cohort study by the PIMMS Management Group. *Journal of Clinical Oncology* 25 (25) 3823-3830.

Vine M F, Calingaert B, Berchuck A and Schildkraut J M (2003) Characterization of prediagnostic symptoms among primary epithelial ovarian cancer cases and controls. *Gynecologic oncology* 90 (1) 75-82.

Von Wagner C, Good A, Whitaker K L and Wardle J (2011) Psychosocial determinants of socioeconomic inequalities in cancer screening participation: a conceptual framework. *Epidemiologic reviews* 33 (1) 135-147.

Waller J, McCaffery K and Wardle J (2004) Measuring cancer knowledge: comparing prompted and unprompted recall. *British journal of psychology* 95 (2) 219-234.

Walter F, Webster A, Scott S and Emery J (2011) The Andersen Model of Total Patient Delay: a systematic review of its application in cancer diagnosis. *Journal of Health Services Research & Policy* 17 (2) 110-118.

Wardle J, Waller J, Brunswick N and Jarvis M J (2001) Awareness of risk factors for cancer among British adults. *Public Health* 115 (3) 173-174.

Watson P, Vasen H F A, Mecklin J P, Bernstein I, Aarnio M, Järvinen H J, Myrhøj T, Sunde L, Wijnen J T and Lynch H T (2008) The risk of extra-colonic, extra-endometrial cancer in the Lynch syndrome. *International journal of cancer* 123 (2) 444-449.

Wells G, Shea B, O'connell D, Peterson J, Welch V, Losos M and Tugwell P (2011) The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. 2011. *URL: http://www.ohri.ca/programs/clinical_epidemiology/oxford. asp*.

Willis G B (1999) Cognitive interviewing: A "how to" guide. In *meeting of the American Statistical Association*.

Willis G B (2005) *Cognitive interviewing: A tool for improving questionnaire design*. Sage Thousand Oaks, CA.

Wilson P and Risk A (2002) How to find the good and avoid the bad or ugly: a short guide to tools for rating quality of health information on the internetCommentary: On the way to quality. *BMJ* 324 (7337) 598-602.

Witte K (1992) Putting the fear back into fear appeals: The extended parallel process model. *Communications Monographs* 59 (4) 329-349.

Witte K and Allen M (2000) A meta-analysis of fear appeals: Implications for effective public health campaigns. *Health Education & Behavior* 27 (5) 591-615.

Wyke S, Adamson J, Dixon D and Hunt K (2013) Consultation and illness behaviour in response to symptoms: a comparison of models from different disciplinary frameworks and suggestions for future research directions. *Social Science & Medicine* 86 79-87.

Wynn M L, Chang S and Peipins L A (2007) Temporal patterns of conditions and symptoms potentially associated with ovarian cancer. *J Womens Health (Larchmt)* 16 (7) 971-986.

Wyper M A (1990) Breast self-examination and the health belief model: Variations on a theme. *Research in nursing & health* 13 (6) 421-428.

Yawn B P, Barrette B A and Wollan P C (2004) Ovarian cancer: the neglected diagnosis. *Mayo Clin Proc* 79 (10) 1277-1282.

Zaza S, Wright-De Agüero L K, Briss P A, Truman B I, Hopkins D P, Hennessy M H, Sosin D M, Anderson L, Carande-Kulis V G and Teutsch S M (2000) Data collection instrument and procedure for systematic reviews in the Guide to Community Preventive Services. Task Force on Community Preventive Services. *American journal of preventive medicine* 18 (1 Suppl) 44-47.

Appendix 1. Search terms for grey literature search

Internet search terms

1. Terms: Ovarian cancer symptoms
   Symptoms of ovarian cancer
   Signs of ovarian cancer
   Ovarian cancer
   Ovarian cancer symptom awareness
   Ovarian cancer signs
   Ovarian cancer detection
   Early signs of ovarian cancer
   Ovarian cancer symptom checker
   Ovarian cancer symptom information
   How to detect ovarian cancer
   Ovarian cancer self diagnosis
   Ovarian cancer self diagnosis tool
   Ovarian cancer risk
   Ovarian cancer warning signs

2. New terms from Department of Primary Care and Public Health: What is ovarian cancer
   Do I have ovarian cancer?
   Common symptoms of ovarian cancer
   Gynaecological cancer symptoms
   Common ovarian cancer symptoms

3. New from Target Ovarian Cancer: Ovarian cysts and their signs and symptoms
   Pelvic pain and increased abdominal size
   Pelvic pain and bloating
   Pelvic pain and difficulty eating
   Pelvic pain and increased urinary frequency

Appendix 2. Database search strategy

Search number	Search Terms: PychInfo, Embase, Medline	Results
1	(ovar* OR gynae* OR gyne*).mp.	693903
2	(cancer* OR malig* OR neoplasm*).mp.	4505303
3	(symptom* OR sign OR indicat* OR detect* OR diagno* OR calculat*).mp.	13533657
4	1 and 2 and 3	102965
5	(aware* OR knowledge* OR attitude* OR recogni* OR lay concept* OR health belief* OR expectation OR information* OR education* OR reconi* OR promot*).mp.	6979549
6	4 and 5	18558
7	(tool OR material* OR aid* OR information OR leaflet OR booklet OR intervention OR health education OR promot*).mp.	6189782
8	6 and 7	10958
9	Limit 16 to English Language	9883
10	Limit 9 to humans	8604
11	Limit 10 to female	6264
12	RNA or RNA messenger or sequence analysis or signal transduction or transforming growth factor beta or DNA fragmentation or apoptosis or exp adenoviridae/ or exp genes or antigens or membrane protein or Immunohistochemistry OR proteomic* or genomic	4753757
13	11 not 12	4411
14	Deduplicate 13	3102

Appendix 3. Data extraction form

Content	Evidence (yes, no and evidence in relevant source column)		
1. Characteristics of the source:	**Tool**	**Website**	**Author**
Who was the tool developed by			
Country of origin of website			
Brief description of website (charity, health provider, heavily advertised, navigation ease etc)			
Affiliation with any other organisations			
Funding source for tool			
Advertisements on the website			
Are responses/data that people input into the tool collected by the source			
Position of website in search engine results			
2. Characteristics of the tool			
Name of tool			
Tool format (diary, video, slideshow etc)			
Does it provide instructions on how to use tool: if so are these presented on the tool itself or the website			
Does the tool concern increasing awareness			
Does the tool concern encouraging presentation			
Is there a specific target audience for the tool (all women, those at risk, GP's etc)			
Information of how tool was created			
References to academic papers for information provided (if these are not provided on the tool itself are they are on the website?)			
If so, are these papers relevant to the target audience and the tool			
Contact information provided on tool			
Is a theory stated for any aspect of the tool content			
Is there a version number and date on the tool			
Is there a next update/review date on the tool			
Does the tool open in a new window or is it embedded in the current window			
How do you use it eg just online, print out			
How long does it take to complete			

Does it have an information standard mark or quality mark for the information provided			
Are terms of use for the tool explained on the tool: if not are these provided on the website?			
3. Provision of information:			
Does the tool try to change knowledge, attitudes or norms?			
Does the website mention any campaigns to advertise their materials?			
Does the tool provide ovarian cancer facts/information: incidence, mortality etc			
Are positive or negative frames used on the tool: eg death and survival rates			
Does it dispel common misconceptions/myths about ovarian cancer (eg smear test does not detect ovarian cancer)			
Are personal accounts of symptom experience included in the tool?			
4. **Communication**:			
What does the tool tell you (ie feedback)			
Is the tool interactive (does it require input or do you simply read it)			
Does the tool provide feedback based on personal health information			
Is the reading age of information provided			
5. Format of tool			
Yes/no responses			
Scales			
Age groups			
Free text			
Numerical information:			
- Percentages			
- Frequencies			
- Probabilities			
Are consistent formats used			
Graphs			
Pictures			
Visual diagrams			
Videos			
How many pages of the tool are there			
Do you move step by step through pages of the tool			

Can you return to previous pages of the tool			
Is it easy to return the tool to the tool if you link to other web pages			
6. Symptoms:			
List ovarian cancer symptoms mentioned in tool			
Any other symptoms mentioned in the tool			
Does the tool provide symptom threshold information			
Does the tool provide information on symptom frequency			
Does the tool provide information of symptom duration			
Positive predictive value of symptoms included in tool?			
Does the tool ask people to recall symptoms			
Does the tool ask people to recognise symptoms			
Does the tool ask about people's confidence in symptom knowledge			
Is any reasoning for symptom recognition given			
7. Risk information			
Are increased risk groups described in the tool			
Are risk factors stated in the tool			
Does the tool suggest places to gain extra information on ovarian cancer: if not does the website provide this information?			
Does the tool allow input for family history of cancer			
Are individuals asked to input perceived personal risk status into the tool			
Is a personal risk status generated by the tool			
8. Behaviour change and medical guidance:			
Does the tool prompt or encourage self monitoring of symptoms			
If so does the tool suggest information on how to carry out said behaviours ie. How often, where etc			
Does the tool provide materials to help change behaviour			
Guidance to visit GP provided in tool?			
Information on when to re-visit GP			

provided in tool?			
Does the tool ask about presentation behaviour (eg how long after noticing a symptom would it take for you to seek help)			
Does the tool ask people to engage in a behavioural contract ie “if… then” goal setting			
Can you print the tool out			
Can you order a physical copy			
Does the tool encourage disclosure to others			
9. Does the tool address:			
Fear or distress			
Self efficacy			
Barriers to presenting with symptoms			
Benefits of symptom awareness			
10. Other			

Appendix 4. Country of origin, format and source information of identified tools

Name of tool	Origin	Format	Source	Website type
1. Australia Awareness Brochure	Australia	Leaflet	www.ovariancancer.net.au	Charity
2. Early detection Australia	Australia	Factsheet	www.canceraustralia.nbocc.org.au	Government
3. Dr Oz	Australia	Diary	www.doctoroz.com	TV show
4. Australia symptom diary	Australia	Diary	www.ovariancancer.net.au	Charity
5. OC Australia factsheet	Australia	Flyer	www.canceraustralia.nbocc.org.au	Government
6. TV advert	Australia	Video	www.nbocc.org.au	Government
7. No one knows your body like you do	Australia	Flyer	www.canceraustralia.nbocc.org.au	Government
8. It's time to shout out	Canada	Factsheet	www.itstimetoshout.com	Charity
9. OC Canada Knowledge Centre	Canada	Quiz	www.ovarianknowledge.ca	Charity
10. Think ovarian!	Canada	Factsheet	www.ovarianknowledge.ca	Charity
11. New Zealand gynaecology leaflet	NZ	Leaflet	www.nzgcf.org.nz	Charity
12. Ashkenazi Inheritance	UK	Leaflet	www.ovarian.org.uk	Charity
13. BEAT Symptom Checker	UK	Symptom checker	www.ovacome.org.uk	Charity
14. BEAT Symptom Tracker	UK	Diary	www.beatonline.info	Charity
15. Detecting OC CRUK	UK	Leaflet	www.cancerresearchuk.org	Charity
16. OC diary Innermost Secrets	UK	Diary	www.innermostsecrets.com	Charity
17. Ovarian Cancer Action diary	UK	Diary	www.ovarian.org.uk	Charity
18. QriskOvary	UK	Risk calculator	www.qcancer.org	
19. Remember the symptoms	UK	Leaflet	www.ovarian.org.uk	Charity
20. Swollen tummy?	UK	Leaflet	www.targetovariancancer.org.uk	Charity
21. Target quiz	UK	Quiz	www.targetovariancancer.org.uk	Charity
22. What women need to know	UK	Leaflet	www.eveappeal.org.uk	Charity
23. 15 symptoms women ignore	USA	Slideshow	www.medicinenet.com	Health
24. Break the silence conversation starter	USA	Leaflet	www.ovarian.org	Charity
25. CDC gynaecology diary	USA	Diary	www.cdc.gov	Government
26. NOCC bookmark	USA	Bookmark	www.ovarian.org	Charity
27. NOCC Quiz	USA	Quiz	www.ovarian.org	Charity
28. Ova-1 calendar	USA	Diary	www.ova-1.com	Drug company
29. Ova-1 Quiz	USA	Quiz	www.ova-1.com	Drug company
30. OC symptoms	USA	Bookmark	www.ovca.net	Charity

31. OC warning signs	USA	Symptom diagram	www.cancerdancer.org	Charity
32. Ovarian Cancer National Alliance (OCNA) app	USA	Diary app	www.ovariancancer.org	Charity
33. OCNA symptom diary	USA	Diary	www.ovariancancer.org	Charity
34. OCNA factsheet	USA	Factsheet	www.ovariancancer.org	Charity
35. OAK symptom card	USA	Symptom card	www.oaky.org	Charity
36. Ovations for the future	USA	Leaflet	www.ovationsforthecure.org	Charity
37. WCN understand your risk	USA	Leaflet	www.wcn.org	Charity
38. WCN women's guide	USA	Leaflet	www.wcn.org	Charity
39. Mahon paper	USA	Leaflet	n/a	n/a

Appendix 5. Symptoms included in identified tools

Name of material	Symptoms
1. Australia awareness Brochure	1. Increased abdominal size or persistent bloating 2. Unexplained abdominal or pelvic pain 3. Difficulty eating or feeling full quickly 4. Needing to urinate often or urgently 5. a change in bowel habits 6.Unexplained weight gain or loss 7.Vaginal bleeding 8.Back pain 9. Indigestion or nausea 10.Excessive fatigue
2. Early detection Australia	1.Abdominal bloating or a feeling of fullness 2.Loss of appetite 3.Unexplained weight gain 4.Constipation 5.Heartburn 6.Back, abdominal or pelvic pain 7.Frequent urination 8.Fatigue 9.Indigestion 10. Pain during intercourse
3. Dr Oz	1.Bloating or increased abdominal size 2.Pelvic or abdominal pain 3.Difficulty eating or feeling full quickly 4.Feeling a frequent or urgent need to urinate
4. Australia symptom diary	1.Pelvic/abdominal pain 2. Increased abdominal size/bloating 3. Urinary frequency/urgency 4.Difficulty eating/feeling full 5.Changes in your bowel habits 6.Unexplained weight gain or loss 7.Bleeding in between periods or after menopause 8.Back pain 9.Indigestion or nausea 10. Excessive fatigue
5. Ovarian cancer: Australia factsheet	1.Abdominal bloating 2.feeling full 3.appetite loss 4.unexplained weight gain 5.constipation 6.heartburn 7.back pain 8. frequent urination 9.Abdominal/pelvic pain 10. fatigue
6. TV advert	1.Abdominal bloating 2.Abdominal or back pain 3.Appetite loss or feeling full 4. Changes in toilet habit 5.Unexplained weight gain or loss 6.Indigestion or heart burn 7.Fatigue
7. No one knows your body like you do	1. Abdominal bloating 2. Abdominal or back pain 3. Appetite loss or feeling full quickly 4. Changes in toilet habits 5. Unexplained weight loss or gain 6. Indigestion or heartburn 7. Fatigue

8. Its time to shout out	1. Fatigue 2. Persistent pressure or pain in abdomen or pelvis 3. Weight gain 4. Frequent or urgent urination 5. Back pain 6. Gas 7. Changes in bowel movements 8. Difficulty eating or feeling full quickly 9. Bloating or swelling of the abdomen 10. Vaginal bleeding 11. Painful intercourse
9. Ovarian Cancer Canada Knowledge Centre	1. Swelling or bloating in the abdomen 2. Pelvic discomfort or heaviness 3. Back or abdominal pain 4. Gas, nausea and indigestion 5. Changes in your bowel habit 6. Needing to empty your bladder frequently 7. Menstrual irregularities 8. Fatigue 9. Weight loss or weight gain not otherwise explained:
10. Think Ovarian!	1.Swelling or bloating of the abdomen 2.Pelvic discomfort or heaviness 3.Back or abdominal pain 4.Fatigue 5.Gas, nausea, indigestion 6.Change in bowel habits 7.Emptying your bladder frequently 8.Menstrual irregularities 9.Weight loss or weight gain
11. NZ Gynaecological lealflet	1.Increased abdominal size 2.persistent bloating 3.Pelvic and/or abdominal pain 4.Difficulty eating and feeling full quick 5.urinary problems, 6.changes in bowel habits, 7.extreme fatigue 8. back pain 9.Abnormal vaginal bleeding or discharge, especially after menopause 10. Pain during sexual intercourse 11. Itchy skin around the opening in the vagina
12. Ashkenazi Inheritance:	1. Persistent pelvic and abdominal pain 2. Difficulty eating/feeling full quickly 3. Increased abdominal size/persistent bloating – not bloating that comes and goes
13. BEAT Symptom Checker	1.Have you noticed an increase in abdominal size or persistent bloating recently? 2.Have you had difficulties eating or have you been feeling full too quickly recently? Eg heartburn, nausea or loss of appetite 3.Have you had persistent pelvic or abdominal pain recently? 4.Have you experienced urinary problems, changes in bowel habit, extreme fatigue or back pain recently?
14. BEAT Symptom Tracker	**1.**Abdominal bloating (Belly feels noticeably fuller and tighter or as if it's pressured or full of gas) **2.**Bigger than usual abdomen (Size of belly feels bigger than usual) **3.**Tight or hard abdomen (Belly feels harder than usual)/Can feel lumps in abdomen (Any unusual lumps or bumps in your belly not noticed before **4.**Feeling full more quickly than usual (Eating small amounts of food fills you up more quickly than usual) **5.** Reduced appetite (Off food or noticeably lower appetite than usual) **6.**Heartburn (A burning sensation at the bottom of the chest that radiates toward the throat or mouth) **7.** Nausea or vomiting (Feeling sick or being sick)

	8. Burping more than usual (Trapped wind in your stomach) **9.**Not getting food down or regurgitating food (Difficult to get food down to the extent that liquid or food can feel like it's coming back up) **10.** Abdominal pain or discomfort (Feeling uncomfortable, cramping or other pain in your belly) **11.** Indigestion (A feeling of belly discomfort brought on by eating food) **12.** Pain on passing urine or opening bowels (Pain before, during or after passing urine or opening bowels) **13.** Groin, vaginal or rectal pain (Pain in the pelvis, vagina or groin, or rectum) **14.** Pain during/after sexual intercourse (Pain during or after sex) **15.** Other pains such as back, chest, leg, shoulder (Pains in the back or the side of the body. Pains in the chest and shoulder. Pains in the buttocks, hips, legs) **16.** Constipation or diarrhoea (Straining or difficulty opening bowels. Or loose bowel motions (or even loss of bowel control) **17.** Excessive passing of wind (Noticeably increased flatulence.) **18.** Rectal bleeding (Blood coming from the bottom.) **19.** Vaginal discharge or bleeding (Discharge of fluid (including blood) from the vagina which is out of the ordinary) **20.** Passing urine frequently (or leaking) (Noticeably increased number of visits to toilet to pass urine, or occasional leaking accidents.) **21.** Difficulty passing urine (Reduced urine flow (difficulty start or dribbling flow). **22.** Cough (Cough or tickly throat either with or without sputum) **23.** shortness of breath (noticeably out of breath or panting after little or no exertion) **24.** Tiredness or Lack of energy (Tired out more than usual or by minimal exertion) **25.** Weight loss or gain without trying (Noticeable loss of weight without any change in your diet)
15. Detecting ovarian cancer: CRUK	1.Pelvic or tummy pain 2.Increased tummy size 3.Bloating that does not go away 4.Difficulty eating or feeling full quickly: 5. changes in bowel habit, 6. passing urine more often than usual, 7.bleeding after the menopause, 8.extreme tiredness 9. back pain.
16. Ovarian Cancer diary: Innermost secrets	1.Pelvic or abdominal pain 2. Increased stomach size 3.bloating - not bloating that comes and goes **4.**Difficulty eating/ feeling full quickly 5.Urinary symptoms/ 6. Changes in bowel habit/ 7.Excessive tiredness/ 8. Backache 9. Persistent stomach pain 10.increased abdominal size and persistent bloating 11. similar to IBS
17. Ovarian Cancer Action diary	1.Pelvic/abdominal pain 2.Increased stomach size/bloating - not bloating that comes and goes 3.Difficulty eating/feeling full quickly 4.Urinary symptoms 5.Change in bowel habit 6.Excessive tiredness 7.Backache
18. Qrisk Ovary	Are you currently experiencing: 1.Rectal bleeding? 2.Postmenopausal bleeding? 3. Abdominal pain?

	4.Abdominal distension? 5. Loss of appetite? 6.Unintentional weight loss?
19. Remember the Symptoms	**1.**Persistent pelvic/stomach pain **2.**Increased stomach size **3.**Persistent bloating **4.**Difficulty eating/Feeling full quickly **5.**Needing to urinate suddenly or more often **6.** Changes in bowel habit e.g. diarrhoea or constipation **7.** Excessive tiredness **8.** Back pain
20. Swollen tummy?	1.Persistent pelvic or abdominal pain (that's your tummy and below) 2.Increased abdominal size/persistent bloating – not bloating that comes and goes 3.Difficulty eating or feeling full quickly 4.Urinary symptoms (needing to wee more urgently or more often than usual) 5.Changes in bowel habit 6. Extreme fatigue (feeling very tired) 7.Unexplained weight loss
21. Target quiz	**1.** Feeling full or having difficulty eating, on most days **2.** Persistent tummy pain **3.** Being bloated or having a swollen tummy on most days **4.** Urinary symptoms (needing to wee more urgently or often than usual)
22. What women need to know…	1. Persistent pelvic and abdominal pain 2. Increased abdominal size/persistent bloating – not bloating that comes and goes 3. Difficulty eating and feeling full quickly
23. 15 Symptoms women ignore	1. Bloating 2. Abdominal pain or pelvic pain 3. Feeling full quickly - even without eating much 4. Urinary problems, such as having an urgent need to go to the bathroom
24. Break the silence conversation starter	1. Bloating 2. Pelvic or abdominal pain 3. Trouble eating or feeling full quickly 4. Feeling the need to urinate urgently or often 5. Fatigue or a persistent lack of energy 6. Upset stomach, 7. heartburn (persistent indigestion), 8. gas, or nausea 9. Back pain 10. Pain during intercourse 11. Constipation, unexplained changes in bowel habits, or diarrhea 12. Menstrual changes 13. Unexplained weight loss or gain 14. sleep changes 15. bowel habits 16. headaches"
25. CDC diary	1. Abnormal vaginal discharge 2. Pelvic pain or pressure 3. Abdominal or back pain 4. Bloating 5. Changes in bathroom habits 6. Abnormal vaginal bleeding
26. NOCC Bookmark	1.Bloating 2.Trouble eating or feeling full quickly 3.Pelvic or abdominal pain 4. Feeling the need to urinate urgently or often 5.Fatigue 6. Upset stomach or heartburn 7.Back pain 8.Pain during sex 9.Constipation

	10. Menstrual changes
27. NOCC Quiz	1. Pelvic or abdominal pain or discomfort 2. vague but persistent gastrointestinal upsets such as gas, nausea, and indigestion 3. frequency and/or urgency of urination in the absence of an infection 4. unexplained weight gain or weight loss 5. pelvic and/or abdominal swelling, 6. bloating and/or feeling of fullness; 7. Ongoing unusual fatigue 8. Unexplained changes in bowel habits.
28. Ova-1 calendar	1.Abdominal pain 2.Bloating 3.Difficulty eating/feeling full quickly 4.Urinary urgency or frequency 5.fatigue 6.upset stomach 7. back pain 8.pain during intercourse 9. constipation 10. menstrual changes
29. Ova-1 quiz	1. Or you may have irregular menstrual periods. 2. It can also cause constipation. 3. Abdominal swelling that makes clothes fit tighter can occur. 4. This swelling is often accompanied by weight loss.
30. Ovarian cancer symptoms	1. Bloating 2. Pelvic or abdominal pain 3. Difficulty eating or feeling full quickly 4. Urinary symptoms (urgency or frequency) Other symptoms: 5. Fatigue 6. Indigestion 7. Back pain 8. Pain with intercourse 9. Constipation
31. Ovarian cancer warning signs	1.Abdominal pressure 2.fullness 3.swelling or bloating 4.Persistent indigestion, gas or nausea 5.Changes in bowel habit, such as constipation 6.Loss of appetite or quickly feeling full **7.**Increased abdominal girth or clothes fitting tighter around your waist 8.A persistent lack of energy /Fatigue 9. Lower back pain 10. Pelvic discomfort or pain 11. Bloating and gas 12. Slender poop
32. OCNA app	1.Bloating 2. Pelvic or abdominal pain 3. Difficulty eating or feeling full quickly 4. Urinary symptoms (frequency or urgency)
33. OCNA symptom diary	1.Bloating 2.Pelvic/abdominal pain 3. Difficulty eating or feeling full quickly 4.Urinary symptoms
34. OCNA factsheet	1. Bloating 2. Pelvic and abdominal pain 3. Difficulty eating or feeling full quickly 4. Urinary symptoms (urgency or frequency) 5. Fatigue / 6. Indigestion 7. Back pain 8. Pain with intercourse

	9. Constipation 10. Menstrual irregularities
35. OAK Symptom Card	1. Bloating 2. Pelvic or abdominal pain 3. Difficulty eating or feeling full quickly 4. Urinary symptoms (urgency or frequency) 5. fatigue 6. indigestion 7. back pain, 8. pain with intercourse 9. constipation 10. menstrual irregularities
36. Ovations for the future	1. Bloating 2. Pelvic or abdominal pain 3. Trouble eating or feeling full quickly 4. Urinary symptoms, such as urgent or frequent feeling of needing to go
37. WCN understanding your risk	1. Bloating 2. Pelvic or abdominal pain 3. Difficulty eating or feeling full quick 4. Urinary symptoms (urgency or frequency) 5. Fatigue 6. Indigestion 7. Back pain 8. Pain with intercourse 9. Constipation 10. Menstrual irregularities
38. WCN womens guide	1.Bloating 2.Pelvic or abdominal pain 3. Difficulty eating or feeling full quickly 4.Urinary symptoms (urgency or frequency) 5. Fatigue **6.**Indigestion **7.**Back pain **8.**Pain with intercourse **9.**Constipation 10.Menstrual irregularities
39. Mahon (1996) paper	**1.** Vague, unexplained abdominal pain or swelling **2.** A sense of abdominal fullness **3.** Loss of appetite **4.** Nausea and vomiting

Appendix 6. Health Belief Model construct coverage in identified tools

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
Perceived susceptibility																																							
Risk factors	✓	✓	✓		✓			✓	✓	✓	✓	✓	✓		✓				✓	✓	✓	✓		✓		✓	✓		✓			✓	✓	✓	✓	✓	✓	✓	✓
Risk reduction	✓							✓	✓	✓	✓				✓												✓		✓			✓					✓	✓	
Family history info			✓										✓	✓				✓		✓				✓			✓					✓					✓	✓	
Personal risk status generated																		✓														✓					✓		
Perceived severity																																							
Facts	✓	✓			✓		✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓	✓					✓		✓			✓	✓	✓	✓	✓	✓	
Perceived benefits																																							
Reasoning for symptom awareness	✓						✓		✓		✓	✓			✓	✓	✓		✓	✓	✓	✓		✓							✓	✓	✓	✓		✓	✓	✓	
Directly suggests places to get information	✓	✓			✓		✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
Confidence	✓			✓		✓	✓		✓	✓						✓			✓	✓	✓			✓			✓		✓				✓						
Perceived barriers																																							
Dispel myths	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓							✓	✓	✓	✓				✓	✓		✓	✓	✓	✓		✓	✓			✓	
Vague nature of symptoms	✓	✓			✓		✓		✓		✓					✓				✓	✓	✓		✓		✓						✓		✓					✓
Reduce fear/ distress	✓	✓							✓			✓		✓						✓				✓	✓											✓			
Cues to action																																							
Symptom duration	✓		✓	✓				✓	✓	✓	✓	✓			✓	✓	✓			✓			✓	✓	✓	✓		✓		✓			✓		✓	✓	✓	✓	
Symptom frequency	✓			✓						✓		✓			✓	✓	✓		✓	✓	✓	✓		✓		✓							✓		✓	✓	✓	✓	
When to revisit GP	✓			✓					✓	✓						✓	✓		✓	✓		✓		✓									✓						
Total /14	12	6	3	4	5	2	6	5	11	9	8	8	3	4	7	7	5	4	8	12	8	8	2	10	3	5	7	2	5	3	3	9	8	6	6	7	9	9	2

Appendix 7. Ethical approval 1

School of Medicine
Dean Professor B Paul Morgan PhD MRCP FRCPath FMedSci

Ysgol Meddygaeth
Deon Yr Athro B Paul Morgan PhD MRCP FRCPath FMedSci

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Cardiff University
School of Medicine
Heath Park
Cardiff CF14 4XN

Prifysgol Caerdydd
Ysgol Meddygaeth
Mynydd Bychan
Caerdydd CF14 4XN

Thursday 20th September 2012

Stephanie Smits
Cochrane Institute of Primary Care
& Public Health
School of Medicine
Cardiff University
Neuadd Meirionnydd
Heath Park

Dear Stephanie,

Re: Development of an ovarian cancer symptom awareness tool for women at increased risk of ovarian cancer. Phase One of the OvSTAT study

SMREC Reference Number: 12/53

Re: GPs knowledge, awareness and beliefs of ovarian cancer. Phase two of the OvSTAT study.

SMREC Reference Number: 12/54

This application was first reviewed by the School of Medicine Research Ethics Committee on Wednesday 15th August 2012.

Ethical Opinion

On review of the above projects, the Committee granted ethical approval for both provided that Dr Kate Brain's details as supervisor are added to the Information Sheet for both Phase One and Phase Two.

Conditions of Approval

The Committee must be notified of any proposed amendments to the methodology and protocols outlined in your submission. Also, any serious or unexpected adverse reactions that may arise during the course of the study must be reported to the Committee.

Documents Considered

Document Type:	Version:	Date Considered:
Application Form (Phase One)	V1 31/07/2012	15/08/2012
Attachment 1 (Phase One)	V1 31/07/2012	15/08/2012
Attachment 2 (Phase One) Invitation Letter	V1 31/07/2012	15/08/2012
Attachment 3 (Phase One) Information Sheet	V1 31/07/2012	15/08/2012
Attachment 4 (Phase One) Consent Form	V1 31/07/2012	15/08/2012
Attachment 5 (Phase One) Questionnaire	V1 31/07/2012	15/08/2012
Appendix 1: Outline of PhD	V1 31/07/2012	15/08/2012
Application Form (Phase Two)	V1 31/07/2012	15/08/2012
Attachment 1 (Phase Two)	V1 31/07/2012	15/08/2012
Attachment 2 (Phase Two) Invitation Email	V1 31/07/2012	15/08/2012
Attachment 3 (Phase Two) Information Sheet	V1 31/07/2012	15/08/2012
Attachment 4 (Phase Two) Consent Form	V1 31/07/2012	15/08/2012
Attachment 5 (Phase Two) Questionnaire	V1 31/07/2012	15/08/2012
Appendix 1: Outline of PhD	V1 31/07/2012	15/08/2012

With best wishes for the success of your study.

Yours sincerely,

Dr Andrew Freedman
Chair, School of Medicine Research Ethics Committee

Appendix 8. Questionnaire for women at increased genetic risk

Ovarian cancer symptom awareness and help seeking behaviour in women at increased risk of developing ovarian cancer. Phase one of the OvSTAT study.

The main aim of this study is to find out about women's views on ovarian cancer symptoms

This questionnaire should take about 20 minutes to complete. Please read the instructions for each question carefully and try to complete all the questions you can. We are interested in your answers to the questions so please try not to get help from other people or places such as the internet.

If you have any questions about filling in the questionnaire or about the study in general, you can call Steph Smits on 029206 87202.

All the information you give us will be treated in confidence and will only be seen by the researchers working on the study.

It is important that you read the information sheet and sign the consent form before you complete the questionnaire. When you have completed the questionnaire, please check to make sure you have not missed anything out. Then return the signed consent form and questionnaire to us in the **stamped** envelope provided.

For administration only

OvSTAT study number:

Date of Q issue: **Date Q received:**

Date signed consent received:

1. **Have you, or any friends or family members ever been diagnosed with ovarian cancer?**
   - ☐ Yes, self
   - ☐ Yes, friend or family, If yes, what is your relationship to this person? _____
   - ☐ No

   If you have answered "yes, self" please do not complete this questionnaire.

2. **How long were you involved with screening for ovarian cancer?**
   Please state how long in years _____, if less than a year in months _____
   - ☐ I wasn't involved

3. **Have you had a procedure to remove one or more of your ovaries? Please tick one box.**
   - ☐ Yes, one ovary
   - ☐ Yes, both ovaries
   - ☐ No

4. **Compared to most other women your age, how likely do you think it is that you will get ovarian cancer at some time in your life? Please tick one box.**
   - ☐ Much more likely to get it
   - ☐ A little more likely to get it
   - ☐ About the same
   - ☐ A little less likely to get it
   - ☐ Much less likely to get it
   - ☐ Don't know

The 3 questions below ask about concerns you may or may not have about ovarian cancer

(Tick one box from each row)	Not at all	Rarely	Sometimes	Often	Almost all the time
5. How often, if at all, do you worry about getting ovarian cancer someday?	☐	☐	☐	☐	☐
6. How often, if at all, does your worry about getting ovarian cancer affect your mood?	☐	☐	☐	☐	☐
7. How often, if at all, does your worry about getting ovarian cancer affect your ability to perform your daily activities?	☐	☐	☐	☐	☐

8. **If you can think of any symptoms of ovarian cancer, list them in the space below**

9. **How confident, or not, are you that you would notice a symptom of ovarian cancer? Please tick one box.**

- ☐ Not at all confident
- ☐ Not very confident
- ☐ Fairly confident
- ☐ Very confident

10. **If you had a symptom that you thought might be a sign of ovarian cancer, how long would it take you to go to the doctors from the time you first noticed the symptom? Please tick one response that you feel most applies to you.**

- ☐ I would go as soon as I notice
- ☐ Up to 1 week
- ☐ Over 1 up to 2 weeks
- ☐ Over 2 up to 3 weeks
- ☐ Over 3 up to 4 weeks
- ☐ More than a month
- ☐ I would not contact my doctor
- ☐ Other (please specify) _____

Do you think the following could be a sign of ovarian cancer?

(Tick one box from each row)	Yes	No	Don't Know
11. A persistent pain in your abdomen	☐	☐	☐
12. A persistent pain in your pelvis	☐	☐	☐
13. Vaginal bleeding after the menopause	☐	☐	☐
14. Persistent abdominal bloating	☐	☐	☐
15. Increased abdominal size on most days	☐	☐	☐
16. Not wanting to eat because you feel full persistently	☐	☐	☐
17. Difficulty eating your usual amount of food on most days	☐	☐	☐
18. Passing more urine than usual	☐	☐	☐
19. A change in bowel habits	☐	☐	☐
20. Extreme tiredness	☐	☐	☐
21. Back pain	☐	☐	☐

We are interested in what makes people go to the doctors for advice about symptoms they are experiencing.

Below is a list of symptoms. For each symptom fill in the columns saying:

- How long you would expect to experience the symptom before going to get advice
- How often you would expect the symptom to occur during this time

	How long you would wait after noticing the symptom before going to get advice?	How often in this time period it occurs?
22. A persistent pain in your abdomen	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
23. A persistent pain in your pelvis	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
24. Vaginal bleeding after the menopause	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
25. Persistent abdominal bloating	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
26. Increased abdominal size on most days	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
27. Not wanting to eat because you feel full persistently	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
28. Difficulty eating your usual amount of food on most days	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
29. Passing more urine than usual	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
30. A change in bowel habits	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
31. Extreme tiredness	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion
32. Back pain	☐ up to 1 week ☐ 1-2 weeks ☐ 2-3 weeks ☐ 3-4 weeks ☐ more than a month	☐ daily ☐ most days ☐ some days ☐ on one occasion

Please indicate whether any of the following might put you off going to the doctor if you thought you had a symptom of ovarian cancer.

(Tick one box from each row)	Yes, often	Yes, sometimes	No
33. I would be too embarrassed	☐	☐	☐
34. I would be too scared	☐	☐	☐
35. I would be worried about wasting the doctor's time	☐	☐	☐
36. I would have too many other things to worry about	☐	☐	☐
37. I would be worried about what the doctor might find	☐	☐	☐
38. I wouldn't feel confident talking about my symptom with the doctor	☐	☐	☐
39. It would be difficult for me to get an appointment	☐	☐	☐
40. I would be too busy to make time to go to the doctor	☐	☐	☐

41.If there is anything else that might put you off going to the doctors please tell us in the space below

42. **Have you previously been to see a doctor with concerns over possible ovarian cancer symptoms?**

☐ Yes

☐ No

If you answered yes, what prompted you to visit the doctor on that occasion?

_____

_____

_____

Below are 3 statements about ovarian cancer, please indicate how much you agree or disagree with each statement.

(Tick one box from each row)	Strongly disagree	Tend to disagree	Tend to agree	Strongly agree
43. If ovarian cancer is diagnosed early it can be treated more successfully	☐	☐	☐	☐
44. If found early, ovarian cancer can often be cured	☐	☐	☐	☐
45. Going to the doctor as quickly as possible after noticing a symptom of ovarian cancer could increase the chances of surviving	☐	☐	☐	☐

Do you believe any of the following help detect ovarian cancer?

(Tick one box from each row)	Yes	No	Don't Know
46. Pap smear	☐	☐	☐
47. Blood tests	☐	☐	☐
48. Ultrasounds	☐	☐	☐
49. X-ray	☐	☐	☐
50. MRI scan	☐	☐	☐

51. **Have you read any ovarian cancer awareness materials, such as leaflets, posters or flyers?**
    - ☐ Yes
    - ☐ No

    If you have answered yes, please provide the name of the material _____

The following questions are background details about yourself.

52. **What is your age?** _____

53. **What is the highest level of education you have attained? Please tick one option.**
    - ☐ Up to 16 years old
    - ☐ Post 16 (e.g., BTEC, NVQ, HND, HNC, A levels)
    - ☐ Undergraduate college or university (e.g., BA, BSc, BBA)
    - ☐ Graduate or post-graduate school (e.g., MA, MBA, PhD)
    - ☐ Other (please specify) _____

54. **Which of these best describes your current relationship status? Please tick one option.**
    - ☐ Married or cohabiting
    - ☐ In relationship, but not married or cohabiting
    - ☐ Widowed and not living with another partner
    - ☐ Divorced and not living with another partner
    - ☐ Single

55. **How would you describe your ethnic origin? Please tick one box.**
    - ☐ English/Welsh/Scottish/Northern Irish/ British
    - ☐ Irish
    - ☐ Gypsy or Irish Traveller
    - ☐ White and Black Caribbean
    - ☐ White and Black African
    - ☐ White and Asian
    - ☐ Indian
    - ☐ Pakistani
    - ☐ Bangladeshi
    - ☐ African
    - ☐ Caribbean
    - ☐ Chinese
    - ☐ Arab
    - ☐ Other (please specify) _____

Participating in follow-up studies

We would like to contact some women about further studies about ovarian cancer symptom awareness.

Please indicate if you would be happy for us to contact you further by ticking one of the boxes below:

☐ **I would be happy for you to send me information about further studies about ovarian cancer symptom awareness**

OR

☐ **I do not wish to receive information about further studies about ovarian cancer symptom awareness**

Please use the space below to tell us about anything that you feel we have not covered in this questionnaire.

Date questionnaire completed ...../...../.....

Thank you very much for your help

Please return your questionnaire and signed consent form in the stamped envelope

If you are concerned about symptoms you may be experiencing you should contact your GP.

Further information about ovarian cancer symptoms and support for any concerns about ovarian cancer can be found through the following charities:

Ovacome: www.ovacome.org.uk or if you would like to talk to someone call the nurse led support line on 0845 3710554

Target Ovarian Cancer: www.targetovariancancer.org.uk

Appendix 9. Questionnaire from the ICBP that was used to gather data for women from the general population

Ipsos MORI

Awareness and Beliefs about Cancer (ABC) measure

Wales questionnaire

COUNTRY OF ORIGIN AUTOMATICALLY SET BY CATI SCRIPT

IF APPOINTMENT PREVIOUSLY MADE

Please can I speak to [INSERT NAME FROM APPOINTMENT LOG]?

INTRODUCTION

Good morning / afternoon / evening, my name is <<(INSERT>> and I work for the independent research agency Ipsos MORI. We are carrying out a health research survey on behalf of Cancer Research UK and would like to invite you, or a member of your household, to take part.

This is a national survey of people from across Wales who are aged 50 or over and the survey is also being carried out in 7 other countries.

READ OUT ONLY IF ASKED: The participating countries are England, Northern Ireland, Wales, Norway, Sweden, Denmark, Australia and Canada.

READ OUT TO ALL: The results of the survey will be used to explore differences in people's views about cancer across different countries and to help improve cancer information for the general public. It will also help doctors to diagnose cancer earlier.

ASK ALL

SINGLE CODE

ALLOW "REFUSED" OR "DON'T KNOW" BUT THANK AND CLOSE IF THEY DO REFUSE OR DON'T KNOW

QAGE. Please could I speak to a member of the household who is aged 50 or over?

01	Yes, I am aged 50 or over	CONTINUE
02	Yes, I'll just get them INTRODUCTION AND CONTINUE	REREAD
03	No – no-one aged 50 or over is in, please call back later INTERVIEWER TO SET APPOINTMENT CALL BACK TIME	
04	No – no-one in household aged 50 or over	THANK AND CLOSE

Ipsos MORI

ASK ALL

SINGLE CODE

ALLOW "REFUSED" OR "DON'T KNOW" BUT THANK AND CLOSE IF THEY DO REFUSE OR DON'T KNOW

QS1. Could you please tell me how many people aged 50 or over currently live in your household, including yourself?

05	One	CONTINUE TO INFORMATION SECTION
06	Two	ASK QS2
07	Three	ASK QS3
08	Four	ASK QS3
09	Five	ASK QS3
10	Six	ASK QS3
11	Seven	ASK QS3
12	Eight	ASK QS3
13	Nine	ASK QS3
14	Ten	ASK QS3
15	None	THANK AND CLOSE

IF CODE 2 AT QS1: THE CATI SCRIPT WILL SELECT ONE ADULT RANDOMLY: CATI WILL SELECT THE CURRENT RESPONDENT ON 50% OF OCCASIONS, AND THE OTHER HOUSEHOLD MEMBER ON 50% OF OCCASIONS. IF THE CURRENT RESPONDENT IS SELECTED, CONTINUE TO INFORMATION SECTION. IF OTHER HOUSEHOLD MEMBER SELECTED ASK

SINGLE CODE

ALLOW "REFUSED" BUT THANK AND CLOSE IF THEY DO REFUSE

QS2. In households where there are two adults aged 50 or older, we are using a random method to select which one of these adults takes part in this survey. On this occasion, it is the other person that I would like to speak to. May I speak to that person please?

READ OUT ONLY IF ASKED: This is to ensure we achieve a nationally representative sample of adults in Wales.

01	Yes, available	REREAD INTRODUCTION AND CONTINUE TO INFORMATION SECTION
02	Yes, not currently available	MAKE APPOINTMENT, AND LOG NAME OF SELECTED HOUSEHOLD MEMBER
03	No	THANK AND CLOSE

Ipsos MORI

IF CODES 3-10 AT S1: THE CATI SCRIPT WILL SELECT ONE ADULT RANDOMLY – THE PROBABILITY OF SELECTION IS LINKED TO THE NUMBER OF HOUSEHOLD MEMBERS AT S1. CATI WILL SELECT THE CURRENT RESPONDENT IN (1/S1) OCCASIONS. IT SHOULD SELECT THE OTHER HOUSEHOLD MEMBERS IN ((S1-1)/S1) OCCASIONS. IF THE CURRENT RESPONDENT IS SELECTED, CONTINUE TO INFORMATION SECTION. IF OTHER HOUSEHOLD MEMBER SELECTED ASK

SINGLE CODE

ALLOW "REFUSED" BUT THANK AND CLOSE IF THEY DO REFUSE

QS3. Where there are three or more adults aged 50 or older, we are using a random method to select one person to interview. Not including yourself, please could I speak to the person aged 50 or over who has the next birthday?

INTERVIEWER NOTE: THIS DOES NOT INCLUDE THE PERSON YOU ARE SPEAKING TO, IT MUST BE ANOTHER MEMBER OF THE HOUSEHOLD.

READ OUT ONLY IF ASKED: The person with the next birthday is selected to ensure we achieve a nationally representative sample of adults in Wales.

01	Yes, available	REREAD INTRODUCTION AND CONTINUE
02	Yes, not currently available	MAKE APPOINTMENT, AND LOG NAME OF SELECTED HOUSEHOLD MEMBER
03	No	THANK AND CLOSE
04	I don't know who has the next birthday	THANK AND CLOSE

INFORMATION

READ OUT TO MALES: If you do decide to take part, the survey would take around 15 minutes to complete. All information that you give us will be treated in the strictest confidence and your identity will not be passed on to a third party.

READ OUT TO FEMALES: If you do decide to take part, the survey would take around 20 minutes to complete. All information that you give us will be treated in the strictest confidence and your identity will not be passed on to a third party.

Your details will not be passed on to your GP or doctor. Whether or not you decide to take part, this will not affect your health care in any way.

READ OUT ONLY IF ASKED: Your telephone number has been randomly generated. These numbers are not obtained from any commercially available calling list. Using this process we do not know any details about the household we are calling.

READ OUT ONLY IF ASKED: Ipsos MORI is a member of the Market Research Society and your personal data will be held in accordance with the Data Protection Act

VOLUNTARY NATURE OF THE SURVEY

It is up to you to decide whether or not to take part. If you decide to take part you are still free to stop at any time and without giving a reason. If you prefer, you can also skip individual questions on the survey.

Ipsos MORI

ASK ALL

SINGLE CODE

QS4. Now that I have told you about the survey, would you be willing to take part?

01	Yes	CONTINUE
02	No – not available right now AND LOG NAME	MAKE APPOINTMENT TO CALL BACK
03	No – do not want to take part	GO TO QS5

ASK ALL WHO SAY 'NO' AT QS4

MULTICODE

ALLOW "REFUSED"

ENQUIRE GENTLY WITHOUT INSISTING ON AN ANSWER. DO NOT READ OUT

QS5. Please don't feel you have to say, but would you be willing to tell me why you don't want to be interviewed, just to help us get a general idea of why people aren't taking part?

01	It would be upsetting / uncomfortable / emotionally difficult to take part
02	I don't have time
03	Questionnaire is too long
04	I don't take part in surveys
05	I'm not interested
06	I don't know anything about cancer
07	Have personal experience of cancer so would be upsetting to take part
08	Other

END SURVEY

FOR RESPONDENTS WHO APPEAR DISTRESSED AT ANY POINT OR WHO HAVE CONCERNS OR QUESTIONS ABOUT CANCER – OFFER TO END THE TELEPHONE CALL AND OFFER CONTACT DETAILS AS REQUIRED:

TO SPEAK TO A CANCER NURSE, PLEASE CALL CANCER RESEARCH UK'S FREEPHONE HELPLINE 0808 800 4040 (FREEPHONE NUMBER; MON-FRI 9am-5pm)

IF YOU HAVE BEEN AFFECTED BY CANCER, CALL THE MACMILLAN CANCER SUPPORT LINE: 0808 808 0000 (FREEPHONE NUMBER; MON-FRI 9am-8pm)

SAMARITANS: 08457 90 90 90 (NOT FREE BUT OPERATES 24 HOURS A DAY)

TENOVUS: 0808 8081010 (FREEPHONE NUMBER; MON-FRI 9am-5pm)
www.tenovus.org

Ipsos MORI

Awareness and Beliefs about Cancer (ABC) measure

Interview questionnaire

DEMOGRAPHIC / BACKGROUND INFORMATION 1

I would now like to ask you a couple of questions about yourself, which will help us to analyse the results of the survey.

ASK ALL

WRITE IN

ALLOW "REFUSED"

Q1. What was your age last birthday? RECORD EXACT AGE

IF REFUSED PROBE: Which age group applies to you?

SINGLE CODE. READ OUT

ALLOW "REFUSED"

01	50-54
02	55-59
03	60-64
04	65-69
05	70-74
06	75-79
07	80-84
08	85-89
09	90+

ASK ALL

SINGLE CODE

Q2. INTERVIEWER TO CODE GENDER

01	Female
02	Male

Ipsos MORI

ASK ALL WOMEN

SINGLE CODE

ALLOW "REFUSED" OR "DON'T KNOW" BUT THANK AND CLOSE IF THEY DO REFUSE OR DON'T KNOW (SEE BELOW)

QV1A. The following questions are about ovarian cancer but we appreciate that these questions may not be relevant to all women. For example, if you have had a hysterectomy or any other procedure that involves removing the ovaries, these questions will not be relevant. Please could you tell me whether you have had any such procedure?

01	Yes	THANK AND GO TO DEMOGRAPHICS (SEE BELOW)
02	No	

IF CODE 1 AT QV1A

Many thanks for agreeing to complete this section on ovarian cancer but the majority of these questions will not be relevant to you. We would like to thank you for your time and agreeing to help us.

PERCEIVED RISK

ASK ALL WOMEN

SINGLE CODE. READ OUT

ALLOW "DON'T KNOW" OR "REFUSED"

ROTATE RESPONSE OPTIONS FOR 50% OF RESPONDENTS

QV2. Compared to most other women your age, how likely do you think it is that you will get ovarian cancer at some time in your life? Would you say you are …?

01	Much more likely to get it
02	A little more likely to get it
03	About the same
04	A little less likely to get it
05	Much less likely to get it

OVARIAN CANCER WORRY

Most of us have concerns about our health from time to time. The following questions ask about any concerns that you may or may not have had about ovarian cancer.

ASK ALL WOMEN

SINGLE CODE. READ OUT

ALLOW "DON'T KNOW" OR "REFUSED"

ROTATE RESPONSE OPTIONS FOR 50% OF RESPONDENTS

QV3. How often do you worry about getting ovarian cancer someday?

01	Not at all	GO TO QV6
02	Rarely	
03	Sometimes	
04	Often	
05	Almost all the time	

ASK ALL WOMEN EXCEPT THOSE WHO ANSWER 'NOT AL ALL' AT QV3 (CODE 1)

SINGLE CODE. READ OUT

ALLOW "DON'T KNOW", "REFUSED" OR "NOT APPLICABLE"

ROTATE RESPONSE OPTIONS FOR 50% OF RESPONDENTS

QV4. How often, if at all, does your worry about getting ovarian cancer affect your mood?

01	Not at all
02	Rarely
03	Sometimes
04	Often
05	Almost all the time

ASK ALL WOMEN EXCEPT THOSE WHO ANSWER 'NOT AL ALL' AT QV3 (CODE 1)

SINGLE CODE. READ OUT

ALLOW "DON'T KNOW", "REFUSED" OR "NOT APPLICABLE"

ROTATE RESPONSE OPTIONS FOR 50% OF RESPONDENTS

QV5. How often, if at all, does your worry about getting ovarian cancer affect your ability to perform your daily activities?

01	Not at all
02	Rarely
03	Sometimes
04	Often
05	Almost all the time

WARNING SIGNS/SYMPTOMS

This question is about your awareness of, and beliefs about, ovarian cancer; it is not assessing your personal risk of ovarian cancer. This is not a test, we are interested in your thoughts and beliefs so please answer the questions as honestly as you can.

ASK ALL WOMEN

WRITE IN

ALLOW "DON'T KNOW" OR "REFUSED"

Ipsos MORI

QV6. There are many warning signs and symptoms of ovarian cancer. Please name as many as you can think of.

RECORD ALL OF THE WARNING SIGNS OR SYMPTOMS THAT THE PERSON MENTIONS EXACTLY AS THEY SAY IT AND PROMPT UNTIL THE RESPONDENT CANNOT THINK OF ANY MORE SIGNS: Can you think of any others?

01 .....
02 .....
03 .....
04 .....
05 .....
06 .....
07 .....
08 .....
09 .....
10 .....

ANTICIPATED DELAY IN SEEKING MEDICAL HELP

The next question is about going to the doctor.

ASK ALL WOMEN

SINGLE CODE

ALLOW "DON'T KNOW" OR "REFUSED"

QV7. If you had a symptom that you thought might be a sign of ovarian cancer, please tell me how long it would take you to go to the doctors from the time you first noticed the symptom.

IF WOULD NOT GO TO DOCTOR PROBE FULLY FOR REASON

01 Up to 1 week
02 Over 1 up to 2 weeks
03 Over 2 up to 3 weeks
04 Over 3 up to 4 weeks
05 More than a month
06 I would go as soon as I noticed
07 I would not contact my doctor
08 I would go to a pharmacist instead of a doctor:
09 I would go to a nurse (at my GP surgery) instead of a doctor:
10 I would go to a healthcare professional at an NHS Walk In Centre instead of a doctor
11 I would go to a healthcare professional at a hospital instead of a doctor

Ipsos MORI

CONFIDENCE IN NOTICING SYMPTOMS

ASK ALL WOMEN

SINGLE CODE. READ OUT

ALLOW "DON'T KNOW" OR "REFUSED"

ROTATE RESPONSE OPTIONS FOR 50% OF RESPONDENTS

QV8. How confident, or not, are you that you would notice a symptom of ovarian cancer?

01 Not at all confident

02 Not very confident

03 Fairly confident

04 Very confident

WARNING SIGNS/SYMPTOMS

I'm now going to list some symptoms that may or may not be warning signs for ovarian cancer. For each one, can you tell me whether you think that it could be a warning sign for ovarian cancer?

ASK ALL WOMEN

SINGLE CODE FOR EACH PART. ROTATE QUESTIONS QV9-QV19

ALLOW "REFUSED" AND "DON'T KNOW"

QV9-V19. Do you think [INSERT WARNING SIGN] could be a sign of ovarian cancer?

READ OUT ONLY IF ASKED: By persistent I mean that it has lasted for 3-6 weeks.

READ OUT ONLY IF ASKED: By abdomen, I mean your tummy or belly

READ OUT ONLY IF ASKED: By pelvis, I mean below the naval or belly button.

READ OUT ONLY IF ASKED: By vaginal bleeding after the menopause, I mean bleeding from the vagina after a woman reaches the age where her periods stop.

READ OUT ONLY IF ASKED: By persistent bloating, I mean a feeling of fullness in the abdomen that has lasted for some time.

READ OUT ONLY IF ASKED: By abdominal, I mean your tummy or belly

READ OUT ONLY IF ASKED: By passing more urine, I mean weeing more than usual.

READ OUT ONLY IF ASKED: By a change in bowel habits I mean a change in pooing.

QV9. a persistent pain in your abdomen

QV10. a persistent pain in your pelvis

QV11. vaginal bleeding after the menopause

QV12. persistent abdominal bloating

QV13. increased abdominal size on most days

QV14. not wanting to eat because you feel full persistently

QV15. difficulty eating your usual amount of food on most days

QV16. passing more urine than usual

QV17. a change in bowel habits

QV18. extreme tiredness

QV19. back pain

01 Yes

02 No

ACCESS TO CARE: EARLY SYMPTOMATIC PRESENTATION

Sometimes people put off going to see the doctor even when they have a symptom they think might be serious. These are some of the reasons people give for delaying. Could you say if any of these might put you off going to the doctor if you thought you had a symptom of ovarian cancer?

For each one that I read out, please respond either 'Yes, often', 'Yes, sometimes', or 'No'.

ASK ALL WOMEN

SINGLE CODE FOR EACH PART. ROTATE QUESTIONS QV20-QV27

IF RESPONDENT REQUESTS, READ OUT RESPONSES AGAIN

ALLOW "DON'T KNOW" OR "REFUSED"

QV20. I would be too embarrassed

QV21. I would be too scared

QV22. I would be worried about wasting the doctor's time

QV23. I would have too many other things to worry about

QV24. I would be worried about what the doctor might find

QV25. I wouldn't feel confident talking about my symptom with the doctor

QV26. It would be difficult for me to get an appointment with a specialist, either via the GP or directly

QV27. I would be too busy to make time to go to the doctor

01 Yes, often

02 Yes, sometimes

03 No

GENERAL OVARIAN CANCER BELIEFS AND BELIEFS ABOUT EARLY SYMPTOMATIC PRESENTATION AND EARLY DIAGNOSIS OF OVARIAN CANCER

ASK ALL WOMEN

SINGLE CODE FOR EACH PART. ROTATE QUESTIONS QV28-QV31

ALLOW "DON'T KNOW" OR "REFUSED"

For each of the following statements can you tell me how much you agree or disagree with each item?

IF RESPONDENT SAYS AGREE / DISAGREE: Is that strongly or tend to agree / disagree?

QV28. If ovarian cancer is diagnosed early it can be treated more successfully

QV29. If found early, ovarian cancer can often be cured

QV30. If someone gets ovarian cancer, it doesn't matter whether they find it early or late, they will still die from it

QV31. Going to the doctor as quickly as possible after noticing a symptom of ovarian cancer could increase the chances of surviving

01 Strongly disagree
02 Tend to disagree
03 Tend to agree
04 Strongly agree

ASK ALL WOMEN

SINGLE CODE

ALLOW "DON'T KNOW" OR "REFUSED"

QV32. Some people think that a diagnosis of ovarian cancer is a death sentence. To what extent do you agree or disagree that a diagnosis of ovarian cancer is a death sentence?

IF RESPONDENT SAYS AGREE / DISAGREE: Is that strongly or tend to agree / disagree?

01 Strongly disagree
02 Tend to disagree
03 Tend to agree
04 Strongly agree

DEMOGRAPHIC / BACKGROUND INFORMATION 2

I would now like to ask you a few more questions about yourself, to help us analyse the results of the survey.

ASK ALL

SINGLE CODE. READ OUT

ALLOW "REFUSED / PREFER NOT TO SAY"

Q39ENG. Which of these best describes your ethnic group?

White

01 Welsh / English / Scottish / Northern Irish / British

02 Irish

03 Gypsy or Irish Traveller

04 Any other White background

Mixed / multiple ethnic groups

05 White and Black Caribbean

06 White and Black African

07 White and Asian

08 Any other Mixed / multiple ethnic background

Asian / Asian British

09 Indian

10 Pakistani

11 Bangladeshi

12 Chinese

13 Any other Asian background

Black / African / Caribbean / Black British

14 African

15 Caribbean

16 Any other Black/ African / Caribbean background

Other ethnic group

17 Arab

199 Any other ethnic group (SPECIFY)

ASK ALL WHO SAY 'OTHER' AT Q39ENG

WRITE IN

ALLOW "REFUSED"

Q39oENG. Could you please tell me what your other ethnic group is?

ASK ALL

SINGLE CODE

ALLOW "REFUSED"

Q40. What is the main language spoken in your home?

01 English

02 Welsh

50 Other (please specify) .....

ASK ALL WHO SAY 'OTHER' AT Q40

WRITE IN

ALLOW "REFUSED"

Q40o. Could you please tell me what that language is?

ASK ALL

SINGLE CODE. READ OUT

ALLOW "REFUSED / PREFER NOT TO SAY"

Q41. What is the highest level of education you have achieved?

01 Finished school at or before the age of fifteen

02 Completed CSEs, O-levels or equivalent

03 Completed A Levels or equivalent

04 Completed further education but not a degree

05 Completed a Bachelor's degree / Masters degree / PHD

99 Other (please specify) .....

ASK ALL WHO SAY 'OTHER' AT Q41

WRITE IN

ALLOW "REFUSED"

Q41o. Could you please tell me what this other education level is?

ASK ALL

SINGLE CODE. READ OUT

ALLOW "REFUSED" OR "DON'T KNOW"

Q42. Which of these best describes your current marital status?

01 Married or in a civil partnership

02 Living with my partner

03 Single, that is never married and not living with a partner

04 Divorced or separated and not living with another partner

05 Widowed and not living with another partner

ASK ALL

WRITE IN

ALLOW "REFUSED" OR "DON'T KNOW"

Ipsos MORI

QPC. Could you please tell me what your postcode is? The only reason we are collecting this information is so that we can analyse the results by area, it will not be used for any other purpose.

ASK IF REFUSED AT QPC

WRITE IN

ALLOW "REFUSED" OR "DON'T KNOW"

QPC2. Would you be willing to tell me the first part of your postcode please?

AFTER THE INTERVIEW IS FINISHED

That is the end of the survey, thank you very much for your time.

Appendix 10. Principal components analysis of Health Belief Model items for increased genetic risk group.

Item	Factor	IPBa	IIPBe	IIIFear	IV PS
I would be too embarrassed		**0.48**	0.06	0.22	-0.002
I would be worried about wasting the doctor's time		**0.61**	-0.12	0.23	0.18
I would have too many other things to worry about		**0.69**	-0.09	0.27	0.11
I wouldn't feel confident talking about my symptom with the doctor		**0.54**	0.03	0.15	0.24
It would be difficult for me to get an appointment		**0.70**	-0.03	-0.10	-0.26
I would be too busy to make time to go to the doctor		**0.77**	-0.14	-0.07	-0.07
If ovarian cancer is diagnosed early, it can be treated more successfully		0.10	**0.88**	-0.05	0.02
If found early, ovarian cancer can often be cured		-0.11	**0.81**	-0.02	-0.14
Going to the doctor as quickly as possible after noticing a symptom of ovarian cancer could increase chances of surviving		-0.06	**0.84**	-0.09	0.04
I would be too scared		0.15	-0.09	**0.91**	0.02
I would be worried about what the doctor might find		0.19	-0.07	**0.87**	0.06
Compared to most other women your age, how likely do you think it is that you will get ovarian cancer at some time in your life?		0.05	-0.06	-0.003	**0.93**

Appendix 11. Principal components analysis of Health Belief Model items for general population group

Item	Factor	IPE	IIPRB	IIIPBe	IVPS
I would be too scared		**0.84**	0.11	-0.02	0.05
I would be worried about what the doctor might find		**-0.85**	0.05	-0.07	0.01
I would be too embarrassed		**0.56**	0.35	0.01	0.01
I wouldn't feel confident talking about my symptom with the doctor		**0.46**	0.38	-0.04	-0.25
It would be difficult for me to get an appointment[1]		**0.40**	0.34	0.06	-0.14
I would have too many other things to worry about		0.06	**0.75**	-0.06	-0.01
I would be too busy to make time to go to the doctor		0.04	**0.74**	0.04	0.06
I would be worried about wasting the doctor's time		0.22	**0.57**	-0.06	0.07
If ovarian cancer is diagnosed early, it can be treated more successfully		-0.01	0.02	**0.83**	0.05
Going to the doctor as quickly as possible after noticing a symptom of ovarian cancer could increase chances of surviving		0.03	-0.01	**0.80**	-0.05
If found early, ovarian cancer can often be cured		-0.10	0.07	**0.74**	-0.04
Compared to most other women your age, how likely do you think it is that you will get ovarian cancer at some time in your life?		0.01	0.04	-0.04	**0.96**

Appendix 12. Correlation matrix for variables in whole SEM

	1	2	3	4	5	6	7	8	9	Mean (sd)
Experience	1.00									0.37(0.42)
Self-efficacy	.01	1.00								2.31(0.93)
Knowledge	.02	.24**	1.00							6.69(2.70)
Age	.25	.08*	-.05	1.00						62.06(9.5)
Benefits Minus barriers	-.07**	.14***	.15***	.27***	1.00					1.20(2.14)
Threat	0.37***	-.10***	.01	-.42***	-.16**	1.00				
Worry	.21**	-.06**	-.02	-.23***	-.07**	.45***	1.00			5.30(1.44)
Perceived susceptibility	.40	-.11**	-.01	-.45***	-.14**	.85***	.38***	1.00		2.78(0.95)
Anticipated presentation	.01	-.05**	-.04	-.06**	-.24***	-.01	.01	.03	1.00	0.53(0.50)

Appendix 13. Correlation matrix for variables in increased genetic risk SEM

	1	2	3	4	5	6	7	8	9	Mean (sd)
Experience	1.00									0.91(0.29)
Self-efficacy	.17**	1.00								2.20(0.70)
Knowledge	.06	.31***	1.00							6.07(2.60)
Age	.11	.06	-.07	1.00						52.87(10.40)
Benefits Minus barriers	.06	.21**	.15*	.23***	1.00					-0.70(3.60)
Threat	.04	-.10	.07	-.19**	-.05	1.00				
Worry	.02	-.13*	.06	-.18**	-.29***	.98***	1.00			6.15(1.94)
Perceived susceptibility	.01	-.05	.04	-.09	-.11*	.35***	.35***	1.00		4.21(0.71)
Anticipated presentation	-.02	-.05	-.06	-.04	-.34***	-.16***	-.09	-.02	1.00	0.59(0.49)

Appendix 14. Correlation matrix for variables in general population SEM

	1	2	3	4	5	6	7	8	9	Mean (sd)
Experience	1.00									.23(.42)
Self-efficacy	.04	1.00								2.34(.93)
Knowledge	.07*	.22***	1.00							6.85(2.73)
Age	.03	.004	-.05**	1.00						64.53(9.48)
Benefits Minus barriers	.01	.17***	.10**	.04	1.00					1.74(2.14)
Threat	.13	-.19	.19	-.25*	-.02	1.00				
Worry	.09*	-.04	.04	-.08	-.01	.36	1.00			5.3(1.42)
Perceived susceptibility	.04*	-.09**	.10**	-.16**	-.01	.64*	.25***	1.00		2.34(.93)
Anticipated presentation	-.02	-.04**	-.03	-.01*	-.18***	-.01	-.002	-.005	1.00	0.51(.52)

Appendix 15. Increased genetic risk group SEM multigroup invariance analysis across relationship status

	x^2	*Df*	Δx^2	Δdf	CFI	ΔCFI
Configural model	34.13	24			.93	
Model 1	44.80	32	**10.67**	8	.91	.02
Model 2	44.81	33	**10.68**	9	.91	.02
Model 3	57.52	37	23.39*	13	.85	.08
Model 4	64.42	47	**30.29**	23	.87	.06
Model 5	65.14	49	**31.01**	25	.88	.05

Note. Δx^2 =difference in x^2 between models; Δdf= difference in degrees of freedom between models; ΔCFI = difference in CFI between models. Numbers in bold indicate goodness of fit. Model 1= constrained structural weights. Model 2= constrained structural weights and intercepts. Model 3 = constrained structural weights, intercepts and means. Model 4= constrained structural weights, intercepts, means and covariance's. Model 5 = constrained structural weights, intercepts, means, covariance's and residuals. *p<.05.

Δx^2 were not significant for models 1,2, 4 and 5, indicating invariance, with model 3 indicating nonvariance. ΔCFI indicates nonvariance for all models.

Appendix 16. Increased genetic risk group SEM multigroup invariance analysis across education

	x^2	*Df*	Δx^2	Δdf	CFI	ΔCFI
Configural model	33.49	24			.92	
Model 1	39.54	32	**6.05**	8	.94	-.02
Model 2	43.39	33	**9.90**	9	.92	**.00**
Model 3	58.55	37	25.06*	13	.82	.10
Model 4	76.97	47	43.48*	23	.75	.17
Model 5	77.61	49	44.12*	25	.77	.15

Note. Δx^2 =difference in x^2 between models; Δdf= difference in degrees of freedom between models; ΔCFI = difference in CFI between models. Numbers in bold indicate goodness of fit. Model 1= constrained structural weights. Model 2= constrained structural weights and intercepts. Model 3 = constrained structural weights, intercepts and means. Model 4= constrained structural weights, intercepts, means and covariances. Model 5 = constrained structural weights, intercepts, means, covariances and residuals. *p<.05.

Δx^2 were not significant for models 1 and 2, indicating invariance. ΔCFI indicates invariance for model 2

Appendix 17. Interview topic guide

Main points to be gained from interview:

< anchor symptom awareness, confidence and help seeking in past experience, where relevant. If not, then the questions are hypothetical.>

PREVIOUS SYMPTOM EXPEREINCE:

Exploration of what symptoms previously experienced and what action was taken, or hypothetical if have not experienced any

BARRIERS:

Thoughts about the barriers that were identified in the questionnaires

WAYS TO OVERCOME BARRIERS AND FACILITATORS:

Would higher awareness levels and improved confidence make individual more likely to present?

ACCEPTABILITY OF MATERIAL:

Thoughts on a symptom awareness materials: pros and cons, content.

Prologue

1. Introduce yourself, explain where you're from, ensure they're comfortable etc.

2. Check understanding of reason for meeting and role of researcher, give an opportunity for questions:

"Before we start, I wonder if you have any questions about this study or about why I've come to talk with you today?

I am a researcher and I'm not medically trained, so I've not got the expertise to answer questions of a clinical nature. "

3. Set the focus of the interview. Base this around the following:

"You previously completed a questionnaire about ovarian cancer symptom awareness and beliefs. We want to further understand what beliefs woman at increased risk of ovarian cancer have. We would like to know how confident you feel in knowing the symptoms and what you would do if you thought you were experiencing them. We are also interested in finding out if you have any experiences which you think may affect your awareness or behaviour. We are interested in these things as we want to establish whether there is a need for a symptom awareness material to be created."

4. After establishing what is understood about the study, and answering any questions, explain that the interview will be recorded:

"I would like to record what you say as that saves me having to scribble when you're talking and means that I can concentrate on what you're saying. The recording will only be heard by people who are working on this project. The interview will be

transcribed and your identity and the identity of any person you talk about today will be anonymised in any published work. Is that okay with you?"

5. Obtain consent for the interview and for the recording (provide information sheet again). If not already done, set up and switch on the recording equipment while the volunteer signs the consent form.

6. Explain how the interview will work:

"**I've planned some ideas about the sorts of things I'd like us to talk about today, and if it's okay with you we'll try and base our conversation around those points. Having said that, if you want to tell me about anything that I don't ask about, please just tell me. Also, if you find a question difficult to answer, please say and we can move on or I could try to ask it in a different way. Of course, if you'd prefer not to answer any question, that is absolutely fine. There aren't any right or wrong answers to anything I ask you, we're just interested in your own opinions and experiences. Does that all sound alright to you?"**

PREVIOUS SYMPTOM EXPERIENCE/

SYMPTOM APPRAISAL

***Rationale**: Explore whether or not they have experienced OC symptoms, and actual or anticipated confidence in symptom detection and help-seeking.*

Q1: have you ever experienced symptoms that you thought may be OC?
IF YES *Make note of symptoms mentioned for later questions*

- What made you think that the symptoms were possibly related to OC?
- Did you do anything to find out more information about the symptoms you were experiencing?
- How were they detected – by yourself or through ovarian screening?
- Did you tell anyone close to you? *(cf. we know that having a confidante encourages women to seek help for breast symptoms)*
- **Go to Q2**

IF NO:

- **Do you think OC has symptoms?**
  Make note of symptoms mentioned for later questions
- If you were experiencing these symptoms, how confident do you feel that you would notice them?
- Is there anything you think you would do to help you monitor the symptoms?
- **Would you feel confident going to your doctor to talk about these symptoms if you did experience them in future?**
  - What would make you confident in going?

- What would make you decide not to go? (if they mention particular symptoms that would make them more/less confident in going, could also explore type of symptom/time frame here.)

- **GO TO Q3**

Q2 Did you go to see the doctor with symptoms you thought were possibly related to OC?

-if went to the doctor

Q2a: at what point did you decide to go to the doctor?

- how long after noticing it did you go?
- Did you feel confident going to your doctor?
- Did one of the symptoms you experienced make you go more so than others?
- Did something change in the symptom to make you go?
- Did the length of time you experienced the symptom have any influence of decision to go?

-if did not go to the doctor

Q2b: Did you think about going to your GP?

- What made you decide against going to the GP?
- What would make you go to the GP?
  -type of symptom?

  -the amount of time you experienced the symptom for?

Q3: have any of your relatives or close friends experienced OC symptoms?

IF YES

- What symptoms were they?
- How were these symptoms experienced?
- Has the symptom experience of this person influenced your thoughts about OC symptoms?
  -probes: has it made you look out for this symptom more?

IF NO: move to next section

***Rationale**: To elaborate on barriers that were identified as important determinants of awareness, worry and presentation from the questionnaire.*

BARRIERS

If we could now talk about things that might put you off going to the doctor to seek advice if you were experiencing symptoms you thought might be OC …..

Q4: can you think of anything that might put you off going to the doctor in such a situation?

- **IF YES**, can you tell me more about this?
  -prompts: what would be the main reason to stop you from going?
  Are there any other reasons?
- **IF NO**, can you tell me why?
  -prompts: is this because you feel nothing would put you off?
  Is this because you would not go to the doctor at all?

Q5: Would you feel comfortable talking to your GP about possible OC symptoms you were experiencing?

- **IF YES:** can you explain why?
  would you do any preparation prior to visit?
  Would you take anything to the GP with you to help you talk?
- **IF NO;** can you explain your reasons?
  Would you go somewhere else?
  Would anything help you go to the GP?

Q6: have any of your friends or family previously been to the GP to seek help for symptoms they were experiencing?

- **IF YES**: did they feel confident about going to see the GP?
  Did they find the visit to the GP useful?
  Do you think their experienced has influenced what you would do if you experienced symptoms you thought might be OC?
- **IF NO**: is this because they did not go to the GP? Or do you not know of anyone who has previously experienced symptoms they thought were OC?

Rationale: *Would increasing symptom awareness and confidence reduce barriers?*

WAYS TO REDUCE BARRIERS

Q7: do you think that women at increased risk of OC should have better awareness of OC symptoms?

IF YES:

- Can you explain why you think improved symptom awareness is needed?

IF NO:

- Can you explain why you don't think better symptom awareness is needed?

Q8: do you sometimes worry about whether or not you know the symptoms of OC?

IF YES:

- **Why do you think that is?**
- **Do you do anything to help you find out about symptoms? Ie internet?**
- **Do you think having clear information on what the symptoms of OC are would help you worry less?**

IF NO:

- **Is that because you are confident in your OC symptom knowledge?**
- **Or is because you tend to worry**

Q9: Do you think that information on what the symptoms of OC are would help you in deciding to go the GP if you were experiencing them?

IF YES:

- Can you explain why you think this would be?
- Do you think that additional information about what to do when symptoms are experienced is needed to help with this decision?
  -prompts: do you think it would be more useful to have this info?
  Do you think this info would make no difference?
  Do you think something else would more important?
  -If yes, can you tell me about what you think?

IF NO:

- Can you explain why you think this might be?
- Can you think of other types of information that would help you decide to go to the GP if you were experiencing symptoms of OC?
- Do you think information about what to do when symptoms are experienced would be helpful?
  -prompts: do you think it would be more useful to have this info?
  Do you think this info would make no difference?

ACCEPTABILITY OF AWARENESS MATERIAL

Rationale: *Whether they think there is a need for a symptom awareness tool.*

If we could now talk about a symptom awareness material. As mentioned, we are considering creating a symptom awareness material specific for women at increased risk.

Q10: Do you think a symptom awareness material should be created?

- Can you think of any advantages of having a symptom awareness material?
- Can you think of any disadvantages?
- Can you think of anything you think should be included in such a material?
- Do you think there is anything that should not be included?

Q11: I have brought along an example of a symptom awareness material, can you tell me what you think of it? <give them time to look at material>

- Can you tell me what you like most about it?
- Can you tell me what you like least about it?
  -prompts: What do you think about the length of it?

  What do you think of the pictures/illustrations?

  What do you think about the colours?

Do you think it is informative?

Would you prefer to read this information on the website?

Is there anything particular you would like to see in it?

ROUND UP

1. CLARIFICATION OF QUESTIONNAIRE RESPONSES:

As appropriate, clarify:

Anything not completed / ambiguous

Pursue any additional threads of interest that were highlighted during the interview

- Explain the findings of the interviews will go together to with those of the questionnaire to help with the creation of a symptom awareness material
- Ask if have any questions

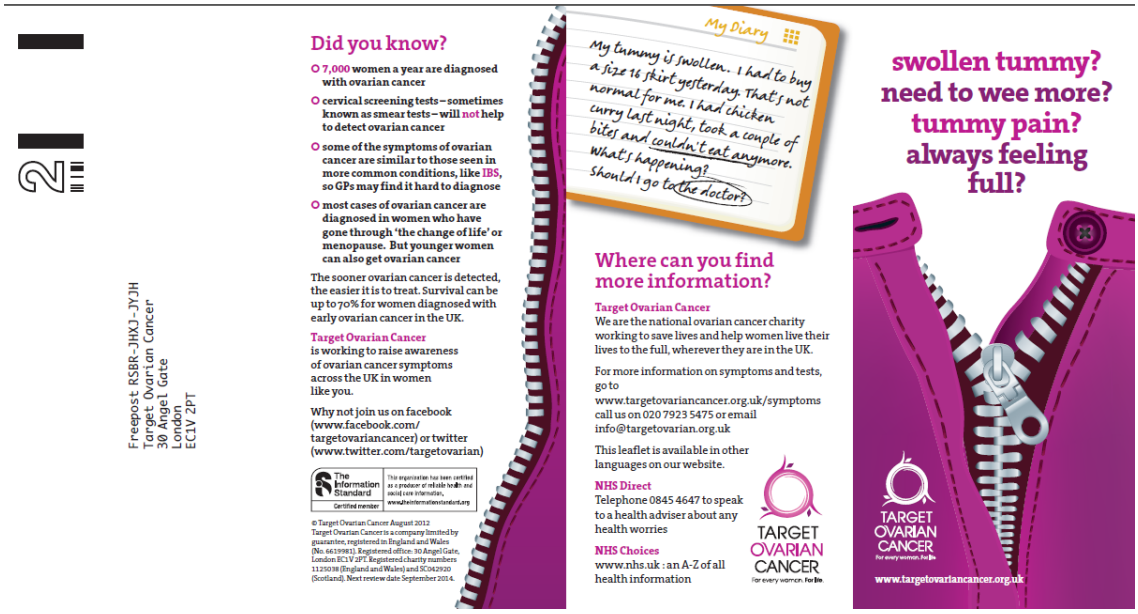
2. FUTURE CONTACT

i. **Ensure that they know how to contact us for further help/information/to add further information**
   - If any clinical questions, will direct them to their GP and have helpline numbers/charity details to hand.

ii. **Check if it is okay to contact them later after listening to the conversation if there is anything you want to clarify**

3. THANKS and GOODBYE

Appendix 18. Target ovarian cancer leaflet



Freepost RSBR-JHXJ-JYJH
Target Ovarian Cancer
30 Angel Gate
London
EC1V 2PT

Did you know?

- **7,000 women a year are diagnosed with ovarian cancer**
- **cervical screening tests – sometimes known as smear tests – will not help to detect ovarian cancer**
- **some of the symptoms of ovarian cancer are similar to those seen in more common conditions, like IBS, so GPs may find it hard to diagnose**
- **most cases of ovarian cancer are diagnosed in women who have gone through 'the change of life' or menopause. But younger women can also get ovarian cancer**

The sooner ovarian cancer is detected, the easier it is to treat. Survival can be up to 70% for women diagnosed with early ovarian cancer in the UK.

Target Ovarian Cancer is working to raise awareness of ovarian cancer symptoms across the UK in women like you.

Why not join us on facebook (www.facebook.com/targetovariancancer) or twitter (www.twitter.com/targetovarian)

The Information Standard Certified member

This organisation has been certified as a producer of reliable health and social care information. www.theinformationstandard.org

Where can you find more information?

Target Ovarian Cancer
We are the national ovarian cancer charity working to save lives and help women live their lives to the full, wherever they are in the UK.

For more information on symptoms and tests, go to www.targetovariancancer.org.uk/symptoms call us on 020 7923 5475 or email info@targetovarian.org.uk

This leaflet is available in other languages on our website.

NHS Direct
Telephone 0845 4647 to speak to a health adviser about any health worries

NHS Choices
www.nhs.uk : an A-Z of all health information

TARGET OVARIAN CANCER
For every woman. For life.

swollen tummy? need to wee more? tummy pain? always feeling full?

TARGET OVARIAN CANCER
For every woman. For life.
www.targetovariancancer.org.uk

"I noticed that my tummy was swelling even though my appetite was not good. My symptoms were put down to stress at the time because I'd lost my dad and brother close together. I was first diagnosed with IBS. Later on I had a colonoscopy which came back negative. Finally I had a TVU (internal scan) which showed I had a large mass. That was a shock. I had no idea it could be ovarian cancer. I would advise any woman not to be worried about 'bothering the doctor'. You know your body and when there's something different or unusual get it checked."

Lindy xxx

Ovarian cancer symptoms

Ovarian cancer symptoms are:

- frequent – they usually happen more than 12 times a month
- persistent – they don't go away
- new – they are not normal for you and may have started in the last year
  - **persistent pelvic or abdominal pain (that's your tummy and below)**
  - **increased abdominal size/persistent bloating – not bloating that comes and goes**
  - **difficulty eating or feeling full quickly**
  - **urinary symptoms (needing to wee more urgently or more often than usual)**

Occasionally there are other symptoms:

- changes in bowel habit
- extreme fatigue (feeling very tired)
- unexplained weight loss

If you regularly experience any of these symptoms, which are not normal for you, it is important that you see your GP.

It is unlikely that your symptoms are caused by a serious problem, but it is important to be checked out.

Worried about your symptoms?

Be aware note in your diary when you get a symptom.

Talk to your GP about symptoms that are new for you and come out of the blue. Tell your GP if **two** or more relatives in your close family have had ovarian or breast cancer.

Return if your symptoms don't clear up, go back to your doctor or seek a second opinion, even if you've had tests.
Other conditions such as IBS have symptoms similar to ovarian cancer so take this leaflet to help explain what is happening to you.

What tests might your GP do?

If you are having symptoms more than 12 times a month your GP should do a CA125 blood test. Depending upon the result they may order scans of your tummy and ovaries. One is an internal scan, but it's quick and easy.

Help us make other women aware of the symptoms of ovarian cancer

Just 3% of women are very confident at spotting a symptom of ovarian cancer. Why not help us to make sure more women know what to look out for? You can do this by ordering leaflets to give to your friends, family, neighbours or work colleagues.

Please let us know if you , a friend , or a relative has had ovarian cancer.

To find out how our other publications and events may be of use, please visit **www.targetovariancancer.org.uk** or call us on 020 7923 5475

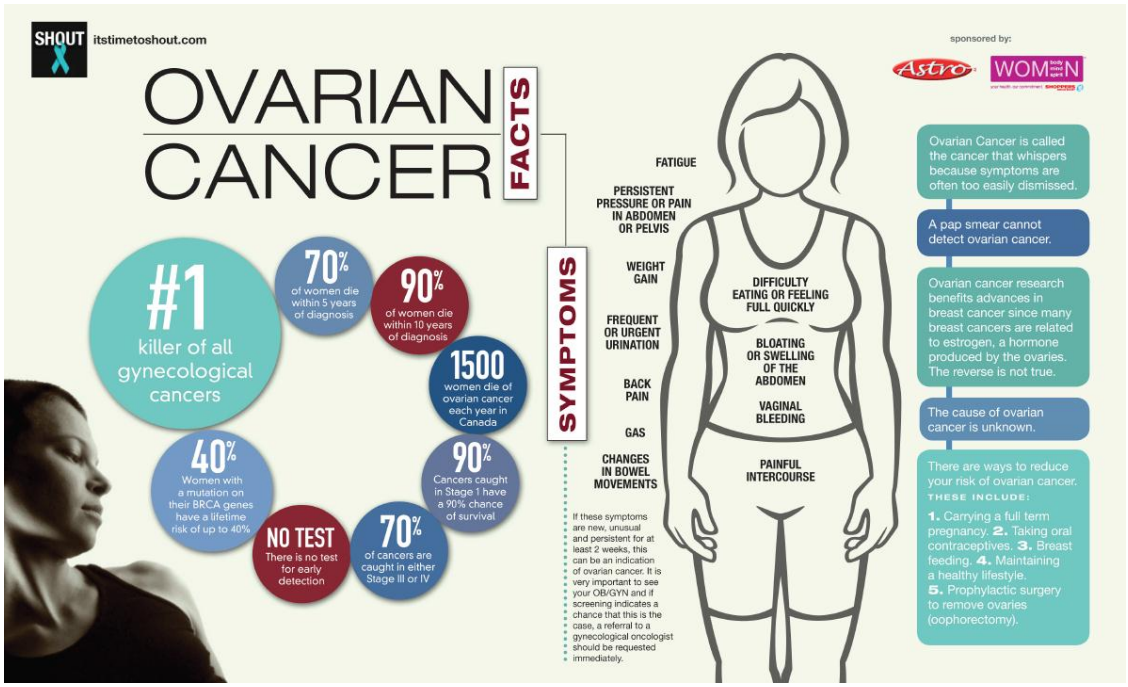
Where did you pick up this leaflet?

We will keep the details you provide and use them to contact you about our work. If you do not wish to receive this information, please tick this box . We will not pass your details to any third parties without your prior consent.

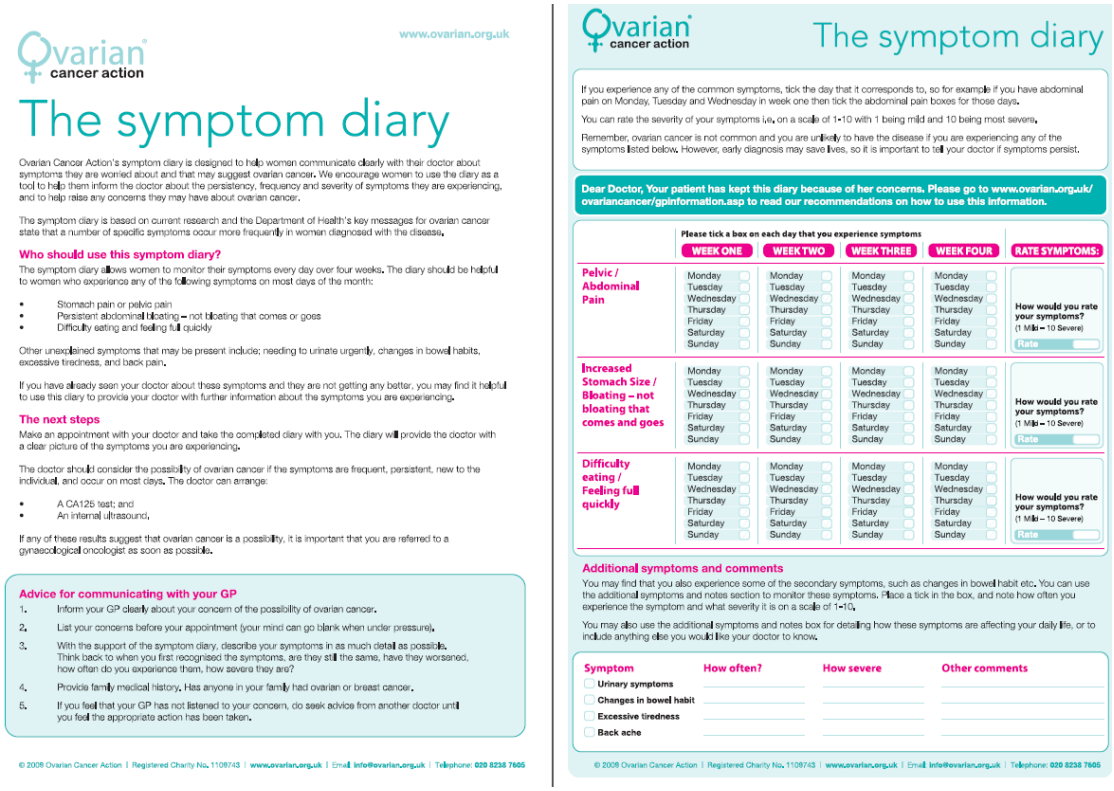
Name
Address
Postcode
Email
Tel
Mobile

Please return this form to Target Ovarian Cancer at the above address. No stamp needed.

Appendix 19. It's time to shout out factsheet



Appendix 20. Ovarian Cancer Action symptom diary



Ovarian cancer action

www.ovarian.org.uk

The symptom diary

Ovarian Cancer Action's symptom diary is designed to help women communicate clearly with their doctor about symptoms they are worried about and that may suggest ovarian cancer. We encourage women to use the diary as a tool to help them inform the doctor about the persistency, frequency and severity of symptoms they are experiencing, and to help raise any concerns they may have about ovarian cancer.

The symptom diary is based on current research and the Department of Health's key messages for ovarian cancer state that a number of specific symptoms occur more frequently in women diagnosed with the disease.

Who should use this symptom diary?

The symptom diary allows women to monitor their symptoms every day over four weeks. The diary should be helpful to women who experience any of the following symptoms on most days of the month:

- Stomach pain or pelvic pain
- Persistent abdominal bloating – not bloating that comes or goes
- Difficulty eating and feeling full quickly

Other unexplained symptoms that may be present include: needing to urinate urgently, changes in bowel habits, excessive tiredness, and back pain.

If you have already seen your doctor about these symptoms and they are not getting any better, you may find it helpful to use this diary to provide your doctor with further information about the symptoms you are experiencing.

The next steps

Make an appointment with your doctor and take the completed diary with you. The diary will provide the doctor with a clear picture of the symptoms you are experiencing.

The doctor should consider the possibility of ovarian cancer if the symptoms are frequent, persistent, new to the individual, and occur on most days. The doctor can arrange:

- A CA125 test; and
- An internal ultrasound.

If any of these results suggest that ovarian cancer is a possibility, it is important that you are referred to a gynaecological oncologist as soon as possible.

Advice for communicating with your GP

1. Inform your GP clearly about your concern of the possibility of ovarian cancer.
2. List your concerns before your appointment (your mind can go blank when under pressure).
3. With the support of the symptom diary, describe your symptoms in as much detail as possible. Think back to when you first recognised the symptoms, are they still the same, have they worsened, how often do you experience them, how severe they are?
4. Provide family medical history. Has anyone in your family had ovarian or breast cancer.
5. If you feel that your GP has not listened to your concern, do seek advice from another doctor until you feel the appropriate action has been taken.

Ovarian cancer action

The symptom diary

If you experience any of the common symptoms, tick the day that it corresponds to, so for example if you have abdominal pain on Monday, Tuesday and Wednesday in week one then tick the abdominal pain boxes for those days.

You can rate the severity of your symptoms i.e. on a scale of 1-10 with 1 being mild and 10 being most severe.

Remember, ovarian cancer is not common and you are unlikely to have the disease if you are experiencing any of the symptoms listed below. However, early diagnosis may save lives, so it is important to tell your doctor if symptoms persist.

Dear Doctor, Your patient has kept this diary because of her concerns. Please go to www.ovarian.org.uk/ovariancancer/gpinformation.asp to read our recommendations on how to use this information.

Please tick a box on each day that you experience symptoms

	WEEK ONE	WEEK TWO	WEEK THREE	WEEK FOUR	RATE SYMPTOMS:
Pelvic / Abdominal Pain	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	How would you rate your symptoms? (1 Mild – 10 Severe) Rate
Increased Stomach Size / Bloating – not bloating that comes and goes	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	How would you rate your symptoms? (1 Mild – 10 Severe) Rate
Difficulty eating / Feeling full quickly	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	Monday Tuesday Wednesday Thursday Friday Saturday Sunday	How would you rate your symptoms? (1 Mild – 10 Severe) Rate

Additional symptoms and comments

You may find that you also experience some of the secondary symptoms, such as changes in bowel habit etc. You can use the additional symptoms and notes section to monitor these symptoms. Place a tick in the box, and note how often you experience the symptom and what severity it is on a scale of 1-10.

You may also use the additional symptoms and notes box for detailing how these symptoms are affecting your daily life, or to include anything else you would like your doctor to know.

Symptom	How often?	How severe	Other comments
Urinary symptoms			
Changes in bowel habit			
Excessive tiredness			
Back ache			

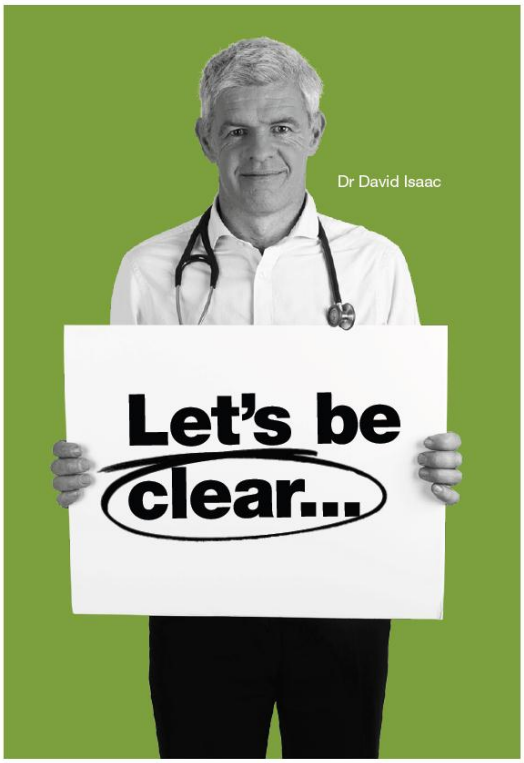
Appendix 21. Be clear on cancer leaflet

NHS

Dr Alison Wint

Feeling bloated most days for 3 weeks? Tell your doctor.

BE CLEAR ON CANCER



...about ovarian cancer

There are over 5,800 new cases of ovarian cancer in England each year. It causes more than 3,350 deaths in England annually, but this needn't be the case. Knowing what to look out for saves lives.

Most cases of ovarian cancer occur after the menopause. Around 8 out of 10 new cases are in women over 50 years of age.

If you have two or more close relatives (mother, sister or daughter) who developed ovarian cancer or breast cancer, you may be at higher risk of developing the condition.

...about how to spot it

You need to see a doctor if you have any of the following symptoms, most days, for 3 weeks or more:

- Unexplained bloating
- Feeling full quickly or loss of appetite
- Pelvic or stomach pain
- Needing to pee urgently or more frequently than normal.

...about how important it is to see your doctor

If you notice any of these symptoms, tell your doctor. You're not wasting anyone's time by getting it checked out and, if it's not serious, your mind will be put at rest. Chances are it's nothing to worry about, but it could be a sign of something that needs treatment.

Detecting cancer early makes it more treatable, so seeing your doctor quickly may save your life.

If you know anyone who has any of these symptoms, insist they see their doctor.

You can find your doctor's contact details online at nhs.uk/persistentbloating

"My advice to anyone with persistent bloating is to take yourself straight to the doctor."

Lou Pescod, ovarian cancer survivor

...about how seeing your doctor early could save your life

Bloating was the main symptom for me, but I put it down to getting older. I pointed it out to my sister and she urged me to see a GP. My doctor examined me and referred me to a local hospital where I had surgery to remove a lump. After further tests, the lump was confirmed as cancer of the right ovary. I had three months of chemotherapy and my treatment was over by 2009. My advice to anyone with persistent bloating is to take yourself straight to the doctor. Don't put it down to your age as it could be a symptom of something more serious.

Lou Pescod, aged 65,
Supporter of Ovarian Cancer Action

In March 2006, after an energetic holiday, I began to feel extremely uncomfortable with a bloated stomach. My trousers had become tight and I felt like I was pregnant. I'd also lost my appetite. My doctor referred me to the hospital where I was diagnosed with ovarian cancer – with a tumour on each of my ovaries. I had an operation and six months of chemotherapy. Six years on, I still lead an active life. I work part-time and enjoy walking and playing golf.

Laurain Chapman, aged 63,
Supporter of Ovacome

...about how to reduce your chances of getting ovarian cancer

Stop smoking

It's never too late to stop smoking. No matter what age you stop, it reduces your chances of developing ovarian cancer and makes a real difference to your health in general. There's plenty of support and help available from the NHS. Visit **smokefree.nhs.uk** or call **0800 169 0169**.

Look after yourself

If you are overweight you can lose weight by combining regular exercise and a calorie-controlled diet.

Stay active

Swimming, cycling, dancing – the more you can do, the better. Even walking to your local shops instead of taking the car can make a difference.

Eat healthily

Try to get your 5-a-day. So eat more vegetables and fruit, fish and wholegrain foods. Eat less fatty foods like cakes and pastries and fewer processed meats like bacon and ham.

Unclear on anything?
Visit nhs.uk/persistentbloating

Appendix 22. Ethical approval 2

School of Medicine
Dean Professor B Paul Morgan PhD MRCP FRCPath FMedSci

Ysgol Meddygaeth
Deon Yr Athro B Paul Morgan PhD MRCP FRCPath FMedSci

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Cardiff University
School of Medicine
Heath Park
Cardiff CF14 4XN

Prifysgol Caerdydd
Ysgol Meddygaeth
Mynydd Bychan
Caerdydd CF14 4XN

Monday 18th March 2013

Stephanie Smits
Cochrane Institute of Primary Care
& Public Health,
Cardiff University School of Medicine
Neuadd Meirionnydd, 2nd Floor
Heath Park

Dear Stephanie,

Re: Interviews exploring ovarian cancer symptom awareness and help seeking behaviour in women at increased risk of developing ovarian cancer. Phase three of the OvSTAT study.

SMREC Reference Number: 13/15

This application was reviewed by the Committee on Wednesday 13th March 2013.

Ethical Opinion

On review, the Committee granted ethical approval for this project.

Documents Considered

Document Type:	Version:	Date Considered:
Application Form	V1 31/07/2012	13/03/2013
Additional Information	V1 28/02/2013	13/03/2013
Flow Chart	V1 09/07/2012	13/03/2013
Interview Schedule	V1 27/02/2013	13/03/2013
Invitation Letter	V1 06/02/2013	13/03/2013
Information Sheet	V1 13/02/2013	13/03/2013
Postal Consent Form	V1 28/02/2013	13/03/2013
Interview Confirmation Letter	V1 28/02/2013	13/03/2013
Consent Form	V1 28/02/2013	13/03/2013

With best wishes for the success of your study.

Yours sincerely,

Dr Andrew Freedman
Chair, School of Medicine Research Ethics Committee

Appendix 23. Search strategy for systematic search

The below symptoms from the Department of Health Key Messages (2009) and NICE guidelines (2012) were entered into PubMed.

1. Bloating AND ovarian cancer
2. Pelvic pain AND ovarian cancer
3. Abdominal pain AND ovarian cancer
4. Distension AND ovarian cancer
5. Full AND ovarian cancer
6. Appetite AND ovarian cancer
7. Fatigue AND ovarian cancer
8. Back pain AND ovarian cancer
9. Bowel AND ovarian cancer
10. Urinary AND ovarian cancer

Appendix 24. Extraction sheet for studies identified in the systematic search

Author information	Symptom	Sample	Design	Results	Limitations

Appendix 25. Newcastle - Ottawa quality assessment scale

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

1) Is the case definition adequate?

a) Yes, with independent validation ⍰

b) Yes, eg record linkage or based on self reports

c) No description

2) Representativeness of the cases

a) Consecutive or obviously representative series of cases ⍰

b) Potential for selection biases or not stated

3) Selection of Controls

a) Community controls ⍰

b) Hospital controls

c) No description

4) Definition of Controls

a) No history of disease (endpoint) ⍰

b) No description of source

Comparability

1) Comparability of cases and controls on the basis of the design or analysis

a) Study controls for _____ (Select the most important factor.) ⍰

b) Study controls for any additional factor ⍰ _____

Factors controlled for could include any design factors eg age, medical facility, co-morbidity. If one factor adjusted for select a), if two or more are adjusted for select a) and b)

Exposure

1) Ascertainment of exposure

a) Secure record (eg surgical records) ⍰

b) Structured interview where blind to case/control status ⍰

c) Interview not blinded to case/control status

d) Written self-report or medical record only

e) No description

2) Same method of ascertainment for cases and controls

a) Yes ⍰

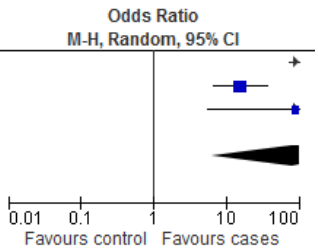
b) No

Appendix 26. Estimation of effect sizes for 16 symptoms identified in systematic search. Symptoms are presented in alphabetical order.

Symptom 1: Abdominal mass

Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Hamilton 2009	71	212	1	1060	33.1%	533.26 [73.51, 3868.12]
Lurie 2009	70	432	6	491	39.6%	15.63 [6.72, 36.38]
Pitta 2013	14	60	0	150	27.3%	93.86 [5.49, 1603.77]
Total (95% CI)		**704**		**1701**	**100.0%**	**81.95 [6.49, 1034.58]**
Total events	155		7			

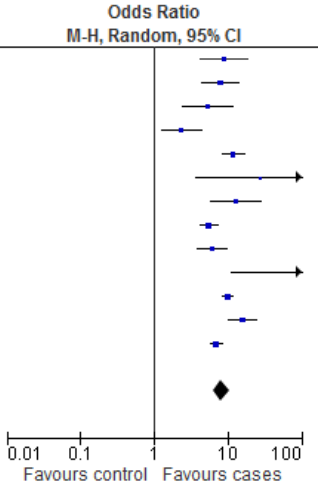
Heterogeneity: Tau² = 4.04; Chi² = 11.80, df = 2 (P = 0.003); I² = 83%
Test for overall effect: Z = 3.41 (P = 0.0007)



Symptom 2: Abdominal pain

Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Behtash 2008	52	100	11	100	6.3%	8.77 [4.19, 18.35]
Devlin 2010	43	82	28	230	7.7%	7.95 [4.42, 14.30]
Friedman 2005	38	69	13	69	6.0%	5.28 [2.45, 11.38]
Goff 2004	22	44	301	1011	7.5%	2.36 [1.29, 4.32]
Hamilton 2009	112	212	92	1060	10.5%	11.78 [8.35, 16.63]
Kim 2009	20	116	1	135	1.4%	27.92 [3.68, 211.58]
Lim 2012	54	191	8	268	6.0%	12.81 [5.93, 27.69]
Lurie 2009	238	432	89	491	11.0%	5.54 [4.11, 7.46]
Olsen 2001	87	168	37	251	9.1%	6.21 [3.91, 9.86]
Pitta 2013	23	60	0	150	0.8%	188.63 [11.20, 3176.89]
Smith 2005	607	1985	253	6024	12.3%	10.05 [8.58, 11.77]
Vine 2003	171	267	32	317	9.3%	15.86 [10.19, 24.70]
Wynn 2007	333	920	207	2760	12.0%	7.00 [5.76, 8.51]
Total (95% CI)		**4646**		**12866**	**100.0%**	**8.10 [6.26, 10.48]**
Total events	1800		1072			

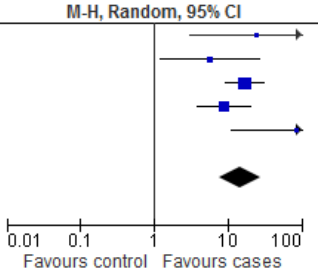
Heterogeneity: Tau² = 0.13; Chi² = 54.60, df = 12 (P < 0.00001); I² = 78%
Test for overall effect: Z = 15.93 (P < 0.00001)



Symptom 3: Appetite loss

Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Devlin 2010	8	82	1	230	8.3%	24.76 [3.05, 201.22]
Friedman 2005	10	69	2	69	13.5%	5.68 [1.20, 26.97]
Hamilton 2009	44	212	16	1060	39.7%	17.09 [9.43, 30.98]
Olsen 2001	34	168	7	251	29.8%	8.84 [3.82, 20.49]
Pitta 2013	22	60	1	150	8.7%	86.26 [11.27, 660.39]
Total (95% CI)		**591**		**1760**	**100.0%**	**14.37 [7.50, 27.54]**
Total events	118		27			

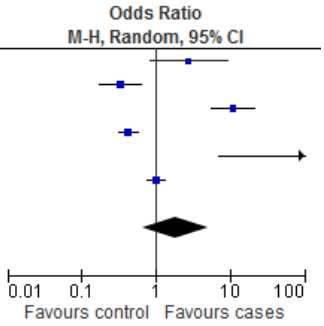
Heterogeneity: Tau² = 0.19; Chi² = 6.22, df = 4 (P = 0.18); I² = 36%
Test for overall effect: Z = 8.03 (P < 0.00001)



Symptom 4: Back pain

Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Friedman 2005	10	69	4	69	15.6%	2.75 [0.82, 9.25]
Goff 2004	15	44	617	1011	18.6%	0.33 [0.17, 0.62]
Lim 2012	61	191	11	268	18.4%	10.96 [5.58, 21.55]
Lurie 2009	87	432	183	491	19.8%	0.42 [0.32, 0.57]
Pitta 2013	17	60	0	150	7.7%	121.09 [7.14, 2054.63]
Wynn 2007	77	920	232	2760	19.8%	1.00 [0.76, 1.30]
Total (95% CI)		**1716**		**4749**	**100.0%**	**1.81 [0.66, 4.94]**
Total events	267		1047			

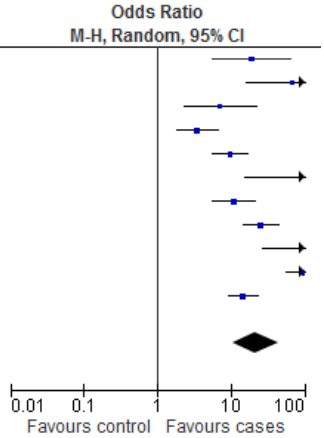
Heterogeneity: Tau² = 1.30; Chi² = 104.02, df = 5 (P < 0.00001); I² = 95%
Test for overall effect: Z = 1.16 (P = 0.25)



Symptom 5: Bloating

Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Behtash 2008	37	100	3	100	8.8%	18.99 [5.61, 64.23]
Devlin 2010	31	82	2	230	7.9%	69.29 [16.06, 298.91]
Friedman 2005	21	69	4	69	9.1%	7.11 [2.29, 22.06]
Goff 2004	30	44	385	1011	10.8%	3.48 [1.82, 6.65]
Hamilton 2009	35	212	21	1060	11.0%	9.78 [5.57, 17.20]
Kim 2009	56	116	0	135	4.2%	253.08 [15.38, 4163.90]
Lim 2012	61	191	11	268	10.7%	10.96 [5.58, 21.55]
Olsen 2001	119	168	22	251	11.0%	25.28 [14.59, 43.80]
Pitta 2013	36	60	0	150	4.2%	448.43 [26.64, 7547.36]
Smith 2005	328	1985	12	6024	11.0%	99.17 [55.60, 176.88]
Vine 2003	166	267	32	317	11.3%	14.64 [9.42, 22.76]
Total (95% CI)		**3294**		**9615**	**100.0%**	**21.49 [10.47, 44.11]**
Total events	920		492			

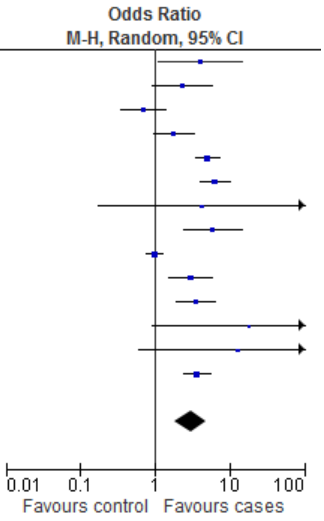
Heterogeneity: Tau² = 1.14; Chi² = 89.51, df = 10 (P < 0.00001); I² = 89%
Test for overall effect: Z = 8.36 (P < 0.00001)



Symptom 6: Bowel changes

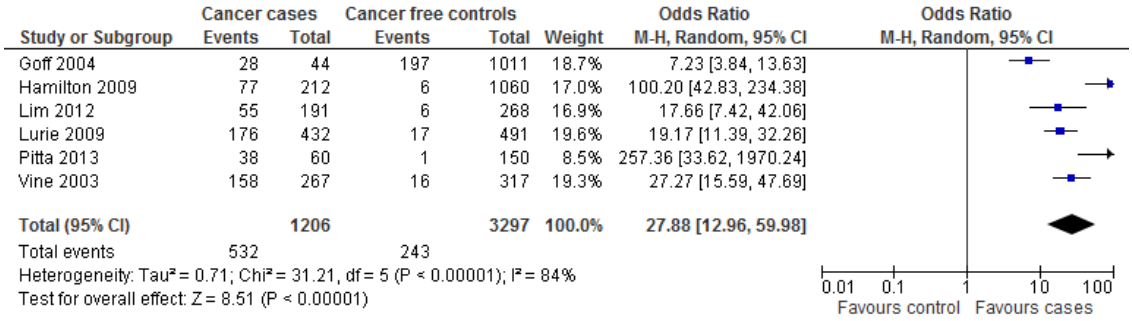
Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Behtash 2008	11	100	3	100	5.9%	4.00 [1.08, 14.79]
Friedman 2005	16	69	8	69	7.5%	2.30 [0.91, 5.81]
Goff 2004	11	44	329	1011	8.5%	0.69 [0.34, 1.38]
Goff 2004*	22	44	363	1011	8.8%	1.79 [0.98, 3.27]
Hamilton 2009	57	212	72	1060	9.5%	5.05 [3.43, 7.43]
Hamilton 2009*	42	212	40	1060	9.3%	6.30 [3.97, 10.00]
Lim 2012	1	191	0	268	1.9%	4.23 [0.17, 104.36]
Lim 2012*	23	191	6	268	7.5%	5.98 [2.38, 14.99]
Lurie 2009	184	432	212	491	9.9%	0.98 [0.75, 1.27]
Olsen 2001	27	168	15	251	8.6%	3.01 [1.55, 5.86]
Olsen 2001*	36	168	18	251	8.8%	3.53 [1.93, 6.46]
Pitta 2013	3	60	0	150	2.2%	18.32 [0.93, 360.26]
Pitta 2013*	2	60	0	150	2.1%	12.86 [0.61, 271.98]
Vine 2003	88	267	38	317	9.4%	3.61 [2.36, 5.52]
Total (95% CI)		**2218**		**6457**	**100.0%**	**2.99 [1.82, 4.91]**
Total events	523		1104			

Heterogeneity: Tau² = 0.63; Chi² = 102.94, df = 13 (P < 0.00001); I² = 87%
Test for overall effect: Z = 4.32 (P < 0.0001)

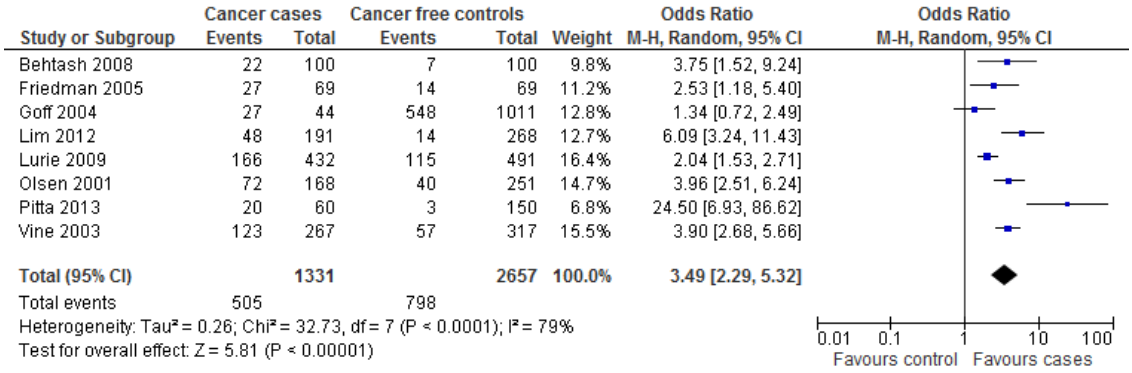


*four studies provide two data entries for bowel symptoms: asterisks denote data for 'constipation' and the other entry for the study refers to data for 'diarrhoea'

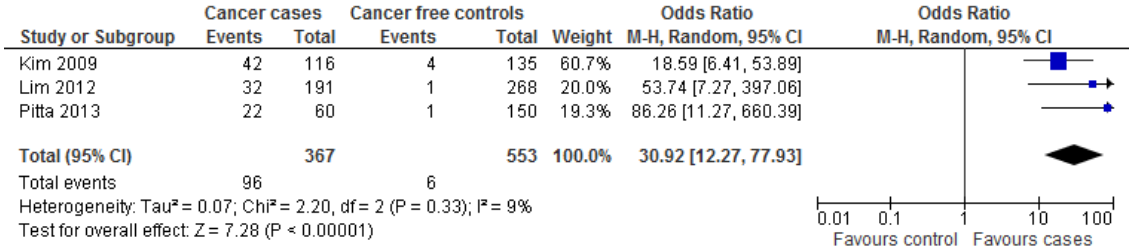
Symptom 7: Distension



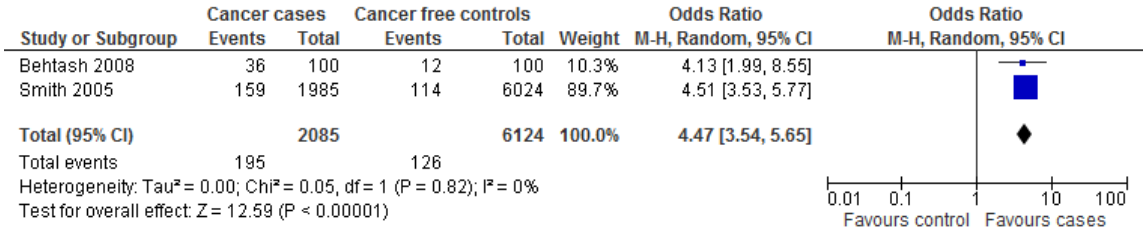
Symptom 8: Fatigue



Symptom 9: Feeling full



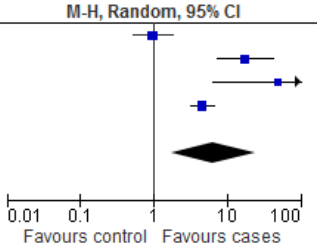
Symptom 10: Gastrointestinal



Symptom 11: Indigestion

Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Goff 2004	16	44	374	1011	27.7%	0.97 [0.52, 1.82]
Lim 2012	55	191	6	268	26.2%	17.66 [7.42, 42.06]
Pitta 2013	15	60	1	150	17.2%	49.67 [6.38, 386.39]
Vine 2003	125	267	51	317	28.9%	4.59 [3.13, 6.74]
Total (95% CI)		**562**		**1746**	**100.0%**	**6.41 [1.72, 23.91]**
Total events	211		432			

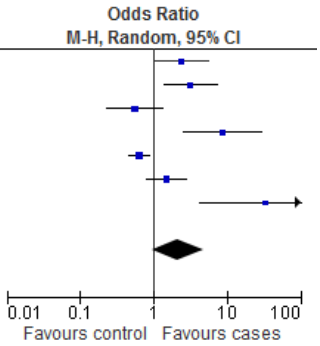
Heterogeneity: Tau² = 1.53; Chi² = 37.62, df = 3 (P < 0.00001); I² = 92%
Test for overall effect: Z = 2.76 (P = 0.006)



Symptom 12: Nausea/ vomiting

Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Behtash 2008	19	100	9	100	15.1%	2.37 [1.02, 5.54]
Friedman 2005	24	69	10	69	15.2%	3.15 [1.37, 7.24]
Goff 2004	6	44	224	1011	14.9%	0.55 [0.23, 1.33]
Lim 2012	17	191	3	268	12.7%	8.63 [2.49, 29.89]
Lurie 2009	69	432	114	491	17.6%	0.63 [0.45, 0.88]
Olsen 2001	21	168	22	251	16.3%	1.49 [0.79, 2.80]
Pitta 2013	11	60	1	150	8.2%	33.45 [4.21, 265.72]
Total (95% CI)		**1064**		**2340**	**100.0%**	**2.14 [0.96, 4.79]**
Total events	167		383			

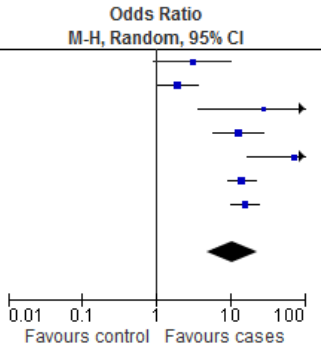
Heterogeneity: Tau² = 0.93; Chi² = 44.90, df = 6 (P < 0.00001); I² = 87%
Test for overall effect: Z = 1.85 (P = 0.06)



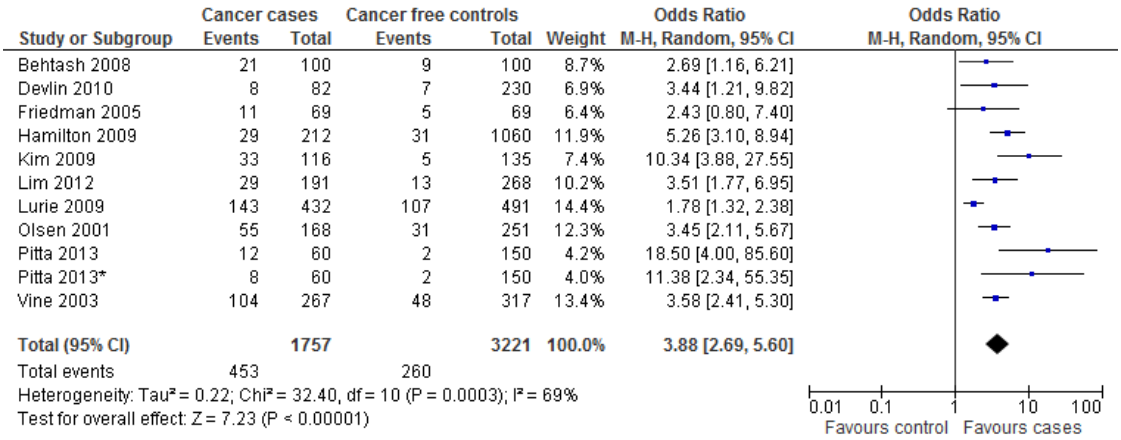
Symptom 13: Pelvic Pain

Study or Subgroup	Cancer cases Events	Total	Cancer free controls Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Friedman 2005	11	69	4	69	13.0%	3.08 [0.93, 10.21]
Goff 2004	18	44	264	1011	16.7%	1.96 [1.06, 3.63]
Kim 2009	20	116	1	135	8.3%	27.92 [3.68, 211.58]
Lim 2012	54	191	8	268	15.8%	12.81 [5.93, 27.69]
Pitta 2013	30	60	2	150	11.2%	74.00 [16.77, 326.44]
Smith 2005	107	1985	24	6024	17.5%	14.24 [9.12, 22.24]
Vine 2003	171	267	32	317	17.6%	15.86 [10.19, 24.70]
Total (95% CI)		**2732**		**7974**	**100.0%**	**10.69 [4.87, 23.44]**
Total events	411		335			

Heterogeneity: Tau² = 0.86; Chi² = 45.60, df = 6 (P < 0.00001); I² = 87%
Test for overall effect: Z = 5.91 (P < 0.00001)

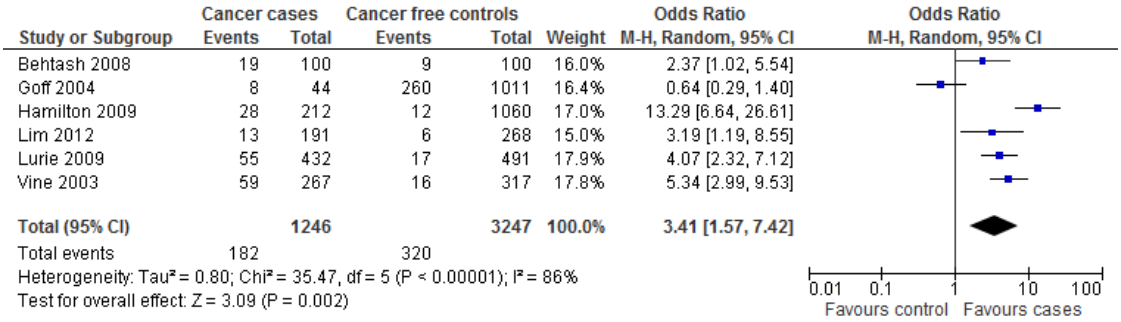


Symptom 14: Urinary

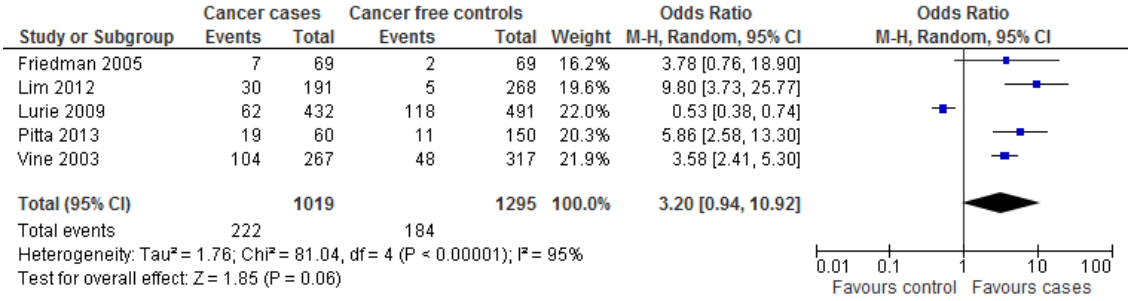


*One study provide two data entries for urinary symptoms: asterisks denote data for 'urinary urgency' and the other entry for the study refers to data for 'urinary frequency'

Symptom 15: Vaginal bleeding



Symptom 16: Weight change



Appendix 27. Ethical approval 3.

School of Medicine
Dean Professor B Paul Morgan PhD MRCP FRCPath FMedSci

Ysgol Meddygaeth
Deon Yr Athro B Paul Morgan PhD MRCP FRCPath FMedSci

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Cardiff University
School of Medicine
Heath Park
Cardiff CF14 4XN

Prifysgol Caerdydd
Ysgol Meddygaeth
Mynydd Bychan
Caerdydd CF14 4XN

Tuesday 29th October 2013

Stephanie Smits, Dr Kate Brain,
Prof Jacky Boivin, & Prof Usha Menon
Cochrane Institute of Primary Care
& Public Health,
School of Medicine, Cardiff University,
Neuadd Meirionnydd, 2nd Floor
Heath Park

Dear Stephanie, Kate, Jacky & Usha,

Re: Virtual reference group to develop and review content of draft OvSTAT. Phase four of the OvSTAT study.

SMREC Reference Number: 13/59

This application was reviewed by the Committee on Wednesday 23rd October 2013.

Ethical Opinion

On review, the Committee have granted ethical approval for this project.

Conditions of Approval

The Committee must be notified of any proposed amendments to the methodology and protocols outlined in your submission. Also, any serious or unexpected adverse reactions that may arise during the course of the study must be reported to the Committee.

Documents Considered

Document Type:	Version:	Date Considered:
Application Form	V1 14/10/13	23/10/2013
Attachment 1: Additional information for ethics application	V1 30/09/13	23/10/2013
Attachment 2: Timeline	V1 30/09/13	23/10/2013
Attachment 3: Letter to volunteer	V1 30/09/13	23/10/2013
Attachment 4: Information Sheet	V1 08/10/13	23/10/2013
Attachment 5: Consent Form	V1 03/10/13	23/10/2013
Attachment 6: Email to scientific experts	V1 30/09/13	23/10/2013
Attachment 7: Virtual reference group	V1 30/09/13	23/10/2013
Attachment 8: Consent Form	V1 03/10/13	23/10/2013

With best wishes for the success of your project.

Yours sincerely,

Dr Andrew Freedman
Chair, School of Medicine Research Ethics Committee

BUDDSODDWR MEWN POBL
INVESTOR IN PEOPLE

Appendix 28. Cognitive interview topic guide

Interviewer note: need to stress to the respondent that:

- We are not primarily collecting survey data on them, but rather testing the leaflet before it is finalised.
- All comments on the leaflet are welcome – including criticisms.
- Scripted probes are included for each section. One of the key assumptions of the cognitive interviewing approach, however, is that issues may well come up in answering the questions that cannot be anticipated in advance of the interview. **It is therefore important that you as an interviewer are sensitive to such issues and probe spontaneously around areas not covered by the scripted probes if these come up.**

Pre-amble:

Before we begin, I need to give you some information so that you understand why the research is being done and what it would involve.

We are carrying out research to understand people's views of an ovarian cancer information leaflet.

At this stage, we are testing the leaflet before it is finalised, so we are interested in your views, both positive and negative.

Taking part is voluntary. It is up to you to decide whether or not to take part. If you decide to take part you are still free to stop at any time and without giving a reason. If you prefer, you can also skip individual questions on the survey.

All the information that is collected will be anonymous and kept strictly confidential.

I will start by asking you some questions about the leaflet. This will help identify good things in the leaflet as well as things that may need more changing. However, please feel free to stop me at any stage during to mention anything that you think might be relevant. If you feel that you would rather not answer a question then that is fine……..

1. **Usefulness/understanding**
   What do you think about the leaflet?
   - What do you think the purpose of the leaflet is?
     - Do you understand why this leaflet might be offered to people?
   - Did any questions spring to mind when you were reading the leaflet?

- What do you think about the information in the leaflet?
  - Do you think it is informative?
  -is there too much/too little information?

2. **Content and layout**
   - Is the leaflet easy to read?
     - Was the content/wording clear? Was it too simplistic or complex?
     - Were there any words that were unfamiliar to you?
     - Were there any parts you did not understand?
     - Was the text an easy size to read?
     - What do you think about the colours?
   - What do you think about the length of the leaflet?
     - What do you think about the order of information?
       - What do you think about the different sections?
     - What do you think of the pictures/illustrations?
     - Do you think there should me more pictures/illustrations?
   - Would you prefer to read this information on a website?

3. **Improvements**
   - Can you tell me what you like most about the leaflet?
     - Can you tell me what you like least about it?
   - Do you think the leaflet would be useful for women wanting to find out about the symptoms of ovarian cancer?
   - Are there areas that need improving? (language, font, format, graphics)
     -Are there any things that should be removed to improve it?
     -Is there anything particular you would like to see in it that is not currently included?

Section for GPs/Genetics: (ask about the section for women at increased risk if it is not brought up in discussion through the above questions)

- What do you think about the section for women at increased risk of cancer?

Other probes that could be used:

- Did any questions come to mind when you were reading it?
- Why do you think that might be important?
- Why do you think that should be changed?
- Is there anything else you would like to mention about the leaflet?

Appendix 29. Draft OvSTAT (side one)

If you have a family history of ovarian cancer...

Some women have a family history of ovarian cancer. These women may have talked to their doctor about their own risk of developing ovarian cancer. If a woman is at increased risk because of her family history, she may decide to have surgery to remove her ovaries to reduce her risk. But not all women choose this option. Women who decide not to have surgery are recommended to be aware of the symptoms of ovarian cancer.

At your medical appointment

Your doctor may not know about your family history. Telling your doctor about this personal information may be upsetting for you. However, giving your doctor this information is important and will help you and your doctor decide what is best for your health.

Who can I talk to?

If you have a family history of ovarian cancer you should go and speak to your doctor. They may be able to refer you to your local Clinical Genetics Service for genetic counselling.

If you have already been referred to Clinical Genetic Services, you can go back if you have concerns about your risk. You can also return to see your doctor if you have concems.

What to do now...

Keep this leaflet so you can read it when needed.

If you have any of the symptoms for 3 weeks or more you should go and see your doctor. It may be nothing, but it's good to get it checked out. The doctor will be able to reassure you or refer you to a specialist team.

If you have symptoms that do not go away, or they come back, it is important to go and see your doctor again.

For further information and support:

Target Ovarian Cancer are an ovarian cancer charity and can provide further information and support.

You can visit www.targetovariancancer.org.uk or call 020 7923 5475

This leaflet was created as part of a research project at Cardiff University. Funding was also received from the Medical Research Council. Information on the study and sources of information for this leaflet can be found here: www.ovstat.com

OvSTAT leaflet v2 June 2014

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

OVSTAT

Ovarian Cancer
Symptom Awareness Tool

An information leaflet on ovarian cancer symptoms for women, including women with a family history of ovarian cancer

Final OvSTAT (Side two)

What is this leaflet for?

This leaflet will give you information on the symptoms of ovarian cancer. It will also tell you what to do if you think you have these symptoms.

This leaflet has been designed to give information to all women. There is also a section for women who have been identified at increased risk of developing ovarian cancer.

If ovarian cancer is detected at an early stage it is easier to treat. This is why it is important to be aware of the symptoms.

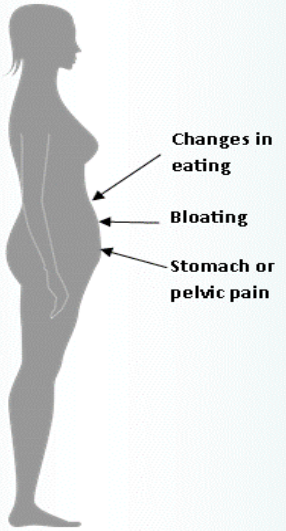
This leaflet will help you make decisions about when to go and see your doctor if you are worried about your symptoms.

Ovarian cancer truths

- It is important to be aware of the symptoms as there is no current ovarian cancer detection method.
- There is no screening programme to detect ovarian cancer offered by the NHS.
- The smear test does not detect ovarian cancer. It is a test for cervical cancer, not ovarian cancer.

What are the symptoms of ovarian cancer?

You should go and talk to your doctor if you have any of the symptoms below on most days for **3 weeks** or more.



Changes in eating means feeling full quicker than usual or a loss of appetite

Bloating means when your tummy feels like it has gone "up" and stays "up"

Stomach or pelvic pain means a pain around the area of your tummy

When should I go and see my doctor?

From time to time women will have these symptoms. They usually go away after a few days. But if you have any of the symptoms for 3 weeks or more you should go and see your doctor.

Remember, if you are experiencing these symptoms it does not mean you have ovarian cancer. But it is important to get them checked out, whether it is ovarian cancer or not.

What to expect at the doctors

- Your doctor will ask you what symptoms you have been experiencing. They will also ask how long you have had them for.
- You could show your doctor this leaflet to help explain about your symptoms.
- You may also want to write down a list of things you want to say to your doctor before you visit, in case your mind goes blank.

Appendix 30. Final OvSTAT (side one)

If you have a family history of ovarian or breast cancer...

If you have a family history of ovarian or breast cancer you may have talked to your doctor about your own risk of developing ovarian cancer. If a woman is at increased risk because of her family history, she may decide to have surgery to remove her ovaries to reduce her risk. But not all women choose this option. Women who decide not to have surgery are recommended to be aware of the symptoms of ovarian cancer.

Who can I talk to?

If you have a family history of ovarian or breast cancer you should go and speak to your doctor. The doctor will assess your family history and may be able to refer you to your local Clinical Genetics Service to discuss your personal risk.

If you have already been referred to Clinical Genetic Services, you can go back if you have concerns about your risk. You can also return to see your doctor if you have concerns.

At your medical appointment

Your doctor may not know about your family history. Telling your doctor about this personal information may be upsetting for you. However, giving your doctor this information is important and will help you and your doctor decide what is best for your health.

What to do now...

Keep this leaflet so you can read it when needed.

If you have any of the symptoms on most days for **3 weeks** or more you should go and see your doctor. It may be nothing, but it's good to get it checked out. The doctor will be able to reassure you or refer you to a specialist team.

If you have symptoms that do not go away, or they come back, it is important to go and see your doctor again.

For further information and support:

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CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

OvSTAT leaflet v3 June 2014

OVSTAT

Ovarian Cancer
Symptom Awareness Tool

An information leaflet on ovarian cancer symptoms for women, including women with a family history of ovarian or breast cancer

Final OvSTAT (side two)

What is this leaflet for?

This leaflet will give you information on the symptoms of ovarian cancer. It will also tell you what to do if you think you have these symptoms.

This leaflet has been designed to give information to all women. There is also a section for women with a family history of ovarian or breast cancer.

If ovarian cancer is detected at an early stage it is easier to treat. This is why it is important to be aware of the symptoms.

This leaflet will help you make decisions about when to go and see your doctor if you are worried about your symptoms.

Ovarian cancer truths

- There is no screening programme to detect ovarian cancer offered by the NHS.
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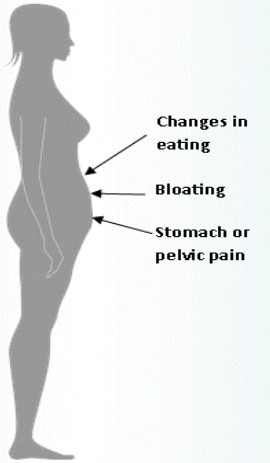

Changes in eating means feeling full quicker than usual or a loss of appetite

Bloating means when your tummy feels like it has gone "out" and stays "out"

Stomach or pelvic pain means a pain around the area of your tummy

When should I go and see my doctor?

From time to time women will have these symptoms. They usually go away after a few days. But if you have any of the symptoms on most days for **3 weeks** or more you should go and see your doctor.

Remember, if you are experiencing these symptoms it does not mean you have ovarian cancer. But it is important to get them checked out, whether it is ovarian cancer or not.

What to expect at the doctors

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