EndoNeeds Phase 1: A protocol for research exploring the physical, psychological and social needs of Australian women with endometriosis.

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Abstract

Endometriosis is a chronic gynaecological condition that causes pain and infertility and can have a significant impact on the physical, psychological and social wellbeing of women. This thesis outlines the protocol for exploratory qualitative research that is required to develop a survey for women with endometriosis that will measure the things they need to improve their wellbeing – their unmet needs. If unmet needs can be measured, targeted interventions can be designed to meet these needs, and ultimately improve quality of life.

The aim of this research is to identify key needs and domains of needs in this population. The research will be conducted using focus group discussions, and data will be analysed using a grounded theory approach to identify needs to include in the unmet needs survey. An important way of enhancing the content validity of survey instruments is through the involvement of patients in their development, through exploratory qualitative research. In this case, the identification of a broad range of needs in this population will aid in the development of a robust, easy to use instrument that can be used to inform clinical practice at an individual and population level.
Affirmation

This thesis presents work undertaken to partially fulfill the requirements of the degree of Master of Public Health at The University of Melbourne.

All views contained within are those of the author and may not reflect the views of The University of Melbourne and/or The Melbourne School of Population and Global Health.

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**CHAPTER 1 - BACKGROUND**

**Endometriosis description and epidemiology:**

Endometriosis is a common but often debilitating condition characterised by endometrial-like tissue outside the uterine cavity. These endometriotic lesions are usually pelvic in location, may by superficial or deeply infiltrating, and may form cysts on the surface of the ovaries called endometrioma.\(^1\) Like normal endometrial tissue, the lesions respond to hormonal changes during the menstrual cycle, causing inflammation and adhesions within the peritoneal cavity.\(^2\) It is difficult to determine the population prevalence of endometriosis due to variability of symptoms and the method of definitive diagnosis (laparoscopy), but it is estimated that around 6-10% reproductive-age women are affected.\(^3\) Prevalence in certain sub-populations is much higher: 25-50% in women with infertility\(^4\) and 33% in women with chronic pelvic pain.\(^5\) World-wide, it is estimated that 176 million women, or 1 in 10 reproductive-age women, are affected.\(^6\)

The exact cause and pathogenesis of endometriosis remains uncertain, but current evidence points to a complex combination of genetic, immunological and environmental factors.\(^7\) Genetic studies suggest a polygenic inheritance pattern.\(^2, 8\) Immune dysfunction is also thought to play a part, as endometrial cells are not effectively cleared from the peritoneum after the normal process of retrograde menstruation.\(^2\) Adding weight to the immune dysfunction theory is the reported association of endometriosis with immune disorders such as lupus, rheumatoid arthritis, multiple sclerosis and thyroid disorders, and with fibromyalgia.\(^9, 10\) Age is an additional major risk factor for endometriosis, with risk at its highest between menarche and menopause,\(^11\) but this is likely to be a proxy for the period during which women ovulate. Lastly, conditions or lifestyle factors that result in an increased
number of lifetime ovulations are associated with a higher risk of endometriosis – examples include nulliparity, early menarche and short menstrual cycles. The risk factors described above point to a complex and multifactorial pathogenesis which may never be fully described, adding to the difficulties in diagnosis and treatment of this disease.

Symptoms and treatment of endometriosis:

The symptoms experienced by women with endometriosis are highly heterogeneous, but the most common is pelvic pain. The pain is usually (but not always) associated with menstruation (dysmenorrhea). In addition, women often experience pain during sexual intercourse (dyspareunia), urination (dysuria) and defecation (dyschezia). Aside from pelvic pain, endometriosis is associated with cyclic leg pain, back pain, gastrointestinal upset and migraine headache. Pelvic pain that continues for six months or more is defined as chronic pelvic pain and develops due to changes in the central nervous system (central sensitisation).

Endometriosis is found in 33% of laparoscopies performed for chronic pelvic pain, and the development of this condition can have a major psychosocial impact, particularly as the pain may persist despite surgical removal of endometriotic lesions. The broad range of pain symptoms described above is one of the reasons endometriosis is so difficult to manage.

Infertility is the other key symptom of endometriosis, affecting 30-50% of women with the disease. Although the impact of severe endometriosis on fertility could be expected due to distortion of the pelvic anatomy and adhesions, infertility is also associated with mild endometriosis, and may not be linked to pain symptoms. It is thought that the inflammatory environment in the pelvis affects the ovulation process. It is also theorised that the eutopic endometrium of women with endometriosis is abnormal, causing implantation failure. This suggests multiple mechanisms are at the root of infertility in these women.
Endometriosis is associated with a range of other symptoms (usually related to the location of lesions) that include abdominal bloating, rectal bleeding, diarrhoea and obstructed defecation due to bowel lesions, urinary frequency or urgency due to bladder lesions, and even pleural effusion and haemoptysis due to pleural lesions. The heterogeneity and unpredictability of the symptoms described above is a major cause of diagnostic delay and can have a significant impact on quality of life.

Endometriosis can only be definitively diagnosed via laparoscopy and histological biopsy, however, imaging techniques such as trans-vaginal ultrasound and Magnetic Resonance Imaging are improving in the diagnosis of certain types of endometriosis. On average, women with endometriosis wait up to nine years for formal diagnosis, with the delay being predominately attributed to misdiagnosis and normalisation of symptoms by women and doctors. While laparoscopic diagnosis is relatively simple, staging of endometriosis based on surgical observations only weakly correlates with symptom severity and infertility, another frustrating and confusing aspect of the disease from the perspective of the patient.

Medical treatment options for endometriosis depend on symptoms, reproductive plans and medical history. The most common medical treatments aim to reduce disease activity and pain by suppressing ovulation. Perhaps due to the variable symptomatology and chronic nature of the disease, and the fact that many clinicians will treat suspected endometriosis empirically (either prior to or in the absence of laparoscopy), much of the evidence around treatment efficacy is inconsistent. In addition, some drugs may cause unpleasant side-effects such as weight-gain, acne and irregular bleeding, and may increase the risk of adverse events such as thromboembolism in some women. In the absence of a ‘wonder drug’ to
treat endometriosis, a trial and error approach is usually taken with medical treatment, based on the individual woman’s treatment needs.\textsuperscript{22}

Surgical treatment for endometriosis usually involves laparoscopic excision or ablation of endometriosis lesions or ovarian endometriomas.\textsuperscript{1} These operations require skilled and experienced surgeons due to their complex nature and risk of morbidity (e.g. bowel perforation and infertility), especially in the excision of deep infiltrating endometriosis.\textsuperscript{1, 22}

While surgical treatment is often effective, recurrence of symptoms is common, with 40-50\% of patients experiencing recurrence within 5 years of their initial surgery.\textsuperscript{23} Thus, many women require multiple operations to treat their endometriosis, each with its own risk of infection, adhesions and impact on fertility.\textsuperscript{23} Hysterectomy with bilateral salpingo-oophorectomy is also an option in women who do not wish to have children, although this results in medical menopause, with associated health consequences.\textsuperscript{1}

Many women use complementary therapies to help them cope with the symptoms of endometriosis. These include physiotherapy, Chinese herbal medicine, vitamins, supplements and acupuncture.\textsuperscript{24} Lifestyle and psychological interventions such as dietary changes, exercise, mindfulness practices and other self-care strategies are also discussed in the literature.\textsuperscript{25-27} There is a growing body of evidence on the efficacy of complementary therapies in endometriosis, but there is a paucity of well-designed research at present.\textsuperscript{21} Despite this, many women spend considerable amounts of time and money on these therapies when mainstream treatments prove inadequate.\textsuperscript{24}

Despite advances in medical and complementary therapies and surgical techniques to treat endometriosis, it remains a chronic and incurable disease.\textsuperscript{7}
Medical therapies have variable efficacy, may not provide long-lasting symptom relief and may be associated with undesirable side-effects.\textsuperscript{28} Although surgical treatment has better efficacy, it is much more invasive with a risk of complications, recurrence, and long-term effects (e.g. infertility). The uncertainty around endometriosis treatment has been described as a ‘medical merry-go-round’\textsuperscript{29} and can have devastating psychosocial consequences, which are described in the following section.

**Psychosocial impact of endometriosis:**

The symptoms, disease progression, diagnostic process and treatments described above all influence the impact of endometriosis on the psychological and social wellbeing of women. Numerous studies have shown that women with endometriosis have a higher prevalence and risk of psychiatric disorders such as depression and anxiety.\textsuperscript{30, 31} Health-related quality of life studies in endometriosis consistently report poorer quality of life, specifically in the domains of pain, psychological function and social function.\textsuperscript{32} Additionally, the economic cost of endometriosis to both the individual and the state is huge. A recent European multi-country study estimated the annual direct health-care cost of endometriosis to be €3113 (AU$4285) per woman, a figure comparable to the health-care costs of diabetes mellitus.\textsuperscript{33} Aside from direct health care costs is the (much more difficult to quantify) loss of productivity and earning potential experienced by women with endometriosis and their families: it is estimated that women with endometriosis in Australia lose 11 working hours per week through being unable to work or working less effectively, due to their symptoms.\textsuperscript{6} The impact of endometriosis on education is also a major issue, especially since adolescence is a common time for symptoms of endometriosis to appear.\textsuperscript{34} Women and adolescents with endometriosis report having to take time off school and university, and in some cases withdraw from
education, due to their symptoms. The psychosocial impact of endometriosis is felt at an individual, family and societal levels, and efforts to reduce this impact must be prioritised.

**Patient-reported outcomes:**

The impacts of endometriosis and the issues surrounding its diagnosis and treatment show that care of women with this disease must take into account not just clinical considerations, but also their psychosocial wellbeing. The variability of symptoms and treatment efficacy demonstrates the need for a more individualised model of care. A patient-centered model of care - one that puts the woman at the centre of her care, enhancing communication and promoting shared decision-making between her and her health professionals - may help to alleviate some of the detrimental effects of this disease. Patient-centered care, healthcare that is “respectful of, and responsive to, the preferences, needs and values of patients and consumers” has been adopted by governments and health services world-wide since its introduction in the 1990’s. This model of care uses the patient’s perception of their health and healthcare as a central concept. This means that the methods used to elicit and measure the experiences of patient, carers, and other healthcare consumers have become increasingly important.

Patient-reported information can be captured in a variety of ways, depending on its intended use, available resources and the patient population being studied. Qualitative research methods, such as focus groups and interviews, can be used to gain in-depth information from the patient perspective, although results lack generalisability, and data collection and analysis are often resource-intensive. Consumer feedback, satisfaction forms and data from complaints systems are also useful sources of patient-reported information, and can range from open-ended survey questions to standardized metrics. Patient-reported outcome
measures, which are designed to quantify patient-reported information, are the focus of this section.

A patient-reported outcome is defined as:

‘Any report on the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.’

A patient-reported outcome measure (PROM) is a tool or instrument used to measure these outcomes. PROMs can be used to quantify many aspects of patient care, health status and health behaviour. PROMs can be used at multiple levels of healthcare to improve patient care and strengthen health systems:

- At the individual level, PROMs can be used to provide more personalised care to patients, taking into account their specific clinical and psychosocial situation and enhancing communication and decision-making between patient and health professionals.

- At a health service level, aggregated PRO data can be used for quality assurance activities, to inform clinical guidelines, in the evaluation of interventions, and in the development of patient information (such as decision aids).

- At a health system level, PROMs can be used to inform health policy, identifying population-level trends in outcomes.

The term PROM has come to represent a wide range of instruments designed to measure an equally wide range of constructs: health status, health-related quality of life (HR-QoL), well-being, treatment satisfaction, symptoms and adherence to treatment are common examples.
The majority of PROMs are used to measure the impact of a health condition on a person’s life: their symptoms, daily functioning and psychosocial issues. In contrast, a less well-known PROM, the ‘unmet needs survey’, can be used to measure the things a patient feels they need to improve their quality of life or better cope with their condition.45

**Unmet needs surveys:**

An unmet need is defined as ‘the requirement of some action or resource that is necessary, desirable or useful to attain optimal wellbeing’.46 Unmet needs surveys are designed to investigate the aspects of care patients feel they need help with, and the extent to which those needs are being met. This type of measure has been used extensively in the field of cancer care, with multiple instruments developed and validated in populations with different types and stages of cancer.47-54 They have also been developed for use in other chronic health conditions, such as heart failure and stroke.55-57 There is substantial overlap between the domains included in unmet needs surveys and HR-QoL instruments, as unmet needs are closely linked to quality of life: for example, if a patient has an unmet need for more information about their condition, they may experience unnecessary anxiety, which could affect their quality of life. Studies in cancer populations have found a statistically significant correlation between high unmet needs and reduced quality of life.58 The goal of an unmet needs survey is to identify areas of need so that interventions can be designed and delivered to meet them, hopefully resulting in an improvement in quality of life.59
The EndoNeeds Project:

Given the chronic and unpredictable nature of endometriosis, and its effect on quality of life, it is reasonable to assume that women with this disease may have a high level of unmet need. The EndoNeeds Project was initiated to identify and quantify these needs so that interventions can be designed to meet them, and improve the experience of these women. The overall project will consist of three phases:

1. Initial development of survey questions.
2. Refinement, piloting and psychometric validation of the EndoNeeds survey.
3. Administration of the full EndoNeeds survey.

Phase 1:

The aim for phase 1 is to develop the EndoNeeds survey, using the following methods:

a) A systematic review of the literature around the use of PROMs in endometriosis: This review is described in chapter 2.

b) Formation of a working group comprised of clinicians, researchers and women with endometriosis to guide survey development.

c) Exploratory qualitative research into the physical and psychosocial needs of Australian women with endometriosis: The protocol for this research is the focus of this thesis, and is described in chapter 3.

d) Development of the EndoNeeds pilot survey using the findings of the above research and input from the working group.

Phase 2:

Following a process of stakeholder engagement, the pilot survey will be released via email to a limited population drawn from Royal Women’s Hospital gynaecology clinics and consumer organisations. Once the survey questions have been finalised, basic psychometric testing will be performed.
Phase 3:
The full EndoNeeds online survey will be released via the Royal Women’s Hospital and consumer groups’ websites and social media.

A table summarising the research plan for the entire EndoNeeds Project is included in Appendix 1.

Overview of thesis:
This thesis will focus on the work needed to justify and develop a sound theoretical base for the development of the EndoNeeds survey:

- **Chapter one** has provided a background on endometriosis, and the concepts of patient-centred care and PROMs, specifically unmet needs surveys.

- **Chapter two** will describe a systematic review of the use of PROMs in endometriosis, to investigate whether there are any existing unmet needs surveys in this area, identify potential needs and review the methodology used to develop other unmet needs surveys.

- **Chapter three** will consist of a detailed protocol for qualitative research that, along with the results of the literature review, will be the basis for the development of survey questions. Important design issues will be discussed, along with the predicted clinical impact and public health implications of this research.
CHAPTER 2 – SYSTEMATIC REVIEW OF PROMs IN ENDOMETRIOSIS

Introduction:

Endometriosis has a significant impact on the physical, psychological and social wellbeing of women with the disorder (Chapter 1). A patient-centered approach in the care of women with endometriosis could help them to cope better with this disease. For this reason, it is important to have well-designed patient-reported outcome measures (PROMs) to capture the patient’s perspective of their condition. This chapter describes a systematic literature review to support the development of a new PROM for women with endometriosis.

The aims of this literature review were:

- To describe the use of PROMs in endometriosis research, and identify any unmet needs instruments among them.
- To identify needs from the PROMs and qualitative evidence in endometriosis.
- To identify domains of needs and the methodology used for Unmet Needs survey development in other areas of healthcare.

This review provides a contextual base to demonstrate the requirement for the EndoNeeds survey. The findings of the review will inform the methodology required for the qualitative component of the project (focus groups), key areas of need and subsequently, the development of the EndoNeeds survey questions.
**Methods:**
The literature search was conducted in April 2017 using the biomedical and social sciences databases Medline, PsychINFO, PubMed and CINAHL. Searching focused on four key concepts:

1. PROMs in endometriosis
2. Unmet Needs measures in endometriosis
3. Unmet Needs measures in other health conditions
4. Qualitative research in women with endometriosis.

The search terms used are listed in table 2 (A2). The reference lists for articles that met the eligibility criteria were searched for further relevant publications. An internet search was also conducted to identify relevant grey literature.

Studies were included if they:

- Were published in English;
- were published in peer-reviewed journals;
- described research in humans;
- described the key concepts listed above; and
- described populations diagnosed with endometriosis, or their partners or families (concepts 1, 2 and 4 only).

Studies were excluded if they:

- Reported on animal studies
- Reported the results of an intervention
Figure 1 outlines the study selection process. The titles and abstracts of all citations were screened and full text of all potentially relevant articles obtained. The following data were then extracted from relevant articles:

- Citation details;
- study aim/research question;
- research population/design/methods;
- PROM instruments used (generic and endometriosis-specific);
- domains covered by the PROM and unmet needs instruments;
- any unmet needs addressed by the instrument; and
- for qualitative studies, any needs mentioned in the results or discussion sections.

The literature search and review was conducted by one investigator (ES), with input in planning and review from the rest of the team (JG&MP).
Results and discussion:

A total of 113 titles were reviewed (66, 2, 14 and 31 from concepts 1-4 respectively). The review revealed that the types of PROMs used in endometriosis research vary widely depending on study type, population and location, and could be divided into the following main areas: symptoms, quality of life, psychiatric symptoms, psychological wellbeing, satisfaction, work/financial issues, sexual satisfaction, social support and information seeking behaviour. Of the generic PROMs used in endometriosis research, the most popular were
measures of psychiatric and psychological morbidity, quality of life and sexual satisfaction (Table 3, A3). Studies usually used a combination of PROMs depending on the research question being addressed; some individual PROMs covered multiple domains. For example, Melis et al\textsuperscript{61} used the Female Sexual Function Index, the Medical Outcomes Study short-form 36, the Beck Depression and Anxiety Inventories and the Body Attitude Test to evaluate sexual function, quality of life and perceived body image in women with deep infiltrating endometriosis compared to healthy controls.

There were 10 endometriosis-specific instruments identified in the review (Table 4, A4). The most commonly used was the Endometriosis Health Profile 30\textsuperscript{62} (EHP-30), a validated scale measuring the health-related quality of life of women with endometriosis. Unlike generic scales, the EHP-30 includes domains specific to endometriosis, such as fertility and sexual function. Other condition-specific PROMs included symptom scales (e.g. Endometriosis Pain and Bleeding Diary\textsuperscript{63}), satisfaction questionnaires (e.g. Endometriosis Treatment Satisfaction Scale\textsuperscript{64}) and an instrument to measure the cost of endometriosis-related symptoms and treatment (Endocost questionnaire\textsuperscript{33}). In addition, there were multiple author-devised, non-validated questionnaires that addressed various domains, including symptoms\textsuperscript{65}, medical history\textsuperscript{66} and diagnostic delay.\textsuperscript{67} None of these author-devised questionnaires were assigned a name, making it impossible to know if these instruments were subjected to psychometric validation at a later stage or used more than once.

There were only two surveys that specifically mentioned the needs of women with endometriosis. The first was a mixed methods survey that focused on the informational needs of women with endometriosis related to diagnosis, disease knowledge, laparoscopy and managing at home; however, the survey was not designed to quantify needs and the extent to
which needs were being met.\textsuperscript{68} The second was a survey of members of the Dutch Endometriosis Society evaluating the Society’s efforts to meet the information needs of women with endometriosis.\textsuperscript{69} Again, it was not designed to quantify needs. Neither of these measures had been validated and only appear to have been used once.

The domains explored by PROMs in endometriosis illustrate the wide-ranging physical and psychosocial effects of the disease (Tables 3 & 4, A3&4). Physical symptoms, predominately pain-related, were explored in detail, as were the impacts they have on daily living, employment, finances, relationships, sex life and mental health. In addition, some measures explored the ways in which women access healthcare, their satisfaction with treatment and their relationship with healthcare providers. Importantly, the vast majority of questions in these PROMs explored the \textit{impact} that endometriosis has on each domain. They did not specifically ask whether the woman has a need for help in each area. While some needs may be inferred from these PROMs, only a dedicated unmet needs survey can systematically identify what women feel their needs are, and whether they are being met.

A review of the qualitative literature in endometriosis revealed similar areas of impact to those explored by PROMs (Table 5, A5). Researchers highlighted the negative effect of endometriosis symptoms on daily living,\textsuperscript{70} employment,\textsuperscript{71} education,\textsuperscript{35} social life,\textsuperscript{72} relationships,\textsuperscript{73} and mental health.\textsuperscript{74} Additionally, the qualitative literature raised issues with the healthcare system, such as lack of information,\textsuperscript{75} diagnostic delay,\textsuperscript{16} communication difficulties with health care professionals\textsuperscript{76} and inadequate access to healthcare.\textsuperscript{77} Again, very few qualitative studies specifically addressed the \textit{needs} of women with endometriosis. The authors of a number of reviews of qualitative studies inferred various unmet needs, particularly in knowledge and education of women and health professionals, access to
appropriate healthcare and help explaining the condition to employers and family. While these findings will be useful in the development of the EndoNeeds survey, they should be regarded as distinct from a formal, patient-reported measure, as the women themselves have not expressed the needs. Additionally, while qualitative studies provide a source of in-depth data, the populations studied are unlikely to be representative of all women with endometriosis.

To date, formal unmet needs surveys are largely limited to the field of cancer care. Numerous surveys have been developed and validated in populations with different types of cancer, and at different stages of the disease. In addition, unmet needs surveys have been developed for people supporting a friend or family member with cancer. Outside cancer care, unmet needs surveys have been developed for populations with heart failure, mental illness and stroke. Broadly, the majority of unmet needs surveys cover the following domains of need: healthcare/access to care, mental health, sexuality, daily living, social, informational, physical, spiritual/existential, financial and employment/education (Table 6, A6).

It is important to note that the exact types of needs differ depending on the population being studied. For example, the Survivors Unmet Needs Survey (SUNS) covers domains such as employment and informational needs, whereas the Needs at the End-of life Screening Tool (NEST) includes the domains of spirituality and acceptance. In comparison, the Camberwell Assessment of Need a tool for assessing need in people with severe mental illness, covers a much broader range of needs, from basic (food and housing) to culture and religion. When the methodology used in the development of the various existing unmet needs studies is examined (Table 6, A6), the importance of a systematic approach becomes apparent. Most studies described a process involving input from experts in the field,
qualitative research (individual interviews or focus groups) and psychometric testing. The differences between unmet needs surveys developed for different populations show that, when developing an instrument for a new population, an approach that includes exploratory qualitative research is necessary.\textsuperscript{85}

This review has shown the diversity of PROMs used in endometriosis research. The breadth of domains they covered illustrates the wide-ranging impact of endometriosis on women’s lives. The qualitative literature identified similar domains of impact. Potential areas of unmet need can be inferred from these domains, but in order to quantify exactly which aspects of care women with endometriosis need help with, it is necessary to use a dedicated unmet needs measure. The unmet needs surveys that have been developed for other areas of healthcare show some intersection with domains covered in the endometriosis literature. However, each of these surveys has been developed for a particular disease or population. If we are to comprehensively assess the needs of women with endometriosis, a carefully designed, disease-specific unmet needs survey is required. This instrument can then be used to benefit women at an individual, health service and health system level, allowing for the design of interventions to meet their needs, and improve quality of life.
CHAPTER 3 - EndoNeeds PHASE 1 STUDY PROTOCOL

Introduction And Rationale:

As described in chapter 1, endometriosis is a chronic and often debilitating condition that has a major impact on women’s quality of life. Chapter 2 outlined the various patient-reported outcome measures (PROMs) that are used in endometriosis, demonstrating that there are multiple instruments to measure symptoms and quality of life in women with endometriosis, but none that measure the care or support that women need or desire to achieve optimal wellbeing – their ‘unmet needs’. Unmet needs surveys have been extensively used in cancer care, with emerging use in other chronic health conditions such as stroke and heart failure. In cancer care, higher unmet needs correlate with reduced quality of life scores and the identification of unmet need has resulted in improvements in clinical care with corresponding reduction in patient distress. Such a tool would be beneficial in the context of endometriosis, yet currently none exists.

Due to the chronic and incurable nature of endometriosis, it is reasonable to assume that there would be some intersection in the domains of needs important to cancer and endometriosis populations. However, there are unique differences between these two chronically ill populations that are likely to influence specific needs. For example, as cancer is a potentially fatal disease unmet needs surveys in this group address spiritual and existential concerns that are not likely relevant to endometriosis. Thus, it would not be appropriate to administer a cancer unmet needs survey to an endometriosis population. Rather, an endometriosis-specific measure should be used.
A review of the methodology used in the development of unmet needs surveys in cancer\textsuperscript{47-54, 91} and other chronic health conditions\textsuperscript{89, 92} revealed that many researchers used a combination of literature review, qualitative research (i.e. patient interviews and/or focus groups) and input from expert panels to develop the list of domains to be covered in the survey. Following this, a survey was developed, which then underwent several steps for validation including consultation with patients and clinicians, pilot testing to eradicate weak or irrelevant questions, and finally administration to the population in question to measure their level of unmet need.

As there is a dearth of literature on unmet needs in women with endometriosis, the process of survey development needs to begin by exploring the needs of women with endometriosis using a constructivist approach and qualitative methodology. Focus groups obtain rich data from a collective perspective through group discussion, illustrating both coherence and diversity of opinion and attitudes between participants.\textsuperscript{93} Liamputtong recommends the use of focus groups for obtaining views on shared experiences, as the homogeneity of the group enables participants to feel comfortable discussing their experiences, while being stimulated to question and comment by group interaction.\textsuperscript{93} The focus group data are then analysed using grounded theory, a rigorous qualitative process that has been advocated by Lasche et al\textsuperscript{94} as an appropriate framework to use when conducting qualitative research in the development of PROMs. Grounded theory is an approach that enables researchers to construct a conceptual framework from focus group and interview data in order to develop meaningful domains and generate survey items, rather than test a preconceived hypothesis.\textsuperscript{94} The iterative and simultaneous process of data collection and analysis that is central to grounded theory means that ambiguous concepts can be re-examined through further analysis.
or additional data collection. The survey items obtained using this approach can then be validated until a clinically relevant assessment tool is developed.

Research Aims:
The overall aim of the EndoNeeds project is to develop and administer a survey to measure the physical, psychological and social needs of Australian women with endometriosis, and the extent to which those needs are being met. The qualitative phase described in this protocol is designed to explore the needs of Australian women with endometriosis in order to develop survey questions for the EndoNeeds survey. The aim of this preliminary research is to produce a list of needs and domains of needs that are specific to women with endometriosis. The research questions this study will attempt to answer are:

“What are the physical, psychological and social needs of Australian women with endometriosis?”

and

“How can these needs be organised into domains?”

Study Design And Methods:

Type of study:
Exploratory, using qualitative methodology.

Study setting:
The Royal Women’s Hospital, a tertiary specialist hospital in Melbourne, Australia.
Study population:

Australian women with surgically diagnosed endometriosis

Eligibility criteria:

To be eligible for the study, participants must:

- Be female;
- Be 18 years old or over;
- Be able to speak and read English, and participate in discussions in English;
- Have had a surgical diagnosis of endometriosis;
- Be able to participate (in person) in a focus group discussion at The Royal Women’s Hospital; and
- Fill at least one of the criteria outlined below.

Sampling:

We will endeavour to obtain a study population that contains women with a breadth of experience in terms of their endometriosis stage and symptoms, including:

1. Newly diagnosed.
2. Variable pain and infertility symptoms.
3. Varying parity.
5. Range of ages.
6. Exploring or using various treatment options, including complementary therapies.

Sampling strategy: purposive, with an aim to recruit women with a broad range of backgrounds and experience with endometriosis. This will be achieved through quota
sampling, where eligible women are recruited based on a list of different experiences of endometriosis, and at least one woman with each experience is recruited.95

**Recruitment:**

Participants will be recruited from three Royal Women’s Hospital outpatient clinics: general gynaecology, chronic pelvic pain, and reproductive services. We aim to recruit a total of 32 women, which, based on previous studies, should be sufficient to achieve data saturation. However, we will request permission to recruit up to 50 women in the event that data saturation is not achieved, or some participants withdraw from the study.

**Recruitment procedure:**

A recruitment checklist will be created for each potential participant to ensure the recruitment procedure is followed for each woman.

Senior clinicians will review clinic lists and identify potentially eligible participants who fit the experience categories. The clinician will introduce the study to potential participants at the end of their clinic appointment, giving them a brief explanation and offering them a recruitment pack. The recruitment pack will contain the following documents:

- A letter of invitation (A7)
- An Expression of Interest form (EOI) (A8)
- A Participation and Consent for (PICF) (A9)

The letter of invitation will describe the EndoNeeds project, and invite women to complete and return the EOI form if they wish to be contacted about participating in the project. The EOI form will ask women to provide their contact details and preferred method, day and time of contact. Potential participants who return the EOI will be contacted by their preferred method by one of the investigators. After obtaining verbal consent, the study details will be
discussed and the investigator will determine which of the categories of endometriosis experience (listed above) the woman fits. If those categories have been filled, the woman will be thanked for her interest in the research, and asked if she is willing to be contacted for phase 2 of the EndoNeeds project, the survey pilot.

Eligible women who are available and willing to participate will be invited to attend one of the focus groups; written informed consent using the PICF will be obtained in person at the start of the focus group meeting. The PICF will describe the study, emphasise that participation is voluntary and that they may choose not to participate; may withdraw at any time, and that their decision to participate or not will not impact their medical care. A toll-free number will be provided to potential participants so that they can ask the researchers any questions. At each focus group, participants will be reminded that they may choose to withdraw from the study at any time. If a participant withdraws, she will be asked to complete a study withdrawal form.

Potential participants who do not respond will be followed up by their preferred contact method by the researchers two weeks after initial contact. If there is still no response, the researchers will contact the potential participant by the alternative methods she has provided. No further follow up will be made to non-responders after this.

**Exposure/outcome of interest:**

As this is an exploratory study, there is no single outcome of interest, other than the identification of the needs of women with endometriosis.
Data Collection:

This research will be conducted using focus group discussions. The focus groups will comprise 8-10 participants, will be facilitated by two researchers, and will run for approximately two hours. Participants will complete a short questionnaire at the start of the session to collect socio-demographic and clinical information (A10). A discussion guide will be used to structure the conversation, which will explore participants’ views on what they perceive to be their needs (past, present and future) in their endometriosis care (A11). Sensitising concepts that have been identified from other unmet needs surveys, the qualitative literature in endometriosis and discussions with the EndoNeeds working group, have been used to structure the discussion guide. The working group is comprised of gynaecologists, pain specialists, a psychologist, a physiotherapist, a nurse and patients, and has been assembled to oversee the EndoNeeds project and provide expert opinion (A12).

The discussion will be digitally recorded, and detailed notes taken by the researchers during the session. The recording of the discussion will be professionally transcribed verbatim. Focus groups will be conducted until data saturation is achieved (that is, no new information is emerging from the discussions). Based on previous qualitative research in this field, it is estimated that approximately four focus groups will be sufficient to achieve data saturation. If (based on interim analysis) data saturation is achieved with fewer groups, the remaining focus groups will still be conducted to give women the opportunity to share their ideas. If data saturation is not achieved with four focus groups, participants will need to be recruited for additional focus group discussions until saturation is achieved.
Data analysis plan:
Data generated from the focus groups will be transcribed *verbatim* and imported into a qualitative data analysis software program (QSR NVivo version 10)\(^{97}\) to facilitate data management and analysis.

Transcripts will be analysed using the constant comparison technique developed for grounded theory research by Glaser and Strauss.\(^{98}\) The goal of this type of analysis is to generate a theory or a set of themes using three stages of analysis:

1. Open coding: The data is broken into smaller units; a descriptor is ascribed to each unit.
2. Axial coding: The codes are grouped into categories.
3. Selective coding: Themes are developed that represent the content in each category.\(^{99}\)

Conclusions are then drawn from the data, based on the themes that have emerged. These conclusions must then be tested, or verified, through further data analysis, and potentially further data collection if there is still ambiguity.\(^{93, 100}\)

For this study, two researchers will conduct the coding process. This process will commence as soon as data are first available, so that there is opportunity to revisit ambiguous concepts in later focus groups for clarification. Once the data are summarised and organised into codes, the researchers will identify themes and sub-themes emerging from the data. This collaborative process of coding and identifying a conceptual framework adds reliability and validity to the research.\(^{94}\) The de-identified demographic data will be compared with the qualitative themes, and relationships described quantitatively, but the findings are not expected to achieve statistical significance.
The themes identified in this study will be used to develop question items for the EndoNeeds survey. All needs identified in the qualitative stage will be included in the pilot survey – item reduction will take place in the next stage of the project.

**Limitations And Strengths:**

There are a number of limitations in this study design. Firstly, basing recruitment at a tertiary women’s hospital may introduce sampling bias, as participants may have more severe endometriosis than those not being treated in hospital. The use of purposive recruitment should minimise this effect, as efforts will be made to recruit women with mild or no symptoms. Additionally, the EndoNeeds pilot survey (which will be distributed to a wider population) will include a free text section, allowing participants to write down any needs that have not been included in the survey.

The focus group method of data collection also has some limitations: there is the potential for results to be influenced by outspoken participants. The facilitators will be aware of this risk, and ensure that everyone in the group has a chance to speak. Additionally, some participants may feel uncomfortable discussing sensitive topics in a group setting. Participants will be invited to contact the researchers with any needs that were not discussed in the focus groups after the session, and this may be the opportunity for some to identify needs of a sensitive nature.

The main strengths of the focus group design, and the reason it is being used, is that it provides a rich source of data, allowing for broad scoping of a topic from a group perspective, without being overly resource-intensive.
Operational Issues:

Funding:
Phase 1 of this project will be funded by a research grant from Endometriosis Australia.

Recruitment:
Clinicians need to be trained to introduce the project to potential participants.

Training:
Emma Steele will need to be trained in focus group facilitation techniques by Michelle Peate.

Logistics:
Focus group venue will need to be booked, gratuities and refreshments organised.

Ethical Considerations
An application for ethical approval for this research will be made to The Royal Women’s Hospital Human Research Ethics Committee after first obtaining peer review and approval from The Royal Women’s Hospital Research Committee.

Confidentiality and privacy:
Confidentiality and privacy will be optimised in the following ways: Potential participants will be approached for recruitment and all other contact in a confidential manner, and no public dissemination of participant details will occur. Secondly, participants will be reminded of the need to respect the privacy of others in the focus groups in the PICF and at the beginning of each focus group session. Finally, the transcripts from the focus group discussions will not contain any identifying data and each transcript will be assigned a unique identifying number. Contact details for the researchers and relevant ethics committee will be supplied to the participants to address any questions or concerns they may have.
De-identified data will be entered into a password-protected database on the University of Melbourne Department of Obstetrics and Gynaecology secure server, as will a separate tracking document linking participant names to their unique transcript number. Only investigators listed in the study protocol will have the authority to access the study data.

Only de-identified results will be published. In qualitative research, direct quotations are usually assigned to a pseudonym rather than a unique identifier. These pseudonyms will be assigned *ad hoc* during manuscript preparation, rather than being permanently associated with a particular participant. Generalised results will be submitted for publication with peer-reviewed journals, and may be presented at professional forums, relevant health network, national and international conferences.

At the end of the study, all interested participants will be sent (via email or post) a summary of the overall results of the study, written in plain language. Only de-identified aggregate findings will be included in this summary, not individual findings.

**Consent:**
To minimise the risk of potential participants feeling pressured to be involved in the study, clinicians will wait until the end of the patient appointment to discuss recruitment, and will stress that involvement is voluntary and will not affect clinical care. Additionally, any further communication the potential participant has about the study will be with the investigators, who are not involved in their clinical care.

The PICF will provide full details of the study and what it involves, including the potential benefits and risks to the participant. When the potential participant is contacted to determine eligibility for the study, they will have the opportunity to ask questions regarding the study.
Contact details for the investigators will also be supplied to the participants should they have any further questions.

Participants will be offered a small gratuity of $30 per participant to cover the cost of parking and transport during the focus group session. Light refreshments will also be provided during the focus group session. It is not anticipated that these small incentives will impair the voluntary nature of consent.

If a participant wishes to withdraw from the study, they can do so at any time without having to give a reason. Withdrawal from the study will not have an adverse impact on the their relationship with clinicians, their services or the researchers. If a participant withdraws from the study once the focus groups have been conducted, it may be difficult to ensure that their contributions to the discussion are not used in the final analysis, as it may not be possible to identify individual participants from the audio recording. This issue will be made clear in the PICF and again at the beginning of each focus group, giving participants the opportunity to leave the session before recording has started if they wish to do so.
Data storage and record retention:

<table>
<thead>
<tr>
<th>Data Format</th>
<th>Data items</th>
<th>Storage</th>
<th>Retention</th>
<th>Deletion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic</td>
<td>Scanned PICFs, transcripts, demographic data</td>
<td>Password-protected server, University of Melbourne Dept Obstetrics and Gynaecology, only accessible by researchers listed in protocol.</td>
<td>5 years (NHMRC guidelines).</td>
<td>Reformatting/rewriting, ensuring that data and any ‘pointers’ in system are inaccessible.</td>
</tr>
<tr>
<td>Audio</td>
<td>Focus group recordings</td>
<td>As above.</td>
<td>Until transcripts have been checked for accuracy.</td>
<td>As above.</td>
</tr>
<tr>
<td>Hardcopy</td>
<td>PICFs, demographic and clinical surveys</td>
<td>Locked storage, University of Melbourne Dept Obstetrics and Gynaecology, only accessible by researchers listed in protocol.</td>
<td>Until completion of study. Paperwork will then be scanned and stored electronically.</td>
<td>Shredded and disposed of using a secure confidential destruction service.</td>
</tr>
</tbody>
</table>

Risks and benefits:

One risk of the study, as with all human studies of identifiable individual respondents, is that privacy or confidentiality may be breached. Measures to mitigate this risk are addressed in sections 7a and c. The other principal risk of this study is that participants may become distressed during or after the focus group sessions. Distress may be due to the sensitive nature of the topics being discussed, which include emotional well-being, relationships, sexuality and infertility. Discussion of these issues may cause participants to experience potentially distressing or discomforing emotions such as embarrassment, anger, sorrow or regret.
Additionally, the nature of the focus group discussion means there is potential for distress as a result of interactions between group members, especially if the topic being discussed is controversial or brings up strong emotions for members. The investigators facilitating the focus groups will be alert to this possibility, and will use facilitation techniques, such as giving everyone a chance to speak or moving the conversation to another topic, to ensure that interactions between members remain respectful and balanced. The potential for distress is disclosed to the participant in the PICF, and they will be reminded during the focus groups that they may decline to participate in any part of the discussion, or leave the group at any time if they wish. The focus group facilitator is able to recognise signs of high levels of distress (tears, difficulty speaking) and will "check in" throughout the session by asking whether participants are experiencing distress. The facilitator will use a distress protocol to guide management of distress (A13). In the event of excessively high distress, the participant will be excused from the focus group and, depending on the degree of risk, the facilitator will refer the participant to mental health or emergency services. Excessively high distress is considered to be a low-probability risk with this research. Participants will be given a toll-free telephone number to call if they experience distress following the focus group sessions. Participants who call this number will be referred to appropriate clinical or mental health services, depending on their individual circumstances.

Individual participants will accrue little direct benefit from their involvement in the study. However, they could gain some benefit through satisfaction at contributing to endometriosis research and social connections formed with other women in their group. The project has the potential to benefit society through the identification of domains of needs specific to women with endometriosis that can be used to design the EndoNeeds survey.
Dissemination Plan:

Data resulting from this project may be disseminated in the following ways:

- Plain-language summary of the results to be sent to participants.
- Submission for publication in peer-reviewed journals.
- Presentation at professional forums, relevant health network, national and international conferences.
- Publication in mainstream media reports.
- Publication on websites and social media of Royal Women’s Hospital, University of Melbourne, Endometriosis Australia and other consumer organisations.

Data resulting from this research project is understood to be owned by the investigators until such time as the information is formally published by a peer-reviewed journal. At that time, it is understood that the journal will own the published form of the results of this project, as per the signed copyright agreement. The criteria of the Australian Code for the Responsible Conduct of Research will be used to guide authorship of publications. Discussion on authorship will occur at an early stage in the research process and be reviewed periodically.

Outcomes And Significance:

The overall goal of the EndoNeeds Project is to improve the lives of women with endometriosis through the identification and quantification of their unmet needs. It will be the first unmet needs survey for women with endometriosis in the world. Phase one of this research, the subject of the current protocol, will provide new information on the types of needs that are relevant to women with endometriosis. This information will then be used to develop the EndoNeeds survey. Once the unmet needs of women with endometriosis are
known, interventions can be designed to address them, and therefore improve quality of life in this population.
SUMMARY & CONCLUSION

This thesis has demonstrated the need for an unmet needs survey in women with endometriosis. Chapter 1 gave a background on endometriosis, highlighted the need for a patient-centered approach in the care of women with this disease, and introduced the unmet needs survey and other patient-reported outcome measures. Chapter 2 described the results of a systematic review that explored the types of PROMs used in the endometriosis literature, identified possible needs of women with endometriosis from the qualitative literature, and investigated the development of unmet needs surveys in other health conditions. A gap in the evidence was demonstrated; while we have a good understanding of the impacts of endometriosis on the lives and wellbeing of women, there is currently no way of systematically identifying and quantifying their needs, so that interventions can be designed to meet them and improve quality of life. Chapter 3 was a protocol for exploratory qualitative research that will provide a conceptual basis for an unmet needs survey for women with endometriosis – the EndoNeeds survey. The design methodology and ethical issues were explored in detail, and all research decisions discussed and justified.

This is just the first step in a large project aimed at developing an unmet needs survey for women with endometriosis. Involvement of patients from the earliest stages of the project will ensure that the concepts of most relevance to the patient are captured in the final instrument. It is hoped that the final survey can be used to enhance individual patient-centered clinical care, drive quality improvement efforts in health services and contribute to the patient-reported evidence around endometriosis, improving the physical, psychological and social wellbeing for women with this condition.
REFERENCES

1.; 2012.
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References

References

References


References


References


References


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174. Denny E. I never know from one day to another how I will feel: pain and uncertainty in women with endometriosis. Qual Health Res. 2009;19(7):985-95.
176. Whelan E. 'No one agrees except for those of us who have it': endometriosis patients as an epistemological community. Sociol Health Illn. 2007;29(7):957-82.
## APPENDICES

### Table 1: Summary of the EndoNeeds Project methodology

<table>
<thead>
<tr>
<th>Study type</th>
<th>PHASE 1 (exploratory research)</th>
<th>PHASE 2 (EndoNeeds Pilot Survey)</th>
<th>PHASE 3 (EndoNeeds Survey)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study type</td>
<td>Qualitative</td>
<td>Pilot survey, mixed methods, cross-sectional</td>
<td>Full survey, mixed methods, cross-sectional</td>
</tr>
<tr>
<td>Study setting</td>
<td>Royal Women’s Hospital, Melbourne (RWH).</td>
<td>1. RWH 2. Endometriosis consumer groups</td>
<td>1. RWH 2. Endometriosis consumer groups 3. Websites and social media of above organisations and other interested parties.</td>
</tr>
<tr>
<td>Sample size</td>
<td>Sample until data saturation is reached. Estimated size = 4-5 focus groups of 8-10 people.</td>
<td>To be confirmed following statistical advice.</td>
<td>To be confirmed following statistical advice.</td>
</tr>
</tbody>
</table>
## The EndoNeeds Project

<table>
<thead>
<tr>
<th>Study population (cont)</th>
<th>Recruitment strategy</th>
<th>PHASE 1 (exploratory research)</th>
<th>PHASE 2 (EndoNeeds Pilot Survey)</th>
<th>PHASE 3 (EndoNeeds Survey)</th>
</tr>
</thead>
</table>

2. Clinician approaches potential participants during clinic appointment.  
3. Offers recruitment pack containing:  
   ▪ Letter of invitation  
   ▪ Expression of interest form  
   ▪ Participant information and consent form  
4. Participants who return expression of interest form contacted by researchers to discuss involvement in study.  

To be confirmed following stakeholder engagement.  
To be confirmed following stakeholder engagement.
## Appendix 1

### The EndoNeeds Project

<table>
<thead>
<tr>
<th>Study population (cont)</th>
<th>Inclusion criteria</th>
<th>PHASE 1 (exploratory research)</th>
<th>PHASE 2 (EndoNeeds Pilot Survey)</th>
<th>PHASE 3 (EndoNeeds Survey)</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Women</td>
<td>Women</td>
<td>Women</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surgically-diagnosed endometriosis</td>
<td>Surgically-diagnosed endometriosis (self-reported)</td>
<td>Surgically-diagnosed endometriosis (self-reported)</td>
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<tr>
<td></td>
<td></td>
<td>18+</td>
<td>18+</td>
<td>18+</td>
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<td></td>
<td></td>
<td>English speaking and reading</td>
<td>English speaking and reading</td>
<td>English speaking and reading</td>
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<td></td>
<td></td>
<td>Melbourne-based and able to</td>
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<td></td>
<td></td>
<td>attend focus group</td>
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<table>
<thead>
<tr>
<th>Exclusion criteria</th>
<th>Cognitive disability</th>
<th>Cognitive disability</th>
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<table>
<thead>
<tr>
<th>Exposure</th>
<th>Exposure of interest</th>
<th>PHASE 1 (exploratory research)</th>
<th>PHASE 2 (EndoNeeds Pilot Survey)</th>
<th>PHASE 3 (EndoNeeds Survey)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>n/a</td>
<td></td>
<td>EndoNeeds pilot survey.</td>
<td>EndoNeeds Survey.</td>
</tr>
</tbody>
</table>

| Outcome of interest    | Identification of the needs of women with endometriosis. | Refinement of question items and psychometric testing. | Measuring the needs of women with endometriosis and the extent to which they are being met. |

<table>
<thead>
<tr>
<th>Data</th>
<th>Data collection</th>
<th>PHASE 1 (exploratory research)</th>
<th>PHASE 2 (EndoNeeds Pilot Survey)</th>
<th>PHASE 3 (EndoNeeds Survey)</th>
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<tr>
<td></td>
<td>Focus groups:</td>
<td></td>
<td>Online survey (REDCap):</td>
<td>Online survey (REDCap):</td>
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<tr>
<td></td>
<td>▪ Estimated running time: 2 hours</td>
<td></td>
<td>▪ Questions developed from literature review, working groups and focus groups.</td>
<td>▪ Questions refined from EndoNeeds Pilot Survey.</td>
</tr>
<tr>
<td></td>
<td>▪ Audio-recorded</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ 2 facilitators</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Data access            | Recording of focus groups transcribed verbatim. | 1. Quantitative data exported from REDCap into SPSS. | 1. Quantitative data exported from REDCap into SPSS. |
|                        |                                                | 2. Qualitative data exported from Redcap into NVivo. | 2. Qualitative data exported from Redcap into NVivo. |
### The EndoNeeds Project

<table>
<thead>
<tr>
<th>Data (cont)</th>
<th>Data analysis</th>
<th>PHASE 1 (exploratory research)</th>
<th>PHASE 2 (EndoNeeds Pilot Survey)</th>
<th>PHASE 3 (EndoNeeds Survey)</th>
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<tbody>
<tr>
<td>Measurement tools</td>
<td>N/A</td>
<td>Thematic analysis using NVivo. 2 researchers will develop coding framework and code data</td>
<td>1. Quantitative analysis plan to be confirmed following statistical advice. 2. Thematic analysis of open questions.</td>
<td>1. Quantitative analysis plan to be confirmed following statistical advice. 2. Thematic analysis of open questions.</td>
</tr>
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</table>

**Measurement tools**

- N/A

**EndoNeeds Pilot Survey**

**EndoNeeds Survey**
Table 2: Systematic review search terms.*

<table>
<thead>
<tr>
<th>Database</th>
<th>Medline (1950 – March 2017) and PsychINFO (1806 – March 2017) – Ovid database</th>
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<tr>
<td><strong>Search concepts:</strong></td>
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<td><strong>Concept 1</strong></td>
<td>(exp Endometriosis/ec, ep, eh, nu, px, rh, th [Economics, Epidemiology, Ethnology, Nursing, Psychology, Rehabilitation, Therapy]) AND (&quot;health-related quality of life&quot; or HR-QOL or &quot;quality of life&quot; or &quot;patient reported outcome*&quot; or &quot;patient satisfaction&quot; or &quot;screening tool*&quot; or &quot;psychometric measure&quot; or wellbeing or psychosocial or survey* or questionnaire* or measure* or instrument* or experience)</td>
</tr>
<tr>
<td><strong>Concept 2</strong></td>
<td>(exp Endometriosis/ec, eh, nu, px, rh, th [Economics, Ethnology, Nursing, Psychology, Rehabilitation, Therapy]) AND (&quot;unmet need*&quot; or &quot;needs assessment tool*&quot; or &quot;needs assessment*&quot; or &quot;health care need*&quot; or &quot;supportive care need*&quot; or survey* or questionnaire* or measure*)</td>
</tr>
<tr>
<td><strong>Concept 3</strong></td>
<td>(&quot;unmet need*&quot; or &quot;needs assessment tool*&quot; or &quot;needs assessment*&quot; or &quot;health care need*&quot; or &quot;supportive care need*&quot;) and (&quot;chronic illness&quot; or cancer or stroke or heart) and review</td>
</tr>
<tr>
<td><strong>Concept 4</strong></td>
<td>(endometriosis and (experience or satisfaction or perception) and (qualitative or interview or &quot;focus group&quot;)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]</td>
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<thead>
<tr>
<th>Database</th>
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<td>(&quot;health-related quality of life&quot; OR HR-QOL OR &quot;quality of life&quot; OR &quot;patient reported outcome*&quot; OR &quot;patient satisfaction&quot; OR &quot;screening tool*&quot; OR &quot;psychometric measure&quot; OR wellbeing OR psychosocial OR bother* OR survey* OR questionnaire* OR measure* OR instrument OR experience) AND (endometriosis)</td>
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<tr>
<td><strong>Concept 2</strong></td>
<td>endometriosis AND (&quot;unmet need*&quot; or &quot;needs assessment tool*&quot; or &quot;needs assessment*&quot; or &quot;health care need*&quot; or &quot;supportive care need*&quot; or survey* or questionnaire* or measure*)</td>
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<tr>
<td><strong>Concept 3</strong></td>
<td>(&quot;unmet need*&quot; or &quot;needs assessment tool*&quot; or &quot;needs assessment*&quot; or &quot;health care need*&quot; or &quot;supportive care need&quot;) AND (&quot;chronic illness&quot; or cancer or stroke or heart) and review</td>
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<tr>
<td><strong>Concept 4</strong></td>
<td>endometriosis AND (experience OR satisfaction OR perception) AND (qualitative OR interview OR “focus group”)</td>
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</table>
# Appendix 2

## Database

Pubmed (1997 – March 2017)

### Search concepts:

<table>
<thead>
<tr>
<th>Concept 1</th>
<th>Search Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concept 1</td>
<td>(&quot;endometriosis/epidemiology&quot; OR &quot;endometriosis/ethnology&quot; OR &quot;endometriosis/nursing&quot; OR &quot;endometriosis/psychology&quot; OR &quot;endometriosis/rehabilitation&quot;) AND (&quot;health-related quality of life&quot; or HR-QOL or &quot;quality of life&quot; or &quot;patient reported outcome*&quot; or &quot;patient satisfaction&quot; or &quot;screening tool*&quot; or &quot;psychometric measure&quot; or wellbeing or psychosocial or survey* or questionnaire* or measure* or instrument* or experience*)</td>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Concept 4</th>
<th>Search Terms</th>
</tr>
</thead>
</table>
| Concept 4 | endometriosis AND (experience OR satisfaction OR perception) AND (qualitative OR interview OR “focus group*”)

* All searches limited to English language and human studies.
Table 3: Generic PROMs in endometriosis research.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>QOL</th>
<th>Psychiatric</th>
<th>Psychological</th>
</tr>
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<tbody>
<tr>
<td>Brief pain inventory SF-19&lt;sup&gt;63&lt;/sup&gt;</td>
<td>Medical outcomes questionnaire (SF-36)&lt;sup&gt;61, 62, 101-119&lt;/sup&gt;</td>
<td>Hamilton anxiety rating scale&lt;sup&gt;120-122&lt;/sup&gt;</td>
<td>Formal characteristics of behaviour-temperament inventory&lt;sup&gt;123&lt;/sup&gt;</td>
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<tr>
<td>McGill pain questionnaire&lt;sup&gt;105, 117, 124, 125&lt;/sup&gt;</td>
<td>National health interview survey&lt;sup&gt;101&lt;/sup&gt;</td>
<td>Beck depression inventory&lt;sup&gt;61, 117, 121, 122, 125-128&lt;/sup&gt;</td>
<td>Beliefs about pain control questionnaire&lt;sup&gt;123&lt;/sup&gt;</td>
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<tr>
<td>Numerical rating scale (pain)&lt;sup&gt;123, 129-131&lt;/sup&gt;</td>
<td>Euroqual 5-D&lt;sup&gt;132&lt;/sup&gt;</td>
<td>Spielberger state-trait anxiety inventory&lt;sup&gt;122, 125, 126, 128&lt;/sup&gt;</td>
<td>Coping strategies questionnaire&lt;sup&gt;105, 117, 128, 133&lt;/sup&gt;</td>
</tr>
<tr>
<td>West Haven-Yale multidimensional pain inventory&lt;sup&gt;134&lt;/sup&gt;</td>
<td>WHO QOL assessment-bref&lt;sup&gt;121, 122, 135, 136&lt;/sup&gt;</td>
<td>Mini mental state examination&lt;sup&gt;121&lt;/sup&gt;</td>
<td>Perceived stress questionnaire&lt;sup&gt;106, 107&lt;/sup&gt;</td>
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<tr>
<td>Pelvic pain visual analogue scale&lt;sup&gt;102, 107, 116, 119, 121, 128, 129, 133, 136-144&lt;/sup&gt;</td>
<td>International physical activity questionnaire&lt;sup&gt;140&lt;/sup&gt;</td>
<td>Centre for epidemiological studies depression scale&lt;sup&gt;106&lt;/sup&gt;</td>
<td>Eysenck personality questionnaire&lt;sup&gt;125, 139&lt;/sup&gt;</td>
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<tr>
<td>Quality of life index&lt;sup&gt;65&lt;/sup&gt;</td>
<td>Hamilton rating scale for depression&lt;sup&gt;122&lt;/sup&gt;</td>
<td>Fertility problems stress scale&lt;sup&gt;133&lt;/sup&gt;</td>
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<tr>
<td>PGI quality of life scale&lt;sup&gt;145&lt;/sup&gt;</td>
<td>Brief symptom inventory&lt;sup&gt;139&lt;/sup&gt;</td>
<td>Post-sleep inventory&lt;sup&gt;140&lt;/sup&gt;</td>
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<tr>
<td>VAS (health status)&lt;sup&gt;146&lt;/sup&gt;</td>
<td>Rand mental health inventory&lt;sup&gt;133&lt;/sup&gt;</td>
<td>Body attitude test&lt;sup&gt;61&lt;/sup&gt;</td>
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<td>Rand health survey&lt;sup&gt;134&lt;/sup&gt;</td>
<td>Beck anxiety inventory&lt;sup&gt;61&lt;/sup&gt;</td>
<td>Mishel uncertainty in illness scale&lt;sup&gt;147&lt;/sup&gt;</td>
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<td></td>
<td>General health questionnaire&lt;sup&gt;125&lt;/sup&gt;</td>
<td>Courthald emotional control scan</td>
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<tr>
<td></td>
<td>Symptom checklist&lt;sup&gt;65&lt;/sup&gt;</td>
<td>Rosenberg self-esteem scale&lt;sup&gt;148&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>State-trait anger expression inventory&lt;sup&gt;65&lt;/sup&gt;</td>
<td>Index of clinical stress&lt;sup&gt;134&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>Self-rating anxiety scale&lt;sup&gt;65&lt;/sup&gt;</td>
<td>Beliefs and attitudes towards menstruation questionnaire&lt;sup&gt;134&lt;/sup&gt;</td>
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</tr>
<tr>
<td></td>
<td>Asha deep depression scale&lt;sup&gt;145&lt;/sup&gt;</td>
<td>Golombok-Rust inventory of marital state&lt;sup&gt;125&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>Self rating depression scale&lt;sup&gt;65&lt;/sup&gt;</td>
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<td></td>
<td>Hospital anxiety and depression scale&lt;sup&gt;112, 130&lt;/sup&gt;</td>
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<td>Treatment satisfaction</td>
<td>Work/financial</td>
<td>Sexual function/satisfaction</td>
<td>Social</td>
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<tr>
<td><strong>Clinical global impression scale</strong>&lt;sup&gt;137&lt;/sup&gt;</td>
<td>Work productivity and activity impairment questionnaire&lt;sup&gt;104, 109, 113&lt;/sup&gt;</td>
<td>Golombok Rust inventory of sexual satisfaction&lt;sup&gt;126, 135&lt;/sup&gt;</td>
<td>Social support scale&lt;sup&gt;106&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Patient reactions assessment</strong>&lt;sup&gt;134&lt;/sup&gt;</td>
<td>Work ability index&lt;sup&gt;149&lt;/sup&gt;</td>
<td>Sabbatsberg’s sexual self-rating scale&lt;sup&gt;138&lt;/sup&gt;</td>
<td>Social adjustment scale&lt;sup&gt;139&lt;/sup&gt;</td>
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<tr>
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</tr>
<tr>
<td>Endometriosis Health Profile</td>
<td>X X X</td>
<td>No</td>
<td>Interviews (n=25), pilot (n=1000)</td>
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<td>Pain and Bleeding Diary</td>
<td>X X</td>
<td>No</td>
<td>Clinician input, focus groups (n=38), iterative cognitive interviews (n=22), pilot (n=128)</td>
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<td>Biberoglu and Behrman Scale</td>
<td>X</td>
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<td>Patient’s Perceived Change in Endometriosis pain</td>
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<td>EndoCOST Questionnaire</td>
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<td>Pilot (n=6)</td>
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<td>EndoCare Questionnaire</td>
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<td>No</td>
<td>Literature review, expert panel, focus groups (n=10)</td>
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<tr>
<td>Endometriosis Treatment Satisfaction Questionnaire&lt;sup&gt;64&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Endometriosis Pain Map&lt;sup&gt;55&lt;/sup&gt;</td>
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<td>Endometriosis Health Profile Short Form 5&lt;sup&gt;113&lt;/sup&gt;</td>
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<tr>
<td>Uterine Pain and Bleeding Women’s Research Study&lt;sup&gt;156&lt;/sup&gt;</td>
<td>X X X</td>
<td>X X X</td>
<td>X No</td>
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<tr>
<td>Unnamed, Cox&lt;sup&gt;68&lt;/sup&gt;</td>
<td>X</td>
<td>X X X</td>
<td>Information</td>
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<tr>
<td>Dutch Endometriosis Society questionnaire&lt;sup&gt;69&lt;/sup&gt;</td>
<td>X X X X X X X X X</td>
<td>Information</td>
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<td>Unnamed, Colwell&lt;sup&gt;101&lt;/sup&gt;</td>
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<td>No</td>
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<tr>
<td>Unnamed, Sinai&lt;sup&gt;157&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
<td>No</td>
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<td>Unnamed, Lagana&lt;sup&gt;65&lt;/sup&gt;</td>
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## Appendix 4

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<tr>
<th>Survey Name</th>
<th>Domains Addressed</th>
<th>Needs Addressed?</th>
<th>Development methodology</th>
<th>Validated?</th>
<th>Validation population</th>
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<tr>
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<td>Symptoms</td>
<td>Daily living</td>
<td>Psychiatric</td>
<td>Social</td>
<td>Treatment satisfaction</td>
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<td>Unnamed, Lemaire(^{147})</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>No</td>
<td>Unknown</td>
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<tr>
<td>Unnamed, Hadfield(^{158})</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>No</td>
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<tr>
<td>Unnamed, Greene(^{159})</td>
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<td></td>
<td>X</td>
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<td>No</td>
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<tr>
<td>Unnamed, Hadelist(^{67})</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Unnamed, Fourquet(^{69})</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>No</td>
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<tr>
<td>Unnamed, Fernandez(^{160})</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Survey Name</td>
<td>Domains Addressed</td>
<td>Needs Addressed?</td>
<td>Development methodology</td>
<td>Validated?</td>
<td>Validation population</td>
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<tr>
<td>Unnamed, Fagervold¹⁶¹</td>
<td>X X X X X</td>
<td>No</td>
<td>Unknown</td>
<td>No</td>
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<tr>
<td>Unnamed, Darrow¹⁶²</td>
<td>X X</td>
<td>No</td>
<td>Unknown</td>
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<td>Unnamed, Chapron¹⁶³</td>
<td>X X X</td>
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<td>Unknown</td>
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<tr>
<td>Unnamed, Bodner¹¹⁸</td>
<td>X X</td>
<td>No</td>
<td>Clinician panel</td>
<td>Yes</td>
<td>Scottish women with endometriosis (n=197)</td>
</tr>
<tr>
<td>Unnamed, Boden¹⁶⁴</td>
<td>X X X</td>
<td>No</td>
<td>Unknown</td>
<td>No</td>
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</table>
Table 5: Qualitative literature in endometriosis.
(Domains NOT included in current endometriosis PROMs or unmet needs surveys for other health conditions are highlighted in bold.)

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Aims</th>
<th>Data collection</th>
<th>Data analysis</th>
<th>Domains</th>
<th>Needs identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grundstrom, 2017&lt;sup&gt;165&lt;/sup&gt;</td>
<td>Swedish women with laparoscopic diagnosis of endometriosis (n=9).</td>
<td>To describe the experience of healthcare encounters.</td>
<td>Interviews</td>
<td>Stevick-Colaizzi-Keen method</td>
<td>Doctor attitudes, empowerment, information.</td>
<td>More open discussion around menstruation and menstrual irregularities, efforts by healthcare professionals to improve knowledge of endo in patients.</td>
</tr>
<tr>
<td>Young, 2016&lt;sup&gt;78&lt;/sup&gt;</td>
<td>Australian women with self-reported laparoscopic diagnosis of endometriosis (n=26).</td>
<td>To investigate women’s experience of healthcare they received for endometriosis and fertility.</td>
<td>Interviews</td>
<td>Thematic</td>
<td>Health system, fertility, doctor communication, doctor attitudes, information.</td>
<td>Information on chance of conceiving, meaning and implications of fertility testing, information relevant to needs.</td>
</tr>
<tr>
<td>Shoebotham, 2016&lt;sup&gt;166&lt;/sup&gt;</td>
<td>US and UK members of online endometriosis support groups (n=69).</td>
<td>To examine the presence of therapeutic affordances as perceived by women who use endometriosis online support groups.</td>
<td>Web-based interviews</td>
<td>Thematic</td>
<td>Support, information, consumer groups.</td>
<td>Clearer privacy policies, using health professionals to moderate content, structuring forums to encourage positive stories.</td>
</tr>
<tr>
<td>Roomaney, 2016&lt;sup&gt;70&lt;/sup&gt;</td>
<td>South African women with endometriosis (n=25).</td>
<td>Examination of health-related quality of life.</td>
<td>Interviews</td>
<td>Thematic</td>
<td>Symptoms, daily living, psychological, sexuality, relationships, fertility, social, employment, information, health system, financial.</td>
<td>Interdisciplinary care, improved measures of quality of life.</td>
</tr>
<tr>
<td>Mellardo, 2016&lt;sup&gt;72&lt;/sup&gt;</td>
<td>Brazilian women with endometriosis and chronic pelvic pain (n=29).</td>
<td>To evaluate social isolation in women with endometriosis and chronic pelvic pain.</td>
<td>Focus groups</td>
<td>Grounded theory, thematic</td>
<td>Social, information, psychological, relationships, sexuality.</td>
<td>Early education on nature and clinical course of endometriosis, rebuilding social ties, multidisciplinary management.</td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Aims</td>
<td>Data collection</td>
<td>Data analysis</td>
<td>Domains</td>
<td>Needs identified</td>
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<tr>
<td>Kundu, 2015</td>
<td>Participants in a training program for women with endometriosis, Germany</td>
<td>Identify supporting and inhibiting factors on disease management to</td>
<td>Open questions on evaluation questionnaire</td>
<td>Thematic</td>
<td>Social, support, treatment, health system, doctor attitudes, doctor communication, financial.</td>
<td>Doctor training, better pre/post-operative care, interdisciplinary teamwork, empathy and belief of symptoms by doctors, support from doctors, financial support for HC costs, communication with surgeon, someone to talk to.</td>
</tr>
<tr>
<td>Hudson, 2015</td>
<td>UK women with endometriosis and their partners (n=44).</td>
<td>Exploring the impact of biographical disruption of endometriosis from</td>
<td>Semi-structured interviews, separately and in couples</td>
<td>Thematic and dyadic analysis</td>
<td>Sexuality, fertility, employment, social, relationships.</td>
<td>Couple-centered approach to endometriosis care.</td>
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<tr>
<td>Riazi, 2014</td>
<td>Iranian women with endometriosis (n=12) and gynaecologists (n=6).</td>
<td>Exploring the perception and experiences of patients and gynaecologists about occurrence and diagnosis of endometriosis.</td>
<td>Semi-structured interviews</td>
<td>Thematic</td>
<td>Symptoms, psychological, social, health system, diagnostic methods.</td>
<td>Accurate, non-invasive diagnostic methods.</td>
</tr>
<tr>
<td>Moradi, 2014</td>
<td>Australian women with endometriosis (n=35).</td>
<td>Exploring women’s experiences of the impact of endometriosis, and whether they differ with age.</td>
<td>Focus groups</td>
<td>Thematic</td>
<td>Symptoms, delayed diagnosis, treatment, doctor knowledge, public awareness, information, psychological, relationships, sexuality, social, education, employment, financial, daily living.</td>
<td>Increasing general practitioner’s (GPs) knowledge, information for patients, more and earlier information in schools, increasing awareness in society, more support groups.</td>
</tr>
<tr>
<td>Fauconnier, 2013</td>
<td>French women with endometriosis (n=41).</td>
<td>Comparison of patient-centered descriptions of endometriosis pain with physician descriptions.</td>
<td>Interviews</td>
<td>Collaizzi’s method (phenomenology)</td>
<td>Symptoms.</td>
<td>PROMs that use same language as patients to describe pain.</td>
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<tr>
<td>Study</td>
<td>Population</td>
<td>Aims</td>
<td>Data collection</td>
<td>Data analysis</td>
<td>Domains</td>
<td>Needs identified</td>
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<tr>
<td>Neal, 2011</td>
<td>Endometriosis blogs (n=11).</td>
<td>Understanding how bloggers present information sources and their authority.</td>
<td>Capture of blog posts over 2 month period</td>
<td>Potter’s discourse analysis</td>
<td>Support, consumer group, information.</td>
<td>Inclusion of carefully selected blogs and forums and account of ‘lived experience’ in patient resources.</td>
</tr>
<tr>
<td>Seear, 2009</td>
<td>Australian women with endometriosis (n=20).</td>
<td>Examination of phenomenon of non-compliance with health advice.</td>
<td>Semi-structured interviews</td>
<td>Thematic – interactive approach</td>
<td>Financial, lifestyle, health system, non-compliance.</td>
<td>-</td>
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<tr>
<td>Seear, 2008</td>
<td>Australian women with endometriosis (n=20).</td>
<td>Women becoming experts in their endometriosis care.</td>
<td>Semi-structured interviews</td>
<td>Thematic – interactive approach</td>
<td>Diagnosis, information, lifestyle, empowerment, support.</td>
<td>Support strategies for women to manage endometriosis, awareness campaigns about specialist endometriosis centres.</td>
</tr>
<tr>
<td>Denny, 2009</td>
<td>UK women with endometriosis (n=30).</td>
<td>Exploring the experience of living with endometriosis.</td>
<td>Semi-structured interviews and diary entries</td>
<td>Narrative analysis</td>
<td>Diagnosis, psychological, information.</td>
<td>-</td>
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<tr>
<td>Markovic, 2008</td>
<td>Australian women with endometriosis (n=30).</td>
<td>Comparison of socially constructed narratives of women with endometriosis according to social backgrounds.</td>
<td>In-depth interviews</td>
<td>Thematic analysis</td>
<td>Normalisation, social, relationships, symptoms, treatment, non-compliance, doctor knowledge, public awareness.</td>
<td>Increased role of schools in education and support in reproductive and gynaecological health, public health education about normality, improved education for health professionals in communication.</td>
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<tr>
<td>Manderson, 2008</td>
<td>Australian women with endometriosis (n=40).</td>
<td>Description of ‘circuit breakers’ that lead women to seek medical advice for endometriosis.</td>
<td>In-depth interview</td>
<td>Thematic analysis</td>
<td>Normalisation, social, doctor attitude, doctor knowledge, diagnostic delay, self-management, information, relationships.</td>
<td>Enhanced education and health promotion in schools, empowering young women to take charge of their own health.</td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Aims</td>
<td>Data collection</td>
<td>Data analysis</td>
<td>Domains</td>
<td>Needs identified</td>
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<td>Gilmour, 2008&lt;sup&gt;71&lt;/sup&gt;</td>
<td>NZ women with endometriosis (n=18).</td>
<td>Impact of endometriosis on work and social participation.</td>
<td>Unstructured interviews</td>
<td>Thematic analysis</td>
<td>Symptoms, employment, education, self-management, empowerment, information, doctor communication, nurse communication, consumer groups.</td>
<td>Information from health professionals, nurses going through written information with patients, development of information to give to employers and social group, flexible working arrangements.</td>
</tr>
<tr>
<td>Denny, 2008&lt;sup&gt;76&lt;/sup&gt;</td>
<td>UK women with endometriosis (n=30).</td>
<td>Experience of women with endometriosis in the primary care setting.</td>
<td>Semi-structured interviews</td>
<td>Narrative analysis</td>
<td>Diagnostic delay, doctor knowledge, doctor attitude, normalisation.</td>
<td>Improved knowledge of endometriosis symptoms by GPs, quicker referral to specialists, acknowledgement and belief of symptoms by GPs.</td>
</tr>
<tr>
<td>Whelan, 2007&lt;sup&gt;77&lt;/sup&gt;</td>
<td>US and Canadian women with endometriosis (n=24).</td>
<td>Epistemological strategies used by an endometriosis patient community.</td>
<td>Focus groups</td>
<td>Thematic (constant comparative method)</td>
<td>Information, support, consumer groups.</td>
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<td>Strzempo Butt, 2007&lt;sup&gt;77&lt;/sup&gt;</td>
<td>US women with endometriosis and their partners (n=26).</td>
<td>Relational patterns of couples living with chronic pelvic pain from endometriosis.</td>
<td>Interviews (individual and as couples)</td>
<td>Thematic, identification of exemplars and paradigm cases</td>
<td>Relationships, sexuality, information, health system, fertility, doctor communication.</td>
<td>Addressing sexual issues in consultations about endometriosis, development of information about sexual aspects of endometriosis, engagement of partners in health-care process.</td>
</tr>
<tr>
<td>Ballard, 2006&lt;sup&gt;16&lt;/sup&gt;</td>
<td>Women attending a pain clinic, UK (n=32).</td>
<td>Investigation of the reasons for and impact of diagnostic delay.</td>
<td>Semi-structured interviews</td>
<td>Thematic</td>
<td>Symptoms, diagnosis, diagnostic delay, doctor knowledge, public awareness.</td>
<td>Improvement in understanding in medical profession and community of “normal” menstruation.</td>
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<tr>
<td>Fernandez, 2006&lt;sup&gt;160&lt;/sup&gt;</td>
<td>Australian male partners of women with endometriosis (n=16).</td>
<td>Exploration of the experience of male partners of women with endometriosis.</td>
<td>Questionnaire and semi-structured interviews</td>
<td>Thematic</td>
<td>Psychological, relationships, support.</td>
<td>Health care support for partners.</td>
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<tr>
<td>Study</td>
<td>Population</td>
<td>Aims</td>
<td>Data collection</td>
<td>Data analysis</td>
<td>Domains</td>
<td>Needs identified</td>
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<td>Huntington, 2005&lt;sup&gt;74&lt;/sup&gt;</td>
<td>NZ women with endometriosis (n=18).</td>
<td>Exploration of women’s perceptions of living with endometriosis.</td>
<td>Semi-structured interviews</td>
<td>Thematic</td>
<td>Symptoms, treatment.</td>
<td>Inclusion of lifestyle changes and alternative therapies in medical and nursing texts, pro-active management of pain from primary care onwards, development of nurse practitioner roles of management of endometriosis.</td>
</tr>
<tr>
<td>Jones, 2004&lt;sup&gt;79&lt;/sup&gt;</td>
<td>UK women with endometriosis (n=24).</td>
<td>Exploring and describing the impact of endometriosis on quality of life.</td>
<td>Semi-structured interviews</td>
<td>Grounded theory</td>
<td>Symptoms, <strong>physical appearance</strong>, daily living, social, psychological, sexuality, employment, <strong>infertility</strong>, relationships, treatment, <strong>doctor knowledge</strong>, <strong>doctor attitude</strong>.</td>
<td>Greater awareness of the psychosocial impact of endometriosis.</td>
</tr>
<tr>
<td>Denny, 2004&lt;sup&gt;80&lt;/sup&gt;</td>
<td>UK women with endometriosis (n=20).</td>
<td>Exploration of the experience of living with the pain of endometriosis, and the delay in diagnosis.</td>
<td>Interviews (story-telling)</td>
<td>Thematic</td>
<td><strong>Diagnostic delay</strong>, <strong>normalisation</strong>, symptoms, <strong>public awareness</strong>, <strong>doctor attitudes</strong>.</td>
<td>-</td>
</tr>
<tr>
<td>Denny, 2003&lt;sup&gt;81&lt;/sup&gt;</td>
<td>UK women with endometriosis (n=15).</td>
<td>Exploration of women’s experience of living with endometriosis.</td>
<td>Semi-structured interviews</td>
<td>Thematic and content analysis</td>
<td><strong>Diagnostic delay</strong>, symptoms, treatment, employment, social, relationships.</td>
<td>Enhancement of nursing role in care of women with endometriosis.</td>
</tr>
<tr>
<td>Cox, 2003&lt;sup&gt;68&lt;/sup&gt;</td>
<td>Australian women with endometriosis (n=465).</td>
<td>Identification of information and support needs of women with endometriosis.</td>
<td>Open questions in questionnaire</td>
<td>Unknown</td>
<td><strong>Diagnosis</strong>, information, treatment, daily living, <strong>doctor communication</strong>, psychological, <strong>consumer groups</strong>.</td>
<td>Increased awareness of endometriosis symptoms among public and health professionals, information on infertility, information from range of sources (gynaecologist, GP, consumer organisations, treating hospital) and range of formats (printed, online), information on laparoscopy, information on managing at home.</td>
</tr>
</tbody>
</table>
## Appendix 5

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Aims</th>
<th>Data collection</th>
<th>Data analysis</th>
<th>Domains</th>
<th>Needs identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cox, 2003</td>
<td>Australian women with endometriosis (n=61).</td>
<td>Use of complementary therapies in endometriosis.</td>
<td>Focus groups</td>
<td>Thematic</td>
<td>Diagnostic delay, doctor attitude, doctor knowledge, psychological, employment, relationships, symptoms, empowerment, treatment, self-management, non-compliance.</td>
<td>Measures of success in interventions should encompass how to adjust to living with endometriosis, and how to ensure quality of life and wellbeing.</td>
</tr>
<tr>
<td>Cox, 2003</td>
<td>Australian women with endometriosis (n=61).</td>
<td>Investigation of consumer needs for information needs related to day-surgery for endometriosis.</td>
<td>Focus groups</td>
<td>Thematic</td>
<td>Diagnostic delay, doctor attitude, doctor knowledge, empowerment, information, self-management.</td>
<td>Education of health professionals about endometriosis, development of information for women, teachers, employers, partners and family members.</td>
</tr>
</tbody>
</table>
## Table 6: Unmet needs surveys in other health conditions.

<table>
<thead>
<tr>
<th>Survey Name</th>
<th>Domains Addressed</th>
<th>Validation population</th>
<th>Development methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Symptoms / physical</td>
<td></td>
<td>Modification of existing survey (cancer needs questionnaire), clinician panel, piloting, psychometric validation.</td>
</tr>
<tr>
<td>Supportive care needs survey</td>
<td>Daily living</td>
<td>X</td>
<td>Cancer patients</td>
</tr>
<tr>
<td></td>
<td>Psychological/psychiatric</td>
<td></td>
<td>Literature review, survey of support persons, expert panel, readability and clear language assessment, piloting, psychometric validation.</td>
</tr>
<tr>
<td></td>
<td>Social / relationships</td>
<td>X</td>
<td>Literature review, survey of cancer survivors, expert panel, piloting, psychometric validation.</td>
</tr>
<tr>
<td></td>
<td>Spiritual / existential / spiritual</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment / health professionals</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sexuality</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Health system</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Support</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Financial</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Information</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Support persons unmet needs survey</td>
<td>Daily living</td>
<td>X X X X X X</td>
<td>Cancer patients’ support persons</td>
</tr>
<tr>
<td></td>
<td>Psychological/psychiatric</td>
<td></td>
<td>Literature review, survey of support persons, expert panel, readability and clear language assessment, piloting, psychometric validation.</td>
</tr>
<tr>
<td></td>
<td>Social / relationships</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Spiritual / existential / spiritual</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Employment</td>
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<td></td>
<td>Treatment / health professionals</td>
<td>X</td>
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<tr>
<td></td>
<td>Sexuality</td>
<td>X</td>
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<tr>
<td></td>
<td>Health system</td>
<td>X</td>
<td></td>
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<td></td>
<td>Support</td>
<td>X</td>
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<td></td>
<td>Financial</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Information</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Survivors unmet needs survey</td>
<td>Daily living</td>
<td>X</td>
<td>Cancer survivors (1-4 yrs post diagnosis)</td>
</tr>
<tr>
<td></td>
<td>Psychological/psychiatric</td>
<td></td>
<td>Literature review, survey of cancer survivors, expert panel, piloting, psychometric validation.</td>
</tr>
<tr>
<td></td>
<td>Social / relationships</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spiritual / existential / spiritual</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Employment</td>
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<tr>
<td></td>
<td>Treatment / health professionals</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Sexuality</td>
<td>X</td>
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<tr>
<td></td>
<td>Health system</td>
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<td>Support</td>
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<td></td>
<td>Financial</td>
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<td></td>
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<tr>
<td></td>
<td>Information</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Survey Name</td>
<td>Domains Addressed</td>
<td>Validation population</td>
<td>Development methodology</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
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<td>-----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Heart failure needs assessment questionnaire</td>
<td>X</td>
<td>Heart failure patients</td>
<td>Unknown</td>
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<tr>
<td>Needs at the end of life screening test</td>
<td>X X X X X X</td>
<td>Patients near to end-of-life</td>
<td>Literature review, focus groups, piloting, psychometric validation.</td>
</tr>
<tr>
<td>Cancer survivors unmet needs measure</td>
<td>X</td>
<td>Cancer survivors</td>
<td>Literature review, qualitative research, expert panel, piloting, psychometric validation.</td>
</tr>
<tr>
<td>Problems and needs in palliative care questionnaire</td>
<td>X X X X</td>
<td>Cancer patients</td>
<td>Literature review, interviews with cancer patients, their support people and clinicians, psychometric validation.</td>
</tr>
<tr>
<td>Survey Name</td>
<td>Domains Addressed</td>
<td>Validation population</td>
<td>Development methodology</td>
</tr>
<tr>
<td>-----------------------------------------------------------------</td>
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<td>-----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Needs assessment for advanced cancer patients(^53)</td>
<td>X X X X X</td>
<td>X X</td>
<td>Advanced cancer patients, Literature review, focus group with patients, expert panel, piloting, psychometric validation.</td>
</tr>
<tr>
<td>Interactive tailored patient assessment(^90)</td>
<td>X X</td>
<td></td>
<td>Cancer patients, Unknown</td>
</tr>
<tr>
<td>Comprehensive needs assessment tool in cancer(^54)</td>
<td>X X X X X</td>
<td>X X</td>
<td>Cancer patients, Literature review, consultation with clinicians and patients, piloting, psychometric validation.</td>
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<tr>
<td>Cancer needs questionnaire young people</td>
<td>X X X X</td>
<td>X X</td>
<td>Adolescent cancer patients, Literature review, focus groups, expert panel, piloting, psychometric validation.</td>
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<tr>
<td>Childhood cancer survivor study needs assessment questionnaire</td>
<td>X X X</td>
<td>X X X</td>
<td>Childhood cancer survivor study participants, Literature review, expert panel, piloting, psychometric validation.</td>
</tr>
<tr>
<td>Survey Name</td>
<td>Domains Addressed</td>
<td>Validation population</td>
<td>Development methodology</td>
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</tr>
<tr>
<td></td>
<td>Symptoms / physical</td>
<td>X</td>
<td>Interviews with patients, piloting, psychometric validation.</td>
</tr>
<tr>
<td></td>
<td>Daily living</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Psychological / psychiatric</td>
<td>X</td>
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<td></td>
<td>Social / relationships</td>
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<td>Existential / spiritual</td>
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<td>Employment</td>
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<td>Treatment / health professionals</td>
<td>X</td>
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<tr>
<td></td>
<td>Information</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Needs evaluation questionnaire</td>
<td>X</td>
<td>X</td>
<td>Cancer patients</td>
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<tr>
<td></td>
<td>X</td>
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<td></td>
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<td>X</td>
<td></td>
</tr>
<tr>
<td>Patient needs assessment tool</td>
<td>X</td>
<td>X</td>
<td>Cancer patients</td>
</tr>
<tr>
<td></td>
<td>X</td>
<td>X</td>
<td>Literature review, expert panel, piloting, psychometric validation.</td>
</tr>
</tbody>
</table>
Appendix 7: Letter of invitation

Dear [patient name],

We are writing to invite you to take part in a study being run by the University of Melbourne’s Department of Obstetrics & Gynaecology at The Royal Women’s Hospital.

Study aims:

This study is part of a larger project called The EndoNeeds Project. The aim of this project is to develop a survey that measures what women need, or want, to help them cope better with having endometriosis. This type of survey is called an ‘unmet needs survey’.

The first part of the EndoNeeds Project involves talking to women with endometriosis about their needs in relation to their condition. The aim of this research is to compile a list of needs that can be included in the EndoNeeds survey.

Study title:

The EndoNeeds Project Phase 1 – exploring the physical, psychological and social needs of women with endometriosis.

Study number:

TBA (pending ethics approval)

What is the study about?

Endometriosis can affect every aspect of women’s lives. At the moment, there is no survey designed to measure the things women with endometriosis need or want that may help them cope better with the condition and improve their quality of life. This study will explore the types of needs women with endometriosis have through small group discussions (called focus groups) to develop the EndoNeeds survey. Once the survey as been developed and tested, health services can use it to measure the unmet needs of women with endometriosis and direct services to areas of need.

Who is invited?

We are inviting about 40 women to take part in the study. To ensure that we explore as many different needs as possible, we will try to recruit women with a range of symptoms and experiences of endometriosis.
Appendix 7

What is involved?

You will be asked to attend a focus group discussion to be held at The Royal Women’s Hospital, Melbourne. The group will consist of approximately 8 women with endometriosis and will be run by two researchers. The discussion will focus on what the group sees as their needs or wants in relation to endometriosis. The focus group will run for approximately two hours, and light refreshments will be provided. A small gratuity of $30 will be given to each participant to cover transport and parking.

How will my information be used?

- Any information you give will be kept private.
- It is up to you to decide whether you take part in the study or not.
- **Whether you say yes or no will not affect your medical care in any way.**

Can I be part of the study?

You may be able to join the study if:
- You are aged 18 or over;
- you have a surgical diagnosis of endometriosis;
- you are able to read, speak and participate in a group discussion in English; and
- you can attend (in person) a focus group discussion at The Royal Women’s Hospital.

How do I find out more?

If you are interested in being part of the study, please:
- fill in the Expression Of Interest form found in your recruitment pack, and
- give it to your clinician OR send the form back to the researchers in the enclosed reply-paid envelope.

A researcher will then contact you to discuss the study in more detail.

This study is partially funded by a grant from Endometriosis Australia.

This study has been approved by the Human Ethics Research Committee of The Royal Women’s Hospital (study number: TBA).

If you would like more information about this study, please contact [TBA] (study manager) on ………. or via email at ………….

Thank you for your time.

Yours sincerely,

[Insert treating clinician details]
Appendix 8: Expression of interest form

Expression of Interest Form

PRIVATE AND CONFIDENTIAL

EndoNeeds Phase One study – exploring the physical, psychological and social needs of women with endometriosis.

☐ Yes, I am interested in getting more information about this study

Name: _________________________________________________________________

Address: _________________________________________________________________

_________________________________________________________________

_________________________________________________________________

The best way to contact me is (fill in all that apply):

☐ Telephone at home:

    Telephone number:__________________   Best times:_______________________

☐ Telephone at work:

    Telephone number:__________________   Best times:_______________________

☐ Mobile:

    Telephone number:__________________   Best times:_______________________

☐ Email: ______________________________________________

Thank you for your interest in this study. One of the researchers will contact you to discuss the study and confirm that you are eligible to participate.
Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, called EndoNeeds Phase One. You have been invited because you are being treated at The Royal Women’s Hospital for endometriosis. You have been given this information at your clinic appointment.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your personal and health information as described.
• Agree to respect the privacy of other participants involved in this research.

You will be given a copy of this Participant Information and Consent Form to keep.
What is the purpose of this research?

Endometriosis can affect every aspect of women’s lives, resulting in a lower quality of life for some women. In order to improve understanding of this condition and health services to manage it, it is important to know what women with endometriosis need or want to help them cope with the condition – their ‘unmet needs’. Surveys that measure ‘unmet needs’ have been used in other areas of medicine, but so far, no such survey has been developed for women with endometriosis. The EndoNeeds Project aims to develop an unmet needs survey that measures the physical, psychological and social needs of women with endometriosis. Phase One of the EndoNeeds project involves research aimed at exploring the types of needs women with endometriosis might have. These needs will be used to develop the EndoNeeds survey.

This research has been initiated by the following researchers:
Drs Jane Girling and Michelle Peate.

This research is partially funded by Endometriosis Australia.

What does participation in this research involve?

This research is a qualitative study design using focus group (small group) discussion.

The consent form will be signed prior to any study assessments being performed.

Initial steps:

Your clinician has indicated that you may be eligible to participate in this study. They have briefly discussed the study with you and given you a recruitment pack. This pack contains the following documents:
- Invitation letter
- Expression of interest form
- Participant Information and Consent Form (PICF)

If you are interested in learning more about this study, please complete and return the Expression of Interest Form to your clinician or clinic staff, or use the enclosed reply-paid envelope. A researcher will then contact you to discuss the study in more detail.

If you decide to participate, you will be invited to attend a focus group discussion at The Royal Women’s Hospital. For logistical reasons, it is not possible for participants to choose the research venue. The group will consist of around 8 women with endometriosis and will be led by two researchers. The focus group will discuss the types of needs women with endometriosis may have. It is expected to run for about two hours, and light refreshments will be provided. There are no costs associated with participating with this research project, nor will you be paid. However, you will be reimbursed for any reasonable travel, parking, meals or other expenses associated with the research project visit to the value of $30.

The focus group discussion will be recorded and transcribed. It will then be analysed by the researchers to produce a list of needs that can be used to develop questions in the EndoNeeds survey. No individual participant will be identified in the transcript or analysis.

This research will be monitored by The Royal Women’s Hospital HREC to ensure that it complies with Australian research ethics standards. It has been designed to ensure that the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. The research project will take approximately six months to complete.
Appendix 9

4 Other relevant information about the research project

We hope to recruit approximately 50 participants for this study, enabling us to run 4-5 focus groups of 8-10 participants per group. This is a small qualitative study that will be conducted at only one site – The Royal Women’s Hospital. This is the first phase in the EndoNeeds Project.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with The Royal Women’s Hospital.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include:
- satisfaction from contributing to research in endometriosis.
- social connections with other focus group participants.

7 What are the possible risks and disadvantages of taking part?

Psychological distress:

You may feel that some parts of the group discussion are stressful or upsetting. You do not have to discuss any topic you don’t want to. If you become upset or distressed during the focus group session, you can leave the discussion to talk to one of the researchers. After this, you can re-join the discussion if you wish. If you become distressed after the focus group session, you will be able to contact the research team for help and support. If needed, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff, who are not members of the research team. This counselling will be provided free of charge.

Group discussions:

Whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment or distress if one of the group members were to repeat things said in focus group session. It will be stressed at the start of the focus group discussion that participants are expected to respect their fellow members’ privacy after the discussion.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a ‘Withdrawal of Consent’ form; this form will be provided to you by the research team.
Appendix 9

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project. Due to the nature of the group discussion, it may not be possible to exclude all of your input from the results.

9  Could this research project be stopped unexpectedly?

It is very unlikely that this project will stop unexpectedly.

10  What happens when the research project ends?

Once the focus group discussions have been analysed and results obtained, you will receive a summary of the results in plain language via email or post. If you consent, your contact details will be retained so that you can be invited to participate in the next phase of the EndoNeeds project, trialing and testing of the EndoNeeds survey.
Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. It will be stored on a secure computer system in the University of Melbourne Department of Obstetrics and Gynaecology. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The personal information that the research team collect and use is:
- Contact information
- Questionnaire answers about your medical history
- Transcripts of the focus group discussion

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Any direct quotes from the discussion transcripts will be assigned a pseudonym (made-up name).

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for the future research described that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

13 Who is organising and funding the research?

This project is being partially funded by Endometriosis Australia.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Royal Women’s Hospital, Melbourne. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.
15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems that may be related to your involvement in the project, you can contact the researcher on [TBA] or any of the following people:

- [TBA]

**Research contact person**

<table>
<thead>
<tr>
<th>Name</th>
<th>[TBA]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>[TBA]</td>
</tr>
<tr>
<td>Telephone</td>
<td>[TBA]</td>
</tr>
<tr>
<td>Email</td>
<td>[TBA]</td>
</tr>
</tbody>
</table>

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

<table>
<thead>
<tr>
<th>Name</th>
<th>[TBA]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>[TBA]</td>
</tr>
<tr>
<td>Telephone</td>
<td>[TBA]</td>
</tr>
<tr>
<td>Email</td>
<td>[TBA]</td>
</tr>
</tbody>
</table>

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

<table>
<thead>
<tr>
<th>Reviewing HREC name</th>
<th>The Royal Women’s Hospital Human Research Ethics Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>HREC Executive Officer</td>
<td>Ms Gillian Phillips</td>
</tr>
<tr>
<td>Telephone</td>
<td>(03) 8345 3720</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:research.ethics@thewomens.org.au">research.ethics@thewomens.org.au</a></td>
</tr>
</tbody>
</table>

**Local HREC Office contact**

<table>
<thead>
<tr>
<th>Name</th>
<th>Mr Arthur Hui</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>Secretary</td>
</tr>
<tr>
<td>Telephone</td>
<td>(03) 8345 3720</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:research.ethics@thewomens.org.au">research.ethics@thewomens.org.au</a></td>
</tr>
</tbody>
</table>
Appendix 9

Consent Form

Title
EndoNeeds Phase One

Protocol Number
TBA (pending ethics approval)

Project Sponsor
Endometriosis Australia

Coordinating Principal Investigator/
Principal Investigator
[TBA]

Associate Investigator(s)
[TBA]

Location
The Royal Women’s Hospital, Melbourne

Declaration by Participant
I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

| Name of Participant (please print) |  
| Signature | Date |

Declaration by Researcher†
I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

| Name of Researcher† (please print) |  
| Signature | Date |

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.
Form for Withdrawal of Participation

Title
EndoNeeds Phase One

Protocol Number
TBA (pending ethics approval)

Project Sponsor
Endometriosis Australia

Coordinating Principal Investigator/Principal Investigator
[TBA]

Associate Investigator(s)
[TBA]

Location
The Royal Women’s Hospital, Melbourne

Declaration by Participant
I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or The Royal Women’s Hospital, Melbourne.

<table>
<thead>
<tr>
<th>Name of Participant (please print)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Date</td>
</tr>
</tbody>
</table>

In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†
I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

<table>
<thead>
<tr>
<th>Name of Researcher (please print)</th>
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<tbody>
<tr>
<td>Signature</td>
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<tr>
<td>Date</td>
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</tbody>
</table>

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.
Appendix 10: Socio-demographic and clinical questionnaire

EndoNeeds Phase 1 socio-demographic and clinical questionnaire

Part A: socio-demographic information:

1. Name: ________________________________________________
2. Postcode: _______
3. Date of birth: ___/___/___
4. Smoking history:
   - Have you ever smoked? Yes ☐ No ☐
   - Do you currently smoke? Yes ☐ No ☐
   - If no, date stopped: ___/___/___
   - How many years have you/did you smoke for?: _______
   - Average number of cigarettes per day during last 6 months of smoking: ______
5. Alcohol history:
   - Do you ever consume alcohol? Yes ☐ No ☐
   - If yes, how often in the last 6 months?:
     - Never ☐ Rarely ☐ 1-2 days per week ☐
     - 3-5 days per week ☐ Every day ☐

Part B: Medical and Surgical history:

Menstrual history:

1. How old were you when you had your first period? _______ years
2. Date of last period: ___/___/___ (Not currently having periods ☐)
3. Cycle length: __________
4. Do you experience bleeding in between your periods? Yes ☐ No ☐
Appendix 10

Gynaecological history:

1. How many times have you been pregnant? _______
2. How many babies have you had? ______
3. Date of last birth or abortion:______
4. When were you diagnosed with endometriosis (year)? _______
5. What age were you when you first had endometriosis symptoms? ______
   (Never had symptoms ☐)

Symptoms:

What symptoms do you/have you experienced?
(Please mark all that apply)

☐ Pelvic pain around the time of your period
☐ Pelvic pain not at the time of your period
☐ Infertility
☐ Heavy bleeding
☐ Pain during or after sexual intercourse
☐ Pain during or after using your bowels
☐ Pain during or after using your bladder

Treatment – surgical:

1. Have you had surgery to remove your endometriosis? Yes☐ No☐
2. How many surgeries have you had for endometriosis? ________
Appendix 10

*Treatment – medical:*

Please list all medications you are currently taking for endometriosis (including over the counter and complementary/alternative therapies):

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Frequency</th>
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<tbody>
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</table>

*Treatment – lifestyle changes:*

Please list any lifestyle changes you have made to help with endometriosis:

<table>
<thead>
<tr>
<th>Change</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>
Appendix 11: Focus group discussion guide.

BEFORE START of Focus Group:
All Participants to sign consent forms

PREAMBLE:

Hello everyone, and welcome to this focus group discussion about the needs of women with endometriosis. My name is Emma and I will be facilitating the discussion today. Also here is Michelle who will be helping out and taking notes.

Firstly, we want to thank you for being involved in this research. It is so important to have your input, and we realise you are taking valuable time out to make the trip into the hospital to be here.

Now for some housekeeping. The toilets are located [TBA] Please help yourselves to tea, coffee and snacks. All the snacks are gluten-free. At the end of the session you will receive a small sum to cover the cost of parking and transport and in appreciation of the time you have given up to be here.

So that we can transcribe and analyse this discussion later, we are going to record this session. Is everyone happy for this to happen? Individual people won’t be identified on the transcript of the recording.

Remember, you can withdraw from this study at any time, but should you decide to withdraw from the study at a later date, we cannot guarantee that your contribution to the discussion won’t be used in the final analysis and results. The reason for this is that it might not be possible to identify individual participants on the audio recording. I’m going to turn the recorder on now.

Next, I want to set out some ground rules for our discussion today:

Firstly, please respect everyone and let them have their say. When someone is speaking, please let them finish before contributing your experiences or thoughts. Also, please don’t take offense if I have to move the discussion along - we have a lot to cover during the session.

Secondly, it is important that you respect the confidentiality of the other group members. You can speak generally about discussions in today’s focus group, but please don’t reveal any identifying information about other participants – names, individual stories or medical information.

You may even come up with some extra ideas when you talk to friends and family about the research. You are welcome to email us after today to let us know about these ideas – they are all valuable!

And remember that we are here to discuss general needs/wants of women with endometriosis – you do not need to go into very personal details.
Lastly, these discussions may bring up strong emotions for some of you. If you become distressed and need some time out, you are welcome to leave the room. Michelle will come out to make sure you’re ok, and you can rejoin the group later if you wish. If you experience any distress or have any questions after this discussion, please call the phone number on your participant information sheet. That will get you through to one of the researchers for this study who will be able to answer questions, offer support and refer you to any services you require.

Do you have any questions so far?

Now, to explain why we’re all here today: Unmet needs.
As you have read, we are designing a survey that will investigate the needs and wants of women with endometriosis, and whether these needs are being met. This is called an unmet needs survey.

The purpose of this discussion is to identify areas of need to be included in the survey. Also, if you previously had a particular need and you have had intervention to help with this need, we’d like you to explain how your needs were met.

Unmet needs, in this sense, are things that women want or desire to achieve optimal wellbeing. They are the things that women feel they need help with in order to cope better with having endometriosis, and to improve their quality of life. They are not limited to things that improve physical health or can be offered by health services.

Examples of needs relate to education and information, financial advice, and social support. Needs may also be things that other people need to do – for example, better training for GPs.

Because we are designing a survey to give a patient’s perspective on what her unmet needs are, it’s really important that we have women with endometriosis involved in the planning of the survey. This part of the research is not about counting how many people have a particular need, it’s about exploring all the possible needs there could be, so even if only one person brings up an idea, that’s still important.

NEEDS BRAINSTORMING:

Each participant will have a pad of large post-it notes and a marker in front of them.

We would like everyone to think of five needs, or things that would help them cope better with having endometriosis. Write one need per post-it. Remember, they can be any type of need, not necessarily just about medical care. It might read “Help with…..”, or could be “More information on ……”, or “Access to…..”

I’ll give you a few minutes to think about things, then we will go around the group, and go over the different ideas.

Let’s see if we can group the needs you have come up with into some broad categories.

If you think of any more needs as we discuss, please write them down and we’ll add them in as we go.
Appendix 11

Take photo of whiteboard at the end of this stage.

DISCUSSION OF DOMAINS:

The second whiteboard will be turned around – domains of needs from other UMN surveys will be written on it.

These are the domains, or categories of needs that are used in unmet needs surveys in other areas, such as cancer care. Can we organise our post-its under these domains? Are there any that are not needed? Or any that are too broad?

Compare needs on post-its with list from working group meeting.
If there are needs raised during meeting that have not been discussed:

Here are a few extra needs that we thought of with a group health professionals, and other women with endometriosis. Do you think they should be included? Any other needs related to them?

WRAP-UP:

We would like to thank you all very much for participating today. If you think of any further needs later on, please contact us and we will add them in. Also, if you have any questions or concerns, please contact us.

The next phase of the project will involve designing and then trialing the survey. We will do some testing to ensure that we are getting the information we need. There will be the opportunity to participate – we will contact you when we are ready to recruit participants for this stage.

Thank you again. Remember to collect your cash on your way out.
## Table 7: EndoNeeds working group membership

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Jane Girling</td>
<td>Reproductive biologist</td>
</tr>
<tr>
<td>Dr Michelle Peate</td>
<td>Behavioural scientist</td>
</tr>
<tr>
<td>Emma Steele</td>
<td>Masters research student</td>
</tr>
<tr>
<td>Dr Angela Chia</td>
<td>Pain specialist</td>
</tr>
<tr>
<td>Dr Martin Healey</td>
<td>Gynaecologist</td>
</tr>
<tr>
<td>Dr Uri Dior</td>
<td>Gynaecology fellow</td>
</tr>
<tr>
<td>A/Prof John McBain</td>
<td>Fertility specialist</td>
</tr>
<tr>
<td>Dr Vanessa Hughes</td>
<td>Reproductive endocrinology and infertility fellow</td>
</tr>
<tr>
<td>A/Prof Christina Bryant</td>
<td>Clinical psychologist</td>
</tr>
<tr>
<td>Lora Adamson</td>
<td>Chronic pelvic pain clinic nurse</td>
</tr>
<tr>
<td>Anne-Florence Plante</td>
<td>Chronic pelvic pain clinic physiotherapist</td>
</tr>
<tr>
<td>Endometriosis consumer 1</td>
<td>Patient</td>
</tr>
<tr>
<td>Endometriosis consumer 2</td>
<td>Patient</td>
</tr>
<tr>
<td>Endometriosis consumer 3</td>
<td>Father of patient</td>
</tr>
</tbody>
</table>
Appendix 13: Distress protocol

Distress protocol for participants (safety script)

(Modified from Draucker et al: Developing distress protocols for research on sensitive topics183.)

Stage 1: Identify distress

- If a participant indicates they are experiencing a high level of distress
- Participant exhibits behaviours suggestive that the discussion is too distressing (such as uncontrolled crying)

⇒ Facilitator stops the discussion: “<name>, I can hear/ I understand that you are upset. Would you like go with <co-facilitator> and have a talk about it?”

Stage 2: Initial response

- Co-facilitator takes participant to a private area and offers immediate support:
  “What I’d like to do is have a little chat about how you are feeling right now to see if there is something we can do to help you with what you are going through.”
- Assess mental status:

<table>
<thead>
<tr>
<th>Questions</th>
<th>Participant responses</th>
<th>Acute distress or safety concern (Y/N)?</th>
<th>Imminent danger (Y/N)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>“How are you feeling right now?”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“What are you thinking about right now?”</td>
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<tr>
<td>“Do you feel you are able to go on with your day?”</td>
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</tr>
<tr>
<td><strong>Prompts (if needed):</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• Is how you are feeling getting in the way of you taking care of yourself?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Is how you are feeling getting in the way of you doing things you need to do?</td>
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<td></td>
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<tr>
<td>“Do you feel safe?”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prompts (if needed):</strong></td>
<td></td>
<td></td>
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<tr>
<td>• Do you intend to harm yourself?</td>
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</tbody>
</table>
Stage 3: Review situation

- If a participant’s responses reflect **imminent danger**: 
  Advise them they should not take further part in the discussion “<name>, it seems like the discussion has caused some worrying thoughts. I think it would be best if you don’t join in the discussion again. Is it ok if I ask you a few questions about what has upset you?”

  Prompts (if needed):
  1. Do you intend to harm yourself?
  2. How do you intend to harm yourself?
  3. When do you intend to harm yourself?
  4. Do you have the means to harm yourself?
  5. Have you had these types of thoughts before?
  6. Are you seeing someone about these thoughts?

  → If there are immediate concerns about harm, referrals will be made for mental health or emergency services as required (depending on level of risk).

  → If there are no concerns about harm → go to stage 3 response.

- If a participant’s responses reflect **acute distress or safety concerns**: 
  - Advise them that they should not take further part in the discussion.
  - Go to stage 3 response.

- If participant feels **able to carry on** → invite them to re-join the discussion: “<name>, since you feel you are able to go on, would you like to go back in to for the rest of the discussion?”
  - If yes → accompany participant back into meeting room.

- If participant is **unable to carry on** → go to stage 3 response.

Stage 3: Elevated response

- Encourage the participant to contact their GP or mental health provider: “<name>, it seems like the discussion has caused some worrying thoughts. Do you have a GP or psychologist that you see to help manage your concerns?”

- If they have a health care provider who manages their mental health: “Because you have someone who knows your situation, it is probably best that you contact them to talk about your feelings and thoughts. Would you be comfortable to do this?” “Ok, I will leave it to you to get in contact with your health care provider.”

- If they don’t have a health care provider who manages their mental health: Offer, with participant consent, a referral to a psychologist or a member of the health care team: “To help with how you are feeling I can organise to put you in contact with a psychologist or a member of your health care team if you would like?”
  → Arrange referral to psychologist or health care team as preferred: “With your permission, I will contact the psychologist/ your health care team and ask them to call you to see if you are okay?”

Stage 4: Follow up

- With participant: “Is it okay with you if one of the lead researchers in this study calls you in the next few days just to check in to see if you are okay?”

- Encourage participant to call if she experiences increased distress in the hours/ days following the interview: “I really want to thank you for taking the time to participate today and I am really sorry that this has been upsetting. Please call me if over the next couple of days thinking about the discussion causes you any more upset.”

- Make note of the conversation, actions and plans in the participant file.