



Human Subjects Protocol A10-M84-07A :

Diagnosing Ovarian Cancer Early (DOvE) by targeting symptomatic women

Principal Investigators:

Dr. Lucy Gilbert

Physician responsible for DOvE clinics

Professor

Department of Obstetrics & Gynecology

Department of Oncology

Director, Division of Gynecologic Oncology

McGill University Health

687 Pine Avenue West, F9.37

Montreal, QC, H3A 1A1

Tel : 514 934-1934 ext. 35249

Pager : 514 406-0688

Email: lucy.gilbert@mcgill.ca

Dr. Olga Basso

Director of Clinical Research

Department of Obstetrics and Gynecology

Department of Epidemiology, Biostatistics, and Occupational Health, McGill University

DOvE clinic contact: 1-866-716-3267, Royal Victoria Hospital, Women's Pavilion F9.37

Co-Investigators: Dr. John Sampalis (McGill University), Dr. Igor Karp (University of Montreal), Dr. Agnihotram V Ramanakumar (McGill University), Dr. Srinivasan Krishnamurthy(McGill University), Dr. Janet Takefman (McGill University) , Dr. Alice Dragomir (McGill University), Dr. Kris Jardon (McGill University), Dr. Michel Welt (University of Montreal).

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2. ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
BSO	Bilateral Salpingo-Oophorectomy
CA-125	Cancer Antigen 125
CIHR	Canadian Institute of Health Research
CLSC	Centre Local de Services Communautaires
CRF	Case Report Form
DOvE	Diagnosing Ovarian cancer Early
HGSC	High-grade serous cancer
ICF	Informed Consent Form
ID	Identification
IRB	Institutional Review Board
MUHC	McGill University Health Centre
OC	Ovarian Cancer
PHI	Protected Health Information
RAMQ	Régie de l'Assurance Maladie du Québec
RVH	Royal Victoria Hospital
SST	Serum separator tube
TVUS	Transvaginal Ultrasound Scan





3. PROTOCOL ABSTRACT

Background

Despite its low incidence, ovarian cancer (OC) is the fifth leading cause of death from cancer in Canadian women. The high fatality ratio is due to the fact that high-grade serous cancer (HGSC) subtype, which accounts for 90% of deaths from OC, is invariably diagnosed when it is too advanced for optimal surgical resection. This has earned this disease its reputation as a “silent killer”. However, numerous studies (Appendix 1) have shown that the majority of women with OC do experience abdominal and pelvic symptoms before diagnosis (Appendix 2), even though these symptoms are vague and non-specific. Despite the fact that all these studies were retrospective and that there was no evidence that assessing symptomatic women would achieve early-stage diagnosis, in June 2007, several influential organizations recommended that women experiencing symptoms seek diagnostic testing. The DOvE (Diagnosing Ovarian cancer Early) project was initiated to determine whether prospective fast-track evaluation of symptomatic women would indeed achieve early-stage diagnosis. In the CIHR-funded pilot phase, which lasted from May 2008 to April 2011, 1455 women were tested with CA-125 tumor marker and transvaginal ultrasound (TVUS); 11 invasive ovarian cancers were diagnosed, the majority of these (9/11) were HGSC. This prevalence of OC is 10 times higher than that found in the large screening trials, which were not focused on women with symptoms. These findings suggest that targeting symptomatic women for early diagnosis of ovarian cancer is indeed worthwhile. Crucially, the DOvE patients had less tumor burden, as measured by CA-125, and were more likely to have no visible disease at the end of surgery than a comparable clinical cohort. As complete resectability is the most important predictor of survival (it increases 5-year survival from 20 to 65%), these findings provide proof of principle that further research on providing fast-track access to symptomatic women is worthwhile. However, our objective of diagnosing OC in early stage, while it was still confined to the ovary, was not achieved. Instead, we found that 7 of 9 HGSC originated outside the ovary. Therefore, concentrating on the ovaries for early diagnosis is likely inappropriate, and the currently available tests for early diagnosis need adapting. The next phase of the study will take advantage of the insights gained from the pilot phase and will address the problems identified, namely, the limited participation of older women who are at particularly high risk of ovarian cancer and most importantly, the inadequacy of the currently available tests, especially TVUS, for the early diagnosis of OC.

Objectives of the DOvE Project

Primary Objectives

1. To determine whether the provision of fast-track diagnostic evaluation of symptomatic women ≥ 50 years will result in a higher proportion of OC, including high-grade serous cancers



(HGSCs), diagnosed in low-volume, completely resectable stage (rather than in early stage, as hypothesized in the pilot phase).

2. To develop predictive algorithms for triaging and testing of symptomatic women in the future, based on the prospectively collected information.

Secondary objectives:

1. To determine the morbidity (psychological and physical) associated with this program.
2. To determine the costs/benefits associated with this strategy.

Methods

We will set up satellite DOvE centres, operating once a fortnight, in partnership with 12 health centers located in areas with a dense population of women ≥65 yrs. This approach minimizes resource requirements, keeps expertise centralized, yet allows us to reach the population at the highest risk. We expect that we will be able to assess approximately 13600 symptomatic patients over 33 months, thus yielding about 100 additional cases of OC. These numbers will allow the development of predictive algorithms.

Name of Institution	Fit Adults	
	Number	Grounds
Royal Victoria Hospital	8100	Symptomatic women
Clinique médicale du Haut-Anjou	500	Symptomatic women
Hôpital Lachine	1000	Symptomatic women
Clinique médicale Pas-À-Pas	500	Symptomatic women
Clinique médicale St. Lambert	500	Symptomatic women
Clinique médicale Plein Ciel	500	Symptomatic women
Hôpital du Sacré-Cœur	1000	Symptomatic women
Hôpital Charles LeMoine	1000	Symptomatic women
Queen Elizabeth Health Complex MUHC Family Medicine	500	Symptomatic women
Total	13600	Symptomatic women



Significance

If our pilot study results are corroborated in this phase, we have the potential to revolutionize diagnosis of high-grade serous cancer while it is still in low volume by recognising its extra-ovarian origin. If predictive algorithms can be developed, this would pave the way for the implementation of a similar model to other parts of Canada and the world. We believe this is a worthwhile investment, as even a modest shift to earlier diagnosis of this disease would produce significant reduction in suffering, lives lost, and burden on the healthcare system.

4. INTRODUCTION

4.1 Background

Despite its low incidence, ovarian cancer (OC) is the fifth leading cause of cancer-related death in women in developed countries¹ and has one of the highest ratios of incidence to death. Cure rates have not meaningfully improved in the past four decades². Currently, about 1 woman in 55 will develop OC over her lifetime, which represents an increase from the 1970 figure of 1 in 70. The incidence of OC is higher in the developed world, where it has the highest mortality rate of all gynecological malignancy³.

The cost of treating this disease has been increasing steadily -approximately 20% per year,⁴ but cure rates have not meaningfully improved in the past four decades², primarily because most cancers are diagnosed in advanced, incurable stages. Currently, OC is staged as follows: Stage I disease -confined to the ovaries, Stage II – metastatic to pelvic organs, such as fallopian tubes and pelvic peritoneum, Stage III –metastatic to abdominal organs and peritoneum, and Stage IV–metastatic beyond the abdominal cavity⁵.

Although there are many subtypes, high grade serous carcinoma is the most important, as these tumours account for about 75% of all cases and more than 90% of all deaths due to ovarian cancer⁶. In other words, ninety percent of OC mortality is due to the high-grade serous subtype, because this subtype is invariably diagnosed in advanced stages.

As 5-year survival is 90% for patients with stage I disease at diagnosis, substantial efforts have been invested into identification of disease while it is confined to the ovary. However, only 2% of HGSC is diagnosed in Stage I⁷. The treatment of advanced OC is surgery, aimed at resecting as much disease as possible, followed by adjuvant chemotherapy. In patients with advanced disease, the most important predictor of survival is complete surgical resection of all visible disease⁸. Incompletely resected disease can be temporarily contained by chemotherapy, but most patients eventually succumb: 5-year survival for patients with completely resected stage III tumours is 65%, but it is only 20% for incompletely resected stage III tumors⁹. Therefore, the key to achieving tangible improvements in the outcome of patients with HGSC would be to diagnose the disease early enough to achieve complete surgical resection.

Two diagnostic tests have been extensively assessed: measurement of cancer antigen (CA-125) concentrations in blood and transvaginal ultrasound (TVUS)¹⁰. Both tests, however, have poor



specificity, which, combined with the low prevalence of OC in the general population, leads to high rate of false-positive results¹⁰.

Even if the risk-benefit ratio of using CA-125 and TVUS does not warrant screening the general population, it may be more favorable in a subgroup with a higher prevalence of OC. One such subgroup may be women with OC symptoms. Although OC used to be known as the “silent killer”, numerous retrospective studies have suggested that it is associated with symptoms that predate diagnosis by 3 to 36 months¹¹⁻¹⁶ (Appendix 1). Owing to the vague and non-specific nature of these symptoms, however, women might delay seeking investigation¹⁷. Even when they do seek help, these symptoms are frequently attributed to benign gastrointestinal or urinary disorders^{14,18}, which leads to further diagnostic delays. In the hope of increasing the proportion of tumors diagnosed in early stage, three major US cancer organizations, the American Cancer Society, the Gynecologic Cancer Foundation (now Foundation for Women's Cancer), and the Society of Gynecologic Oncologists, issued a joint advisory in June, 2007. The recommendation was that women who experience two or more ovarian cancer symptoms (bloating, pelvic or abdominal pain, difficulty eating or early satiety, and increased urinary urgency or frequency) for 2 weeks or longer should undergo gynecological assessment, TVUS, and measurement of CA-125¹⁹. Thirty ovarian cancer alliances have since endorsed this recommendation²⁰, and the 2011 US National Comprehensive Cancer Network guidelines support a full diagnostic work-up for women with these symptoms²¹. To assess the strength of the evidence on which this advisory was based, in 2007 we carried out a systematic review of the literature, which we later updated to 2011 (Appendix 1). We found that all published studies were retrospective and might have suffered from recall or ascertainment bias. Thus, although the relevant symptoms were more frequent in women with ovarian cancer, there was no evidence to indicate that investigating symptomatic women would result in early-stage diagnosis. The purpose of the Diagnosing Ovarian Cancer Early - DOvE study was to address this question prospectively.

4.2 Rationale

Given that the 5-year survival is 90% for patients with stage I disease (confined to the ovary), as opposed to 30 % for stage III-IV disease¹, all efforts on early diagnosis to date have focused on identifying the disease while it is confined to the ovary. This was the aim of screening trials in the general population, as well as of our study, DOvE (Diagnosing Ovarian Cancer Early), which assessed women with symptoms. DOvE was conceived to determine whether open access, fast-track diagnostic testing of symptomatic women ≥ 50 years would achieve early-stage diagnosis. CIHR funded the pilot phase of the study, which began in May 2008 and was completed in April 2011. Despite the small sample size, symptomatic women did indeed have a prevalence of ovarian cancer about 10 times that found in screening trials of women of similar age (11 out of 1455) but, in most cases, diagnosis was not achieved in Stage I, when the disease was confined to the ovary. The reason for this was that the majority of high-grade serous cancer (HGSC), the deadliest subtype of ovarian cancer, did not originate in the ovary. Therefore, by definition, HGSC cannot, in most cases, be diagnosed in stage I because of its extra-ovarian origin. As a corollary, the diagnostic tests used, in particular TVUS, were unsuitable for the early diagnosis of HGSC. The most important implication of these findings is that almost all the fundamental concepts on which research on early diagnosis of ovarian cancer has been based to date are wrong. However, the redeeming feature of our study was



that, although we failed to achieve our stated objective of early-stage diagnosis, we did identify, for the first time in an unselected population, HGSCs early enough in the trajectory of the disease to demonstrate that the ovary was not the site of origin. Furthermore, our preliminary results showed that we were more likely to achieve complete resection of all visible disease in women diagnosed through the DOvE program than in those diagnosed through the routine clinic. As complete resection is the most important predictor of survival, this has important clinical implications.

These findings, if corroborated in a large sample, have the potential to revolutionize the approach to early diagnosis of HGSC and, as a consequence, improve the dismal outcome currently associated with this disease. **In this phase of the DOvE project, we plan to assess approximately 13600 symptomatic patients, during a period of 33 months, to diagnose about 100 cases of OC.**

5. STUDY OBJECTIVES

5.1 Primary Objectives

1. To determine whether the provision of fast-track diagnostic evaluation of symptomatic women ≥ 50 years will result in a higher proportion of OC, including HGSCs, diagnosed in low-volume, completely resectable stage (rather than in early stage, as hypothesized in the pilot phase).
2. To develop predictive algorithms for triaging and testing of symptomatic women in the future, based on the prospectively collected information.

5.2 Secondary Objectives

1. To determine the morbidity (psychological and physical) associated with this program.
2. To determine the costs/benefits associated with this strategy

6. STUDY DESIGN

In this phase, we will retain most of the methods of the pilot phase, but change some crucial aspects to achieve our objectives. The eligibility criteria and study procedures will be the same. Women are eligible for diagnostic testing if they are ≥ 50 years, have at least one ovary, and have been experiencing one or more abdominal or pelvic symptom (such as bloating, abdominal distension, abdominal and pelvic pain or discomfort, early satiety, urinary frequency, and postmenopausal bleeding (Appendix 2) for more than two weeks -but less than one year. As in the pilot phase, both physician and self-referrals will be accepted. Trained DOvE personnel will assess eligibility and schedule appointments within two weeks of the first contact. At the first visit, informed consent will be obtained and the study questionnaires (including detailed information on symptoms, medical history, sociodemographic information, and psychological assessment) filled out (Appendix 3). A specific section of the questionnaire is devoted to assessing the perceived impact of this program. Blood will be drawn for measurement of CA-125 and stored for future studies.



Despite evidence from the pilot phase that TVUS is not particularly helpful in diagnosing HGSC early, we will nonetheless continue to use it, as it did identify a small number of ovarian cancers and several endometrial cancers. The TVUS will be performed at the second visit, which will take place two weeks after the first. At the end of this visit, patients will be informed of their results and classified into four management categories: (a) both test results normal, no evidence to suggest OC, follow-up visit in 4 weeks; (b) one or both test results marginally abnormal, OC unlikely but surveillance/repeat testing warranted; (c) one or both test results abnormal, assessment by gynecologist/gynecologic oncologist required; (d) test results suggest the possibility of another type of cancer, referral to another specialty. The third contact for patients in category (a) will entail a repeat CA125 6 weeks from the first visit. If this is again normal, patients will be discharged from the study. All women will be contacted six months after discharge to ascertain whether they have been diagnosed with OC in the intervening time. Patients with a rising CA-125 will have abdominal imaging with CT scan. Patients with abnormal findings on TVUS will be followed as per standard clinical criteria.

Regarding abnormal values for CA125, for the next phase of the study, we have explicitly defined the threshold of CA125 for post-menopausal women as <20 U/ml; CA125 measurements above this threshold in postmenopausal women will be repeated in 4 weeks. As we learned from the pilot study that women with OC may have an initial CA125 below 20 U/mL, three serial rises of CA125 above 20% will be treated as abnormal, provided the recent value is more than 20. Patients who have serial rise in CA125 will be investigated with a CT scan of the abdomen and pelvis. Women diagnosed with any gynecological cancer in DOvE will be followed-up according to our standard procedures. Any patient treated at our center who appears to be disease-free is seen every 3 months for the first 3 years after completion of treatment, twice a year in the 4th and 5th year, and annually until the 10th year. Patients with persistent or recurrent cancer are seen more often, according to their needs.

The crucial new aspect of this phase of the DOvE study will be the establishment of a network of 12 satellite centers strategically placed across Montreal in areas with a dense population of women over 65, as half of the HGSC occur in this age group. This decision was dictated by the fact that, in the pilot study, participants tended to be younger, more educated, and predominantly Anglophone compared with the source population of women over 50 in Montreal. These differences were highly statistically significant (Appendix 4). We suspected that this might have been an issue with difficulty in accessing the main DOvE centre at the Royal Victoria Hospital (RVH). We predict that, if the center is more accessible, a greater number of older symptomatic women will be willing to take part in the study.

Each satellite clinic will be operational once a fortnight. All calls from potential participants will be taken at the central DOvE office. Patients will be given appointments according to the center that is most convenient to them. A doctor from the study team will assess all results. A doctor from the study team will assess Patients with abnormal or atypical results, or who have symptoms that concern the nurse or the patient, will be assessed by a physician from the study team. The advantage of employing this innovative design of a network of satellite centers working with a central team are that it uses fewer resources while taking expertise to the community. If successful,



this concept may be applicable to other diseases with low prevalence but high burden in terms of mortality, morbidity, and resource utilization.

The study is being carried out by a team from McGill University Health Centre affiliated hospitals (Royal Victoria, Montreal General, Lachine, St Mary’s) as well as the University of Montréal affiliated Hospitals (Sacre Coeur). The team includes oncologists, gynecologists, ultrasound experts, family doctors, a psychologist, a health economist, statisticians, epidemiologists and basic scientists.

7. Eligibility Criteria

7.1 Inclusion Criteria

To qualify for enrolment, subjects must meet the following criteria:

1. Sign an approved informed consent form (ICF).
2. Be ≥ 50 years of age.
3. Have at least one symptom outlined in the table below for a period of ≥2 weeks but ≤ 1 year:

Eligible symptoms
Feeling full after eating only a few bites, loss of appetite
Diarrhoea, constipation, bowel or rectum feels full, change in bowel habits, constant urge to have a bowel movement, painful or burning bowel movements, rectal pain, painful defecation
Bloating, distension of abdomen, clothes around the waist feel too tight, feel an abdominal mass
Weight loss not because of dieting
Nausea, vomiting, heartburn, gas, burping, indigestion
Increased urinary frequency, need to urinate urgently, pressure on the bladder, leaking urine, burning sensation when urinating, need to urinate but unable to do so, unable to empty bladder completely, feeling full after urinating
Vaginal discharge, bleeding, spotting, deep pain on intercourse
Discomfort or pain in abdomen, or pelvic region, or lower back



4. Subjects must be willing to comply with study protocol

7.2 Exclusion Criteria

The presence of any of the following will exclude the subject from the study:

1. Previous bilateral salpingo-oophorectomy (BSO)
2. Previous diagnosis of cancer in the ovaries, fallopian tubes, or peritoneum
3. Current bleeding per rectum, not due to haemorrhoids
4. Current frank haematuria
5. Symptoms that suggest the need for urgent clinical evaluation outside of a research protocol

7.3 Subject Withdrawal Criteria

Subjects may be removed from treatment for any of the following:

1. Noncompliance
2. Voluntary withdrawal

The reason for discontinuation will be documented.

8. DIAGNOSTIC TESTING OF SUBJECTS

8.1 Subject Enrolment

Participants will be recruited through posters, pamphlets, and physician referrals. Posters and pamphlets will be distributed internally and externally of the McGill Community, including pharmacies, clinics, Publisacs, and hospitals.

All subjects will need to meet the inclusion/exclusion criteria before study enrolment. Assessment of criteria will be determined through a telephone interview or, occasionally, face-to-face interview with a DOvE team member. Eligible patients will be given an appointment within 2 weeks. At the 1st visit, informed consent will be obtained after the study protocol is explained and before any study-specific procedures are performed.

8.1.1 DOvE Diagnostic Center - Main

The main DOvE Diagnostic Center is located at the Royal Victoria Hospital, Women's Pavilion, F9.37

8.1.2 DOvE Satellite Center

In addition to the main centre, 12 satellite clinics in areas with a high proportion of residents >65 will provide a similar service to eligible, symptomatic women.



The centres that are currently active or pending include 4 hospitals (Active: Royal Victoria, Lachine Centre, Pending: Charles LeMoyne and Sacré Cœur) and 5 clinics (Active: Queen Elizabeth Centre, Clinique Plein Ciel, Clinique Pas-À-Pas, Anjou Centre, and St. Lambert). In the nearest future, we intend to establish 3 more satellite centres.

The space available is 1 examination room and 1 waiting room. Two members of the DOvE team will provide the diagnostic assessments for a half a day every two weeks. A portable ultrasound machine and blood procurement kits will be transported to each clinic by DOvE personnel. Blood will be analysed at the Royal Victoria Hospital Laboratory or sent to the nearest hospital or CLSC centre.

8.2 Study Procedures

8.2.1 Visit 1 - Day 1

The following events will take place on “Visit 1 – Day1”:

1. Study explained to participant, including procedures to be carried out, subject responsibilities, and duration of study.
2. Written and signed consent obtained (Appendix 3.1a).
3. Study chart is opened and a study ID is granted.
4. Study assessments: After obtaining informed consent, demographic information and a focused medical history, including personal and family cancer history and gynecological/obstetrical history will be obtained. A detailed history of the symptoms including the start date, rating, frequency, and duration will also be obtained
 - All of the above information will be recorded by the patient on Case Report Form 1 (CRF-1) (Appendix 3.1b). CRF 1 will include the following questionnaires:
 - i. Study Registration and Demographics
 - ii. Risk Profile
 - iii. Symptom Questionnaire
 - iv. Pain Assessment
 - v. Spielberger’s State Anxiety Inventory (SAI) (Appendix 3.1c)
 - vi. Spielberger’s State-Trait Anxiety Inventory (STAI) (Appendix 3.1d)
 - vii. Beck Depression Inventory (BDI) (Appendix 3.1e)
 - viii. DOvE Program Impact Assessment (Appendix 3.1f)
5. Subject will have blood drawn for tumour marker testing.

8.2.2 Visit 2 - Week 2

The following procedures will take place on “Visit 2 – Week 2”

1. CRF-2 will be completed (Appendix 3.2a).



2. A transvaginal ultrasound will be performed by a trained study sonographer. “Transvaginal Ultrasound Form” will be completed by sonographer (Appendix 3.2a). All results will be verified by a physician specialised in interpreting TVUS for quality assurance.
3. Subject will be given results of initial CA-125 test and TVUS results, and the implication of these results.
4. Subject will complete Spielberger’s State Anxiety Inventory (Appendix 3.2b), DOvE Program Impact Assessment (Appendix 3.2c) and Beck Depression Inventory (Appendix 3.2d) after having received the results of the tests.

8.2.3 Visit 3 - Week 6

The following procedures will take place on “Visit 3 – Week 6”:

1. Subject will have blood drawn for tumour marker testing.
2. Subject will complete Spielberger’s State Anxiety Inventory (SAI) (Appendix 3.3a), DOvE Program Impact Assessment (Appendix 3.3b) and Beck Depression Inventory (Appendix 3.3c).

A letter with recommendations/management plan will be sent out following the third visit to the patient’s primary physician.

Update from follow-up phone call protocol:

If the participant does not attend the 3rd visit, the study personnel will follow-up with a telephone call within 2 weeks of the missed visit date to reschedule the appointment. If the subject does not respond within a period of 2 weeks, she will be contacted by mail or email. If circumstances dictate, arrangements will be made for the CA125 test to be done at a place that is more convenient for the participant and the study questionnaires completed by mail. Attempts will be made to reschedule the patient’s appointment 3 times, after which she will be considered as having “discontinued” the study. All data collected until this point will be used.

Missing data: If retrievable, the missing information will be added along with a footnote. If non-retrievable, as in the case of a missing visit, a footnote symbol will be entered in the empty field. If an entire paper record is missing, a Note to File (NTF) indicating the reason, impact of missing record will be added. After any of these notes, staff will sign and date the footnote or note.

8.3 Normal / Abnormal Results

The CA-125 results will be classified as either

“**Normal**” if < 35 in patients 50-55 years old or <20 in patients ≥55 years old



“**Abnormal**” if ≥ 35 in patients 50-55 years old or ≥ 20 in patients >55 years old and a rise of 20% in three serial blood tests, provided most recent value is more than 20.

Based on CA-125 levels and TVUS findings, the results will be categorized into the following:

- a) Normal results -OC ruled out, follow-up as per protocol,
- b) Test results atypical -OC unlikely, but surveillance/further assessment by a gynecologist required
- c) Abnormal test results: Further assessment required to rule out gynecological cancer
- d) Abnormal results: Refer to another specialty.

8.4 Repeat Investigations

Any result identified as being abnormal will be evaluated by the study physicians. Abnormal TVUS results will generally be repeated in 4 weeks to 6 weeks depending on the degree of abnormality. Abnormal CA-125 results will be repeated at an interval of 4 weeks at least twice. Other tests may be done at any time as per physician’s discretion (i.e. ThinPrep Pap Test or Endometrial Biopsy (EMB) hysteroscopy, CT scans / MRI).

8.5 Discharge from Active phase of Study

Subject will be informed of the CA-125 results and any follow up that is required. If this result is normal, the patient will be discharged from the active phase of the study.

8.6 Health updates call 6 months after discharge

Six months after the participant is discharged from active follow up (completion of Visit 3), the participants or their designees will be contacted by the site staff to obtain updates on overall health status and to confirm the status of their symptoms. The subjects will be contacted by appropriate means (e.g., phone, e-mail, or letter). The study personnel contacting the patient will collect information on the subject’s health including:

1. The current status of the symptoms investigated in the study.



2. Whether the cause of these symptoms was established by further investigations since discharge from DOvE; specifically, whether a diagnosis of ovarian cancer or any other serious disease has been made.

8.7 Duration of Assessments

Study diagnostic tests will be carried out over a period of 6 to 8 weeks, as described in section 8.2 of the protocol, unless further evaluation is warranted.

8.8 Protocol Compliance

Subjects should attend scheduled clinic visits and comply with the protocol instructions. Missed visits should be made up as soon as feasible.

8.9 Blood Collection for CA-125

8.9.1 Visit 1 - Day 1

On Visit 1 – Day 1, study personnel will be required to draw 1 vial of blood:

One 5ml SST gel tube (containing clot activator and gel for serum separation) will be used for CA-125 testing. The samples will be drawn by a qualified technician and sent to the central laboratory of the RVH or a neighbouring hospital for processing.

8.9.2 Visit 3 - Week 6

On Visit 3 – Week 6, study personnel site will be required to draw 1 vial of blood:

One 5ml SST gel tube (containing clot activator and gel for serum separation) will be used for CA-125 testing. The samples will be drawn by a qualified technician and sent to the central laboratory of the RVH or a neighbouring hospital for processing.



9. ASSESSMENT SCHEDULE

Procedure/ Assessment	Visit 1	Visit 2	Visit 3	Follow-Up	Note
	Day 1	Week 2	Week 6	Week 18	
Demographics, Risk Profile, Symptoms, Pain Assessment	X				See section 8.2.1
Beck Depression Inventory (BDI)	X	X	X		See section 8.2.1;8.2.2 and 8.2.3
Spielberger’s State Anxiety Inventory (SAI)	X	X	X		See section 8.2.1;8.2.2 and 8.2.3
Spielberger’s State-Trait Anxiety Inventory (STAI)	X				See section 8.2.1
DOvE Impact Questionnaire	X	X	X		See section 8.2.1;8.2.2 and 8.2.3
CA-125	X		X		See section 8.2.1 and 8.2.3
Transvaginal Ultrasound		X			See section 8.2.2
Telephone Assessment				X	See section 8.6

10. ETHICAL CONSIDERATIONS AND ADMINISTRATIVE SECTION

The vast majority of women with symptoms identified above will not have OC, and a public health campaign aimed at urging women to note these symptoms and call the DOvE centre risks



engendering fear or anxiety. These endpoints will be monitored closely through the psychological assessment questionnaires as well as the DOvE program impact questionnaires.

10.1 Compliance with Protocol and Protocol Revisions

The study will be carried out as described in the approved protocol. However, this study involves diagnostic assessment of symptomatic patients with the view to ruling out ovarian cancer using tests that are used in routine clinical practice. Therefore, the physician assessing the patient may modify or alter procedures in the individual patient if this is deemed to be in the patient's best interest. All such deviations will be recorded in the patient's notes and IRB informed appropriately.

The protocol will be in compliance with GCP and applicable regulatory requirements. Hard copies of all protocol submissions and modifications will be kept in the DOvE study folder.

10.2 Informed Consent Form

The ICF will be reviewed with the prospective study subjects, or their legal representatives, and the investigator will be available to answer questions regarding procedures, risks, and alternatives. The principal investigator or his/her entitled designee (as defined on the Delegation List) will obtain a written ICF from each subject or from the subject's legal representative or designee as defined by local law. Consent will be obtained before any protocol-specific procedures are performed.

Investigators will ensure that participants are clearly and fully informed about the purpose, potential risks, and other critical issues regarding clinical trials in which they volunteer to participate. The investigator will also ensure that participants are fully informed of their right to decide who may review or use their Protected Health Information (PHI).

The investigator will provide the prospective participant or a legal representative with a copy of the ICF and written information will be non-technical and easily understood. The investigator should allow sufficient time for the subject or subject's legal representative to inquire about the details of the study after which the ICF must be signed and personally dated by the subject or the subject's legally acceptable representative and by the person who conducted the informed consent discussion. The subject or a legal representative will receive a copy of the signed ICF and any other IRB/IEC-approved written information prior to the subject's participation in the trial.

If the subject is illiterate, an impartial witness will be present during the entire time that the informed consent read and discussed. Afterward, the subject will sign and date the ICF, if capable of doing so. The impartial witness will also sign and date the ICF along with the individual who carried



out the informed consent discussion. If the subject is legally incompetent (for example, mentally incapacitated), the written consent of a parent, legal guardian, or legal representative will be obtained.

10.3 Confidentiality

This study involves diagnostic assessment of symptomatic patients using tests that are used in routine clinical practice. Copy of the test results and clinical decisions will be included in the patients' hospital records. Confidentiality will be preserved at all times. The research component is the collection of research-quality data for the purpose of analysis and publication. When data are sent to any DOvE team affiliates, the patient's name or other identifying information will be masked and replaced by a unique identification number and will NOT have your name or other personal identifying information

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12. APPENDICES

12.1 - Appendix 1 – Summary of studies by design, data collection, instrument used, number of cases and controls and percentage of patients presenting any symptom

Study			Design, Data	Age range	Number of		Symptoms %	
Year	Author	Country			Control	Cases	Controls	Case
1979	Ranney	US	D/CR	N/	N/	25	N/	97
1981	Kenned	Canada	D/CR	N/	N/	97	N/	95
1985	Smith	US	D	20-54	N/	82	N/	68
1988	Flam	Sweden	D	N/	N/	36	N/	98
1988	Mantzavino	Greece	D/CR	N/	N/	10	N/	91
				A	A	8	A	
1993	Wikbor	Sweden	D/CR	25-87	N/	16	N/	10
1994	Porteno	USA	D	23-86	N/	15	N/	62
1996	Wikbor	Sweden	D/CR	25-85	N/	16	N/	10
1997	Igo	US	D	35-70	N/	50	N/	94
1997	Petignat	Switzerland	D/CR	26-89	N/	11	N/	80
					A	9	A	
1998	Piura	Israel	D/CR	N/	N/	65	N/	10
1999	Eltabba	US	D/CR	16-89	N/	72	N/	92
1999	Fitch	Canada	D	Mean	N/	31	N/	91
1999	Nelson	Sweden	D/CR	15-40	N/	15	N/	80
2000	Gof	US	D	18-84	N/	172	N/	95
2001	Goldber	US	D	Mean	N/	52	N/	11(urinary
2001	Vin	US	D	20-69	61	15	84	92
2001	Olson	US	CC/Q	<40	16	25	42	93
2002	Fitch	Canada	N	N/	N/	18	N/	qualitative
2002	Kirwan	UK	N	N/	N/	13	N/	92
2002	Takeuc	Japan	D/CR	15-44	N/	38	N/	80
2003	Chan	Hong	D	18-70	N/	80	N/	90
					A		A	
2003	Ferrell	US	Qualitat	N/	N/	21 806	N/	97
2003	Koldjesk	US	D	28-73	N/	19	N/	95
2003	Vin	US	CC/Q	20-74	20	28	84	92
2004	Webb	Australi	D	18-79	N/	81	N/	96
2004	Yawn	US	D/CR	31-98	N/	10	N/	85
2004	Gof	US	CC/Q	15-90	101	12	97	94
2005	Bankhea	UK	M	--	N/	22	N/	77-
2005	Friedma	US	CC/CR	30-87	10	10	N/	Excess diff.
2005	Smith	US,SEER	CC/CR	≥	16 965	198	N/	47.
2007	Gof	US	C	N/	48	14	N/	Symptom
2007	Anderse	US	C	N/	25	75	11.	64
2007	Olsen	Australi	D	18-79	N/	42	N/	66
2009	Ki	Korea	C	18-77	20	11	15.	65.
2009	Lurie	US	C	19-88	49	43	N/	Symptom
2009	Rossing	US	C	35-74	131	81	25.	83
2010	Jensen	US	D	Mean	N/	51	N/	Symptom
				62.1	A		A	Index
2011	Matsuo	US	D	Mean	N/	27	N/	93.
				61.9	A	6	A	5
2011	Gof	US	C	40	100	126	N/	4

D= descriptive (no control group) CR= chart review
 CC= case-control Q= questionnaire MA=meta-analysis



N=newsletter

N/A= not applicable



12.2 Appendix 2- Symptoms

Bloating, distension of abdomen, clothes around the waist feel too tight, feel an abdominal mass

Discomfort or pain in abdomen, or pelvic region, or lower back

Feeling full after eating only a few bites, loss of appetite

Diarrhea, constipation, bowel or rectum feels full, change in bowel habits, constant urge to have a bowel movement, painful or burning bowel movements, rectal pain, painful defecation

Weight loss not due to dieting

Nausea, vomiting, heartburn, gas, burping, indigestion

Need to urinate more often, need to urinate urgently, pressure on the bladder, leaking urine, burning sensation when urinating, need to urinate but nothing there, cannot empty bladder completely, feeling full after urinating

Vaginal discharge, bleeding, spotting, deep pain on intercourse



12.3 Appendix 3- Questionnaires

12.3.1 Forms to be completed on Visit 1 (Also available in French)

The following forms will be completed, along with the informed consent form, at visit 1.



12.3.1.2. Appendix 3.1b: Case Report Form 1 (CRF1)

12.3.1.2. DOvE Study Registration and Demographics Questionnaire

DOVE Study Registration and Demographics Questionnaire

Study ID:

First Name: Last Name:

Royal Victoria Hospital Number: Medicare Number:

Date of Birth: Age: Address:

City: Province: Postal Code:

Telephone (Home): Telephone (Other):

DOVE team members may leave a message for me at home Yes No

DOVE team members may leave a message for me at this number Yes No

E-mail Address: Language of preference: English French Other

Yes, I would like to receive information about DOvE by email

No, please only email me about my own health



Racial or cultural Background: *(Please check as many as apply)*

- White _____
 - Black (Jamaican, Haitian, Somali, etc.)
 - Chinese
 - South-Asian (Indian, Sri Lankan, etc.)
 - Filipino
 - Latin American
 - Southeast Asian (Vietnamese, Cambodian, etc.)
 - West Asian (Iranian, Afghan, etc.)
 - Arab
 - Japanese
 - Korean
 - Aboriginal (Metis, Inuit, etc.)
 - Other: _____
- Anglo-Canadian
 - French-Canadian
 - Jewish
 - Other Canadian (eg. Italian-Canadian, etc.) : _____

What is your current employment status? Employed Unemployed
 Retired Other

Schooling: Less than grade 6 High School (Incomplete) High School (Complete)
 CEGEP or College University (Undergraduate) University (Graduate School)

Name of your regular physician (choose one only):

Physician's / Clinic's Address:

Fax:

MUHC Version: 2013-08-19



DOVE Ovarian Cancer Diagnostic Center
GYNECOLOGIC ONCOLOGY RESEARCH UNIT
 McGill University Health Centre /
 Royal Victoria Hospital
 687 av. des Pins O, Room: F9.37
 Montreal, Quebec, Canada, H3A 1A1

STAMP PATIENT CARD HERE

Date:

Risk Profile

1. Have you ever smoked?

Never Yes, but stopped: years ago. Yes, currently
 Age started smoking:

2. Have you ever been pregnant?

Never Yes → live births abortions/ miscarriages still-births

3. Have you ever used the contraceptive pill?

Never Yes, still use Stopped, but used for: years

4. Have you ever used estrogen / progesterone hormonal supplements?

Never Yes, still use Stopped, but used for: years

Pills:	<input type="checkbox"/> Estrogen	<input type="checkbox"/> Progesterone	<input type="checkbox"/> Unknown
Patch:	<input type="checkbox"/> Estrogen	<input type="checkbox"/> Progesterone	<input type="checkbox"/> Unknown
Cream:	<input type="checkbox"/> Estrogen	<input type="checkbox"/> Progesterone	<input type="checkbox"/> Unknown
Gel:	<input type="checkbox"/> Estrogen	<input type="checkbox"/> Progesterone	<input type="checkbox"/> Unknown

5. Have you ever had surgery to remove your uterus (a hysterectomy)?

No Yes, date: / Reason:
 Month Year

6. Have you ever had surgery to remove your ovaries?

No Yes, date: / Right Ovary Left Ovary Reason:
 Month Year

7. Have you ever had surgery to tie your tubes (tubal ligation)?

No Yes, date: /
 Month Year

8. Last Menstrual Period?

/
 Month Year

9. Have you ever been diagnosed with endometriosis?

No Yes

10. Has anyone in your family ever had cancer?

No Yes (Note: If YES, continue to question 11 - If NO, skip to question 12)

11. Type of cancer (select as many as appropriate) and check off the degree of relationship.

<input type="checkbox"/> Breast:	<input type="checkbox"/> mother <input type="checkbox"/> sister <input type="checkbox"/> aunt <input type="checkbox"/> grandmother <input type="checkbox"/> other	# affected: <input type="text"/>	Ages of diagnosis: <input type="text"/>
<input type="checkbox"/> Ovary:	<input type="checkbox"/> mother <input type="checkbox"/> sister <input type="checkbox"/> aunt <input type="checkbox"/> grandmother <input type="checkbox"/> other	# affected: <input type="text"/>	Ages of diagnosis: <input type="text"/>
<input type="checkbox"/> Colon:	<input type="checkbox"/> mother <input type="checkbox"/> sister <input type="checkbox"/> aunt <input type="checkbox"/> grandmother <input type="checkbox"/> other	# affected: <input type="text"/>	Ages of diagnosis: <input type="text"/>

12. Have you ever had cancer?

No Yes (Note: If YES, continue to question 13 - If NO, skip to next questionnaire)

13. Type of cancer (select as many as appropriate) and give date of diagnosis.

Type of Cancer:	Date (Month/Year):
<input type="checkbox"/> Breast:	<input type="text"/> / <input type="text"/>
<input type="checkbox"/> Endometrial:	<input type="text"/> / <input type="text"/>
<input type="checkbox"/> Colon:	<input type="text"/> / <input type="text"/>
<input type="checkbox"/> Cervix:	<input type="text"/> / <input type="text"/>
<input type="checkbox"/> Other: _____	<input type="text"/> / <input type="text"/>



12.3.1.3. D0vE Symptom Questionnaire

D0vE Symptom Questionnaire:

Instructions: Please Check off which of the following symptom(s) you have been experiencing for **more than 2 weeks** but **less than one year** and answer any subsequent questions related to your symptom(s).

1. Feeling full after eating only a few bites

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?

<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10
NEGLIGIBLE EXTREME	NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, approximately how often does it occur (frequency)?

Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?

sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?

2. Food feels stuck

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?

<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10
NEGLIGIBLE EXTREME	NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?

Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?

sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?

3. Loss of appetite

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?

<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10
NEGLIGIBLE EXTREME	NEGLIGIBLE EXTREME



10. Bloating

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?
 sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?

11. Distension

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?
 sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?

12. Clothes around the waist feel too tight

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?
 sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?



13. Notice an abdominal mass

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

14. Need to urinate more often

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- What makes it feel better?

- What makes it feel worse?

15. Need to urinate more urgently

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- What makes it feel better?

- What makes it feel worse?

16. Need to urinate but nothing there

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- How long does each episode last (duration)?
 sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?



17. Can't empty bladder completely

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- What makes it feel better?

- What makes it feel worse?

18. Burning/pain sensation while urinating

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?
 sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?

19. Feeling full after urinating

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How bad is this symptom right now (1= Negligible, 10= Extreme)? 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?
 sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?



20. Pressure on the bladder

- When did it start? / / *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?

1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10

NEGLIGIBLE EXTREME NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?

Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?

sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?

21. Leaking urine

- When did it start? / / *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?

1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10

NEGLIGIBLE EXTREME NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?

Daily: times a day Weekly: times a week Monthly: times a month

- What makes it feel better?

- What makes it feel worse?

22. Nausea

- When did it start? / / *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?

1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10

NEGLIGIBLE EXTREME NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?

Daily: times a day Weekly: times a week Monthly: times a month

- If this symptom is intermittent, how long does each episode last (duration)?

sec(s). min(s). hr(s). day(s).

- What makes it feel better?

- What makes it feel worse?





26. Burping/ Belching

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?
 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME NEGLIGIBLE EXTREME

- How often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- What makes it feel better?

- What makes it feel worse?

27. Indigestion

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?
 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- What makes it feel better?

- What makes it feel worse?

28. Weight loss not due to dieting

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)?
 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME

- How much weight have you lost? lbs. kg.

29. Vaginal discharge

- When did it start? *(If the day (DD) is unknown type "UNK")
DD* MMM YYYY

- How bad is this symptom at its worst (1= Negligible, 10= Extreme)? - How bad is this symptom right now (1= Negligible, 10= Extreme)?
 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10
NEGLIGIBLE EXTREME NEGLIGIBLE EXTREME

- Is this symptom intermittent or continuous? Intermittent Continuous

- If this symptom is intermittent, how often does it occur (frequency)?
 Daily: times a day Weekly: times a week Monthly: times a month

- What makes it feel better?

- What makes it feel worse?



12.3.1.4.Pain Assessment



DOVE Ovarian Cancer Diagnostic Center
GYNECOLOGIC ONCOLOGY RESEARCH UNIT
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 687 av. des Pins O, Room: F9.37
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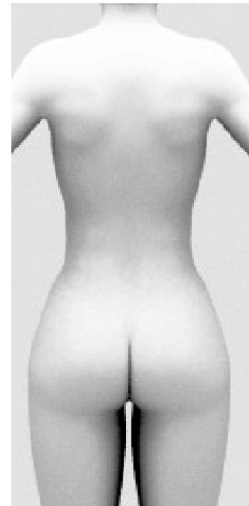
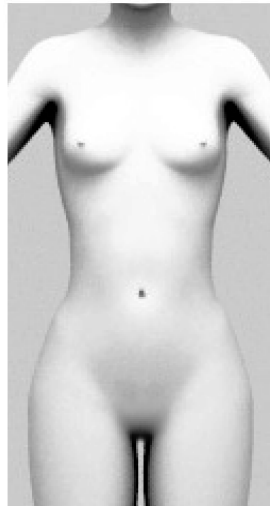
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PART 1: Do you have pain?

- No (if no, continue to next questionnaire)
- Yes (if yes, continue to Part 2.)

PART 2: Where is your pain?

Please mark on the images below, the areas where you feel pain. Put E if external or I if internal, near the areas which you mark. Put EI if external and internal.



PART 3: What does your pain feel like?

Some of the words below describe you **present pain**. Check off **ONLY** those words that best describe it. Leave out any category that is not suitable. Use only a single word in each appropriate category - the one that applies best.

<p>1</p> <input type="checkbox"/> Flickering <input type="checkbox"/> Quivering <input type="checkbox"/> Pulsing <input type="checkbox"/> Throbbing <input type="checkbox"/> Beating <input type="checkbox"/> Pounding	<p>5</p> <input type="checkbox"/> Pinching <input type="checkbox"/> Pressing <input type="checkbox"/> Gnawing <input type="checkbox"/> Cramping <input type="checkbox"/> Crushing	<p>9</p> <input type="checkbox"/> Dull <input type="checkbox"/> Sore <input type="checkbox"/> Hurting <input type="checkbox"/> Aching <input type="checkbox"/> Heavy	<p>14</p> <input type="checkbox"/> Punishing <input type="checkbox"/> Gruelling <input type="checkbox"/> Cruel <input type="checkbox"/> Vicious <input type="checkbox"/> Killing	<p>18</p> <input type="checkbox"/> Tight <input type="checkbox"/> Numb <input type="checkbox"/> Drawing <input type="checkbox"/> Squeezing <input type="checkbox"/> Tearing
<p>2</p> <input type="checkbox"/> Jumping <input type="checkbox"/> Flashing <input type="checkbox"/> Shooting	<p>6</p> <input type="checkbox"/> Tugging <input type="checkbox"/> Pulling <input type="checkbox"/> Wrenching	<p>10</p> <input type="checkbox"/> Tender <input type="checkbox"/> Taut <input type="checkbox"/> Rasping <input type="checkbox"/> Splitting	<p>15</p> <input type="checkbox"/> Wretched <input type="checkbox"/> Blinding <input type="checkbox"/> Annoying <input type="checkbox"/> Troublesome	<p>19</p> <input type="checkbox"/> Cool <input type="checkbox"/> Cold <input type="checkbox"/> Freezing
<p>3</p> <input type="checkbox"/> Pricking <input type="checkbox"/> Boring <input type="checkbox"/> Drilling <input type="checkbox"/> Stabbing <input type="checkbox"/> Lancinating	<p>7</p> <input type="checkbox"/> Hot <input type="checkbox"/> Burning <input type="checkbox"/> Scalding <input type="checkbox"/> Searing	<p>11</p> <input type="checkbox"/> Tiring <input type="checkbox"/> Exhausting	<p>16</p> <input type="checkbox"/> Cruel <input type="checkbox"/> Vicious <input type="checkbox"/> Killing	<p>20</p> <input type="checkbox"/> Nagging <input type="checkbox"/> Nauseating <input type="checkbox"/> Agonizing <input type="checkbox"/> Dreadful <input type="checkbox"/> Torturing
<p>4</p> <input type="checkbox"/> Sharp <input type="checkbox"/> Cutting <input type="checkbox"/> Lacerating	<p>8</p> <input type="checkbox"/> Tingling <input type="checkbox"/> Itchy <input type="checkbox"/> Smarting <input type="checkbox"/> Stinging	<p>12</p> <input type="checkbox"/> Suffocating	<p>17</p> <input type="checkbox"/> Spreading <input type="checkbox"/> Radiating <input type="checkbox"/> Penetrating <input type="checkbox"/> Piercing	
	<p>13</p> <input type="checkbox"/> Fearful <input type="checkbox"/> Frightful <input type="checkbox"/> Terrifying			



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PART 4: How does your pain change with time?

Which word or words would you use to describe the pattern of your pain?

1 <input type="checkbox"/> Continuous <input type="checkbox"/> Steady <input type="checkbox"/> Constant	2 <input type="checkbox"/> Rhythmic <input type="checkbox"/> Periodic <input type="checkbox"/> Intermittent	3 <input type="checkbox"/> Brief <input type="checkbox"/> Momentary <input type="checkbox"/> Transient
--	--	---

PART 5: What is your present pain intensity (PPI)

Which word or words would you use to describe the pattern of your pain?

0 - No Pain
 1 - Mild
 2- Discomforting
 3- Distressing
 4- Horrible
 5- Excrutiating

Comments:



12.3.1.3 Appendix 3.1c Visit 1 Spielberg State Anxiety Inventory (SAI)



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Date:

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then make your selection by circling the appropriate number to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		Not At All	Somewhat	Moderately So	Very Much So
Q1	I feel calm.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q2	I feel secure.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q3	I am tense.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q4	I am regretful.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q5	I feel at ease.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q6	I feel upset.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q7	I am presently worrying over possible misfortunes.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q8	I feel rested.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q9	I feel anxious.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q10	I feel comfortable.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q11	I feel self-confident.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q12	I feel nervous.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q13	I am jittery.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q14	I feel "high-strung."	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q15	I am relaxed.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q16	I feel content.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q17	I am worried.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q18	I feel over-excited and "rattled."	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q19	I feel joyful.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q20	I feel pleasant.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

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Gynecologic Oncology Research Unit
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Date

Spielberger's State-Trait Anxiety Inventory

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate number to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

		Not at all	Somewhat	Moderately so	Very much so
Q1.	I feel pleasant	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q2.	I tire quickly	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q3.	I feel like crying	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q4.	I wish I could be as happy as others seem to be	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q5.	I am loosing out on things because I can't make up my mind soon enough.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q6.	I feel rested	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q7.	I am "calm, cool and collected"	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q8.	I feel that difficulties are piling up so that I cannot overcome them	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q9.	I worry to much over something that really doesn't matter	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q10.	I am happy	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q11.	I am inclined to take things hard	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q12.	I lack self-confidence	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q13.	I feel secure	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q14.	I try to avoid facing a crisis or difficulty	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q15.	I feel blue	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q16.	I am content	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q17.	Some important thoughts runs through my mind and bothers me	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q18.	I take disappointments so keenly that I can't put them out of my mind	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q19.	I am a steady person	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q20.	I get in a state of tension or turmoil as I think over my recent concerns and interests.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

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12.3.1.6. Appendix 3.1e: Visit 1 Beck Depression Inventory (BDI)



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Date:

BDI

Directions: Please read each group of statements carefully, then circle number (0, 1, 2, or 3) next to the statement which best describes the way you have been feeling during the past week, including today. If several statements within a group seem to apply equally well, circle each one. Be sure to read all the statements in each group before making your choice.

<p>1. Sadness</p> <ul style="list-style-type: none"> 0 I do not feel sad. 1 I feel sad. 2 I am sad all the time. 3 I am so sad or unhappy that I can't stand it. <p>2. Pessimism</p> <ul style="list-style-type: none"> 0 I am not discouraged about the future. 1 I feel discouraged about the future. 2 I feel I have nothing to look forward to. 3 I feel that the future is hopeless & that things can not improve. <p>3. Past Failure</p> <ul style="list-style-type: none"> 0 I do not feel like a failure. 1 I feel I have failed more than the average person. 2 As I look back on my life, all I can see is a lot of failures. 3 I feel I am a complete failure as a person. <p>4. Loss of Pleasure</p> <ul style="list-style-type: none"> 0 I get as much satisfaction out of things as I used to. 1 I don't enjoy things the way I used to. 2 I don't get real satisfaction out of anything anymore. 3 I am dissatisfied or bored with everything. <p>5. Guilty Feelings</p> <ul style="list-style-type: none"> 0 I don't feel particularly guilty. 1 I feel guilty a good part of the time. 2 I feel guilty most of the time. 3 I feel guilty all of the time. 	<p>6. Punishment Feelings</p> <ul style="list-style-type: none"> 0 I don't feel I am being punished. 1 I feel I may be punished. 2 I expect to be punished. 3 I feel I am being punished. <p>7. Self-Dislike</p> <ul style="list-style-type: none"> 0 I don't feel disappointed in myself. 1 I am disappointed in myself. 2 I am disgusted with myself. 3 I hate myself. <p>8. Self-Criticalness</p> <ul style="list-style-type: none"> 0 I don't feel I am any worse than anybody else. 1 I am critical of myself for my weakness or mistakes. 2 I blame myself all the time for my faults. 3 I blame myself for everything bad that happens. <p>9. Suicidal Thoughts or Wishes</p> <ul style="list-style-type: none"> 0 I don't have any thoughts of killing myself. 1 I have thoughts of killing myself. 2 I would like to kill myself. 3 I would kill myself if I had the chance. <p>10. Crying</p> <ul style="list-style-type: none"> 0 I don't cry any more than usual. 1 I cry more now than usual. 2 I cry all the time now. 3 I used to be able to cry, but now I can't cry even though I want to.
---	--



11. Agitation

- 0 I'm no more restless or wound up than usual.
- 1 I feel more restless or wound up than usual.
- 2 I'm so restless or agitated that its hard to stay still.
- 3 I'm so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- 0 I have not lost interest in other people.
- 1 I am less interested in other people than I used to be.
- 2 I have lost most of my interest in other people.
- 3 I have lost all of my interest in other people

13. Indecisiveness

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have greater difficulty in making decisions than before.
- 3 I can't make decisions at all anymore.

14. Worthlessness

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15. Loss of Energy

- 0 I have as much energy as ever.
- 1 I have less energy than I used to.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16. Changes in sleeping pattern

- 0 I can sleep as well as usual.
- 1 I don't sleep as well as I used to.
- 2 I wake up 1 – 2 hours earlier than usual and find it hard to get back to sleep.
- 3 I wake up several hours earlier than usual and can not get back to sleep.

17. Irritability

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18. Changes in Appetite

- 0 My appetite is no worse than usual.
- 1 My appetite is not as good as it used to be.
- 2 My appetite is much worse now.
- 3 I have no appetite at all anymore.

19. Weight Loss

- 0 I haven't lost much weight, if any.
- 1 I have lost more than 5 pounds.
- 2 I have lost more than 10 pounds.
- 3 I have lost more than 15 pounds.

20. Physical well being

- 0 I am no more worried about my health than usual.
- 1 I am worried about physical problems such as aches and pains.
- 2 I'm very worried about physical problems that I cannot think about anything else.
- 3 I'm so worried about my physical problems that I cannot think about anything else.

21. Loss of interest in Sex

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

Subtotal Page One: _____

Subtotal Page Two: _____

Total Score: _____



12.3.1.7. Appendix 3.1f: Visit 1, DOvE Program Impact Assessment



DOvE Ovarian Cancer Diagnostic Center
Gynecologic Oncology Research Unit
McGill University Health Centre /
Royal Victoria Hospital
687 Av. Des Pins O., Room F9-37
Montreal, Qc. Canada, H3A 1A1

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IMPACT OF PROGRAM ON PATIENT'S WELL-BEING: VISIT 1

For each question, check the response that is closest to your current thoughts and feelings						
Q1.	Rate your level of distress/worry about your overall health today	<input type="checkbox"/> 1 Extremely high	<input type="checkbox"/> 2 High	<input type="checkbox"/> 3 Moderate	<input type="checkbox"/> 4 Low	<input type="checkbox"/> 5 None
Q2.	Rate your level of worry caused by the information you received in connection with the DOvE program	<input type="checkbox"/> 1 Extremely high	<input type="checkbox"/> 2 High	<input type="checkbox"/> 3 Moderate	<input type="checkbox"/> 4 Low	<input type="checkbox"/> 5 None
Q3.	Are you anxious or worried about participating in the DOvE program?	<input type="checkbox"/> 1 An extreme amount	<input type="checkbox"/> 2 Very much	<input type="checkbox"/> 3 A moderate amount	<input type="checkbox"/> 4 A little	<input type="checkbox"/> 5 Not at all
Q4.	Are you anxious about the possibility of having ovarian cancer?	<input type="checkbox"/> 1 Always	<input type="checkbox"/> 2 Very often	<input type="checkbox"/> 3 Quite often	<input type="checkbox"/> 4 Seldom	<input type="checkbox"/> 5 Never
Q5.	Rate your level of anxiety about the possibility of having ovarian cancer?	<input type="checkbox"/> 1 Extremely high	<input type="checkbox"/> 2 High	<input type="checkbox"/> 3 Moderate	<input type="checkbox"/> 4 Low	<input type="checkbox"/> 5 None

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12.3.2. Forms to be Completed on Visit 2 before patient receives results of the test (Also available in French)

12.3.2.1. Appendix 3.2a: Transvaginal Ultrasound Form

VISIT 2

DETECTING OVARIAN CANCER EARLY

DOVE

Date:

SONOGRAPHER:

PHYSICIAN:

REFERRING MD:

INDICATION:

Stamp Patient Card Here

Method:

Transvaginal (TV) 2D Color Doppler
 Transabdominal (TA) 3D Pulsed Doppler
 TA + TV 2D + 3D

Machine:

Uterus:

Size: D1 mm D2 mm D3 mm Vol ml

Normal
 Abnormal
 Not Examined
 Not Visible
 Absent
 Midline Uterus
 Deviated Right
 Deviated Left

Orientation:

Anteverted
 Retroverted
 Axial
 Absent
 Total Hysterectomy
 Subtotal Hysterectomy

Abnormalities:

None
 Arcuate
 Bicornuate
 Septate
 Subseptate
 Didelphic

Midline Echo:

Intact
 Disrupted
 Normal Triple Layer

Myometrium:

Size: D1 mm D2 mm D3 mm

Type:

Submucous ———— <50%
 Intramural ———— >50%
 Subserous
 Broad Ligament
 Pedunculated

Location:

Left ———— Right ———— Midline
 Anterior ———— Posterior ———— Lateral
 Fundal ———— Lower Segment ———— Cervical

PAGE 1 OF 4





- Endometrium:** Clearly Visualized
 Clear After Saline Instillation
 Cannot Be Seen Clearly

- Findings:** Endometrial thickness normal for post-menopausal woman <5.0mm Size: mm
 Endometrial thickness abnormal for post-menopausal woman >5.0mm

- Cavity:** Normal
 Cystic, consistent with Tamoxifen
 Shows hyperechoic area, possible polyp
 Indistinct and cannot adequately be assessed
 Distorted by submucosal fibroid
 Possible intrauterine adhesion
 IUD in normal position
 Comments: _____

Ovary: RIGHT

- Normal
 Abnormal
 Not Examined
 Not Visible
 Cyst Present
 Partially Visible
 Oophorectomy

Size:
D1 mm D2 mm D3 mm Vol ml

Cysts:
Corpus Luteum Present Absent

Size: D1 mm D2 mm D3 mm Vol ml

Simple Cyst: Unilocular Bilocular

Size: D1 mm D2 mm D3 mm Vol ml

Complex Cyst: Lt Fallopian Tube Lt Ovary Lt Adnexum Uncertain
 Rt Fallopian Tube Rt Ovary Rt. Adnexum

Size: D1 mm D2 mm D3 mm Vol ml

- Structure:**
 Regular
 Irregular

- Septa:**
 None
 <3.0mm
 >3.0mm

- Echogenicity:**
 Anechoic
 Mixed Echogenicity w/ Shadowing
 Around Glass
 Scattered Achoes
 Solid

Wall Thickness: <3.0mm >3.0mm

Papillary Projections: Present Absent

Size: D1 mm D2 mm D3 mm Vol ml



Color Flow: Increased Vascularity Poorly Vascularized

Indices:
RI
PI
S/D
PSV

Cul de Sac/ Pouch of Douglas Free Fluid:

- None
- Visible
- 1-5cc
- >5cc

Subphrenic Area Free Fluid:

- None
- Visible
- 1-5cc
- >5cc

Ovary: LEFT

- Normal
- Abnormal
- Not Examined
- Not Visible
- Cyst Present
- Partially Visible
- Oophorectomy

Size:

D1 mm D2 mm D3 mm Vol ml

Cysts:

Corpus Luteum Present Absent

Size: D1 mm D2 mm D3 mm Vol ml

Simple Cyst: Unilocular Bilocular

Size: D1 mm D2 mm D3 mm Vol ml

Complex Cyst: Lt Fallopiian Tube Lt Ovary Lt Adnexum Uncertain
 Rt Fallopiian Tube Rt Ovary Rt. Adnexum

Size: D1 mm D2 mm D3 mm Vol ml

Structure:

- Regular
- Irregular

Septa:

- None
- <3.0mm
- >3.0mm

Echogenicity:

- Anechoic
- Mixed Echogenicity w/ Shadowing
- Around Glass
- Scattered Achoes
- Solid

Wall Thickness: <3.0mm >3.0mm

Papillary Projections: Present Absent

Size: D1 mm D2 mm D3 mm Vol ml



Color Flow: Increased Vascularity Poorly Vascularized

Indices:
RI
PI
S/D
PSV

Cul de Sac/Pouch of Douglas Free Fluid:

- None
- Visible
- 1-5cc
- >5cc

Subphrenic Area Free Fluid:

- None
- Visible
- 1-5cc
- >5cc

Notes:

Sonographer Signature:

Date:

Physician Signature:

Date:



12.3.2.2. Appendix 3.2b: Spielberger State Anxiety Inventory(SAI)



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GYNECOLOGIC ONCOLOGY RESEARCH UNIT**
 McGill University Health Centre /
 Royal Victoria Hospital
 687 av. des Pins O, Room: F9.37
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Date:

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then make your selection by circling the appropriate number to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		Not At All	Somewhat	Moderately So	Very Much So
Q1	I feel calm.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q2	I feel secure.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q3	I am tense.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q4	I am regretful.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q5	I feel at ease.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q6	I feel upset.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q7	I am presently worrying over possible misfortunes.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q8	I feel rested.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q9	I feel anxious.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q10	I feel comfortable.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q11	I feel self-confident.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q12	I feel nervous.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q13	I am jittery.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q14	I feel "high-strung."	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q15	I am relaxed.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q16	I feel content.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q17	I am worried.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q18	I feel over-excited and "rattled."	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q19	I feel joyful.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q20	I feel pleasant.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4



12.3.2.3. Appendix 3.2c: Visit 2, DOvE Program Impact Assessment



DOvE Ovarian Cancer Diagnostic Center
 Gynecologic Oncology Research Unit
 McGill University Health Centre /
 Royal Victoria Hospital
 687 Av. Des Pins O., Room F9-37
 Montreal, Qc. Canada, H3A 1A1

STAMP PATIENT CARD HERE

Date

IMPACT OF PROGRAM ON PATIENT'S WELL-BEING: VISIT 2

For each question, check the response that is closest to your current thoughts and feelings						
Q1.	Rate your level of distress/worry about your overall health today	<input type="checkbox"/> 1 Extremely high	<input type="checkbox"/> 2 High	<input type="checkbox"/> 3 Moderate	<input type="checkbox"/> 4 Low	<input type="checkbox"/> 5 None
Q2.	Are you anxious about the possibility of having ovarian cancer?	<input type="checkbox"/> 1 Always	<input type="checkbox"/> 2 Very often	<input type="checkbox"/> 3 Quite often	<input type="checkbox"/> 4 Seldom	<input type="checkbox"/> 5 Never
Q3.	Rate your level of anxiety about the possibility of having ovarian cancer?	<input type="checkbox"/> 1 Extremely high	<input type="checkbox"/> 2 High	<input type="checkbox"/> 3 Moderate	<input type="checkbox"/> 4 Low	<input type="checkbox"/> 5 None
Q4.	Participating in this program has:	<input type="checkbox"/> 1 Increased to a great extent my worry about my health	<input type="checkbox"/> 2 Increased somewhat my worry about my health	<input type="checkbox"/> 3 Has not changed my level of worry about my health	<input type="checkbox"/> 4 Somewhat reassured me about my health	<input type="checkbox"/> 5 Reassured me a great deal about my health
Q5.	Has participating in this program interfered with your work life?	<input type="checkbox"/> 1 Extremely	<input type="checkbox"/> 2 Very much	<input type="checkbox"/> 3 Moderately	<input type="checkbox"/> 4 A little	<input type="checkbox"/> 5 Not at all
Q6.	Has participating in this program interfered with you personal/social life?	<input type="checkbox"/> 1 Extremely	<input type="checkbox"/> 2 Very much	<input type="checkbox"/> 3 Moderately	<input type="checkbox"/> 4 A little	<input type="checkbox"/> 5 Not at all
Q7.	Were you anxious or scared while waiting for the results of your medical tests?	<input type="checkbox"/> 1 Extremely	<input type="checkbox"/> 2 Very much	<input type="checkbox"/> 3 Moderately	<input type="checkbox"/> 4 A little	<input type="checkbox"/> 5 Not at all
Q8.	Are you satisfied with the service received from the staff of the DOvE program?	<input type="checkbox"/> 1 Very dissatisfied	<input type="checkbox"/> 2 Dissatisfied	<input type="checkbox"/> 3 Neither satisfied or dissatisfied	<input type="checkbox"/> 4 Quite satisfied	<input type="checkbox"/> 5 Very satisfied

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12.3.2.4. Appendix 3.2d: Visit 2 Beck Depression Inventory (BDI)



DOVE Ovarian Cancer Diagnostic Center
GYNECOLOGIC ONCOLOGY RESEARCH UNIT
 McGill University Health Centre /
 Royal Victoria Hospital
 687 av. des Pins O, Room: F9.37
 Montreal, Quebec, Canada, H3A 1A1

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Date:

BDI

Directions: Please read each group of statements carefully, then circle number (0, 1, 2, or 3) next to the statement which best describes the way you have been feeling during the past week, including today. If several statements within a group seem to apply equally well, circle each one. Be sure to read all the statements in each group before making your choice.

<p>1. Sadness</p> <p>0 I do not feel sad. 1 I feel sad. 2 I am sad all the time. 3 I am so sad or unhappy that I can't stand it.</p> <p>2. Pessimism</p> <p>0 I am not discouraged about the future. 1 I feel discouraged about the future. 2 I feel I have nothing to look forward to. 3 I feel that the future is hopeless & that things can not improve.</p> <p>3. Past Failure</p> <p>0 I do not feel like a failure. 1 I feel I have failed more than the average person. 2 As I look back on my life, all I can see is a lot of failures. 3 I feel I am a complete failure as a person.</p> <p>4. Loss of Pleasure</p> <p>0 I get as much satisfaction out of things as I used to. 1 I don't enjoy things the way I used to. 2 I don't get real satisfaction out of anything anymore. 3 I am dissatisfied or bored with everything.</p> <p>5. Guilty Feelings</p> <p>0 I don't feel particularly guilty. 1 I feel guilty a good part of the time. 2 I feel guilty most of the time. 3 I feel guilty all of the time.</p>	<p>6. Punishment Feelings</p> <p>0 I don't feel I am being punished. 1 I feel I may be punished. 2 I expect to be punished. 3 I feel I am being punished.</p> <p>7. Self-Dislike</p> <p>0 I don't feel disappointed in myself. 1 I am disappointed in myself. 2 I am disgusted with myself. 3 I hate myself.</p> <p>8. Self-Criticalness</p> <p>0 I don't feel I am any worse than anybody else. 1 I am critical of myself for my weakness or mistakes. 2 I blame myself all the time for my faults. 3 I blame myself for everything bad that happens.</p> <p>9. Suicidal Thoughts or Wishes</p> <p>0 I don't have any thoughts of killing myself. 1 I have thoughts of killing myself. 2 I would like to kill myself. 3 I would kill myself if I had the chance.</p> <p>10. Crying</p> <p>0 I don't cry any more than usual. 1 I cry more now than usual. 2 I cry all the time now. 3 I used to be able to cry, but now I can't cry even though I want to.</p>
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11. Agitation

- 0 I'm no more restless or wound up than usual.
- 1 I feel more restless or wound up than usual.
- 2 I'm so restless or agitated that its hard to stay still.
- 3 I'm so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- 0 I have not lost interest in other people.
- 1 I am less interested in other people than I used to be.
- 2 I have lost most of my interest in other people.
- 3 I have lost all of my interest in other people

13. Indecisiveness

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have greater difficulty in making decisions than before.
- 3 I can't make decisions at all anymore.

14. Worthlessness

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15. Loss of Energy

- 0 I have as much energy as ever.
- 1 I have less energy than I used to.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16. Changes in sleeping pattern

- 0 I can sleep as well as usual.
- 1 I don't sleep as well as I used to.
- 2 I wake up 1 - 2 hours earlier than usual and find it hard to get back to sleep.
- 3 I wake up several hours earlier than usual and can not get back to sleep.

17. Irritability

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18. Changes in Appetite

- 0 My appetite is no worse than usual.
- 1 My appetite is not as good as it used to be.
- 2 My appetite is much worse now.
- 3 I have no appetite at all anymore.

19. Weight Loss

- 0 I haven't lost much weight, if any.
- 1 I have lost more than 5 pounds.
- 2 I have lost more than 10 pounds.
- 3 I have lost more than 15 pounds.

20. Physical well being

- 0 I am no more worried about my health than usual.
- 1 I am worried about physical problems such as aches and pains.
- 2 I'm very worried about physical problems that I cannot think about anything else.
- 3 I'm so worried about my physical problems that I cannot think about anything else.

21. Loss of interest in Sex

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

Subtotal Page One: _____

Subtotal Page Two: _____


Total Score: _____





12.3.3.3 Forms to be Completed on Visit 3 (Also available in French)

12.3.3.1. Appendix 3.3a: Spielberg State Anxiety Inventory (SAI)

 <p>DOVE Ovarian Cancer Diagnostic Center GYNECOLOGIC ONCOLOGY RESEARCH UNIT McGill University Health Centre / Royal Victoria Hospital 687 av. des Pins O, Room: F9.37 Montreal, Quebec, Canada, H3A 1A1</p>	<p>STAMP PATIENT CARD HERE</p>
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Date:

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then make your selection by circling the appropriate number to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		Not At All	Somewhat	Moderately So	Very Much So
Q1	I feel calm.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q2	I feel secure.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q3	I am tense.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q4	I am regretful.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q5	I feel at ease.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q6	I feel upset.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q7	I am presently worrying over possible misfortunes.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q8	I feel rested.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q9	I feel anxious.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q10	I feel comfortable.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q11	I feel self-confident.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q12	I feel nervous.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q13	I am jittery.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q14	I feel "high-strung."	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q15	I am relaxed.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q16	I feel content.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q17	I am worried.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q18	I feel over-excited and "rattled."	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q19	I feel joyful.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Q20	I feel pleasant.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4



12.3.3.2. Appendix 3.3b : Impact of Program on Patient's well-being: Visit 3



DOVE Ovarian Cancer Diagnostic Center
Gynecologic Oncology Research Unit
McGill University Health Centre /
Royal Victoria Hospital
687 Av. Des Pins O., Room F9-37
Montreal, Qc. Canada, H3A 1A1

STAMP PATIENT CARD HERE

Date

IMPACT OF PROGRAM ON PATIENT'S WELL-BEING: VISIT 3

For each question, check the response that is closest to your current thoughts and feelings						
Q1.	Rate your level of distress/worry about your overall health today	<input type="checkbox"/> 1 Extremely high	<input type="checkbox"/> 2 High	<input type="checkbox"/> 3 Moderate	<input type="checkbox"/> 4 Low	<input type="checkbox"/> 5 None
Q2.	Are you anxious about the possibility of having ovarian cancer?	<input type="checkbox"/> 1 Always	<input type="checkbox"/> 2 Very often	<input type="checkbox"/> 3 Quite often	<input type="checkbox"/> 4 Seldom	<input type="checkbox"/> 5 Never
Q3.	Rate your level of anxiety about the possibility of having ovarian cancer?	<input type="checkbox"/> 1 Extremely high	<input type="checkbox"/> 2 High	<input type="checkbox"/> 3 Moderate	<input type="checkbox"/> 4 Low	<input type="checkbox"/> 5 None
Q4.	Participating in this program has:	<input type="checkbox"/> 1 Increased to a great extent my worry about my health	<input type="checkbox"/> 2 Increased somewhat my worry about my health	<input type="checkbox"/> 3 Has not changed my level of worry about my health	<input type="checkbox"/> 4 Somewhat reassured me about my health	<input type="checkbox"/> 5 Reassured me a great deal about my health
Q5.	Has participating in this program interfered with your work life?	<input type="checkbox"/> 1 Extremely	<input type="checkbox"/> 2 Very much	<input type="checkbox"/> 3 Moderately	<input type="checkbox"/> 4 A little	<input type="checkbox"/> 5 Not at all
Q6.	Has participating in this program interfered with you personal/social life?	<input type="checkbox"/> 1 Extremely	<input type="checkbox"/> 2 Very much	<input type="checkbox"/> 3 Moderately	<input type="checkbox"/> 4 A little	<input type="checkbox"/> 5 Not at all
Q7.	Were you anxious or scared while waiting for the results of your medical tests?	<input type="checkbox"/> 1 Extremely	<input type="checkbox"/> 2 Very much	<input type="checkbox"/> 3 Moderately	<input type="checkbox"/> 4 A little	<input type="checkbox"/> 5 Not at all
Q8.	Are you satisfied with the service received from the staff of the DOVE program?	<input type="checkbox"/> 1 Very dissatisfied	<input type="checkbox"/> 2 Dissatisfied	<input type="checkbox"/> 3 Neither satisfied or dissatisfied	<input type="checkbox"/> 4 Quite satisfied	<input type="checkbox"/> 5 Very satisfied

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12.3.3.3. Appendix 3.3c: Visit 3 Beck Depression Inventory (BDI)



DOVE Ovarian Cancer Diagnostic Center
GYNECOLOGIC ONCOLOGY RESEARCH UNIT
 McGill University Health Centre /
 Royal Victoria Hospital
 687 av. des Pins O, Room: F9.37
 Montreal, Quebec, Canada, H3A 1A1

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Date:

BDI

Directions: Please read each group of statements carefully, then circle number (0, 1, 2, or 3) next to the statement which best describes the way you have been feeling during the past week, including today. If several statements within a group seem to apply equally well, circle each one. Be sure to read all the statements in each group before making your choice.

<p>1. Sadness</p> <p>0 I do not feel sad. 1 I feel sad. 2 I am sad all the time. 3 I am so sad or unhappy that I can't stand it.</p> <p>2. Pessimism</p> <p>0 I am not discouraged about the future. 1 I feel discouraged about the future. 2 I feel I have nothing to look forward to. 3 I feel that the future is hopeless & that things can not improve.</p> <p>3. Past Failure</p> <p>0 I do not feel like a failure. 1 I feel I have failed more than the average person. 2 As I look back on my life, all I can see is a lot of failures. 3 I feel I am a complete failure as a person.</p> <p>4. Loss of Pleasure</p> <p>0 I get as much satisfaction out of things as I used to. 1 I don't enjoy things the way I used to. 2 I don't get real satisfaction out of anything anymore. 3 I am dissatisfied or bored with everything.</p> <p>5. Guilty Feelings</p> <p>0 I don't feel particularly guilty. 1 I feel guilty a good part of the time. 2 I feel guilty most of the time. 3 I feel guilty all of the time.</p>	<p>6. Punishment Feelings</p> <p>0 I don't feel I am being punished. 1 I feel I may be punished. 2 I expect to be punished. 3 I feel I am being punished.</p> <p>7. Self-Dislike</p> <p>0 I don't feel disappointed in myself. 1 I am disappointed in myself. 2 I am disgusted with myself. 3 I hate myself.</p> <p>8. Self-Criticalness</p> <p>0 I don't feel I am any worse than anybody else. 1 I am critical of myself for my weakness or mistakes. 2 I blame myself all the time for my faults. 3 I blame myself for everything bad that happens.</p> <p>9. Suicidal Thoughts or Wishes</p> <p>0 I don't have any thoughts of killing myself. 1 I have thoughts of killing myself. 2 I would like to kill myself. 3 I would kill myself if I had the chance.</p> <p>10. Crying</p> <p>0 I don't cry any more than usual. 1 I cry more now than usual. 2 I cry all the time now. 3 I used to be able to cry, but now I can't cry even though I want to.</p>
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11. Agitation

- 0 I'm no more restless or wound up than usual.
- 1 I feel more restless or wound up than usual.
- 2 I'm so restless or agitated that its hard to stay still.
- 3 I'm so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- 0 I have not lost interest in other people.
- 1 I am less interested in other people than I used to be.
- 2 I have lost most of my interest in other people.
- 3 I have lost all of my interest in other people

13. Indecisiveness

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have greater difficulty in making decisions than before.
- 3 I can't make decisions at all anymore.

14. Worthlessness

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15. Loss of Energy

- 0 I have as much energy as ever.
- 1 I have less energy than I used to.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16. Changes in sleeping pattern

- 0 I can sleep as well as usual.
- 1 I don't sleep as well as I used to.
- 2 I wake up 1 – 2 hours earlier than usual and find it hard to get back to sleep.
- 3 I wake up several hours earlier than usual and can not get back to sleep.

17. Irritability

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18. Changes in Appetite

- 0 My appetite is no worse than usual.
- 1 My appetite is not as good as it used to be.
- 2 My appetite is much worse now.
- 3 I have no appetite at all anymore.

19. Weight Loss

- 0 I haven't lost much weight, if any.
- 1 I have lost more than 5 pounds.
- 2 I have lost more than 10 pounds.
- 3 I have lost more than 15 pounds.

20. Physical well being

- 0 I am no more worried about my health than usual.
- 1 I am worried about physical problems such as aches and pains.
- 2 I'm very worried about physical problems that I cannot think about anything else.
- 3 I'm so worried about my physical problems that I cannot think about anything else.

21. Loss of interest in Sex

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

Subtotal Page One: _____

Subtotal Page Two: _____

Total Score: _____



Appendix 4- Demographic characteristics of study patients and general population of women

		DOvE patients n=1455	Montreal women >50yrs	p-value
Age	50-64	1053 (72.4%)	175120/342929 (51.1%)	<0.0001
	65+	402 (27.6%)	167809/342929 (48.9%)	
Education	Grade 6 or less	35 (2.4%)	112783/334604 (33.7%)	<0.0001
	Secondary or Trade School	414 (28.5%)	106208/334604 (31.7%)	
	College/University	919 (63.1%)	115613/334604 (34.6%)	
	Unknown**	87 (6%)		
Language	French	575 (39.5%)	167450/286030 (58.5%)	<0.0001
	English	748 (51.4%)	30880/286030 (10.8%)	
	Other	132 (9.1%)	87700/286030 (30.7%)	

*Estimates provided by the Institute de la Statistique du Quebec & Statistic Canada (Population Census 2006) for all administrative regions of Montreal. Slight differences in the denominators reflect the difficulties inherent in collecting such data. Language values are for the entire city of Montreal.



**Excluded from calculation of the chi-square statistic.