Implementation of patient involvement in the development of a health-related quality of life patient-reported outcome measure for ovarian cancer

Sharolin Boban
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Implementation of patient involvement in the development of a health-related quality of life patient-reported outcome measure for ovarian cancer

Sharolin Ann Boban
Bachelor of Science with Honours (Biomedical Science)

A thesis submitted in fulfilment of the requirements for Master of Health Science by Research

The University of Notre Dame Australia
School of Health Sciences
Fremantle Campus
February 2021
Author’s Declaration

I declare this thesis is my own account of my research and contains as its main content work which has not been previously submitted for a degree at any tertiary education institution.

Signature:  
Name: Sharolin Ann Boban  
Date: 01/02/2021
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List of Abbreviations

CCWA, Cancer Council Western Australia
CI, Cognitive Interviewing
CIC-Cancer Project, Continuous Improvement in Care-Cancer Project
CONSORT-PRO, Consolidated Standards of Reporting Trials-Patient Reported Outcome
CTA, Concurrent Think-Aloud
EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer Patients
EORTC QLQ-OV28, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Ovarian
FACIT FACT-G, Functional Assessment of Chronic Illness Therapy Functional Assessment of Cancer Therapy–General
FACT-O, Functional Assessment of Cancer Therapy–Ovarian
FOSI, Functional Assessment of Cancer Therapy–ovarian cancer symptom index
GPs, General Practitioners
HPs, Health Professionals
HRQOL, Health-Related Quality of Life
ICHOM, International Consortium for Health Outcomes Measurement
MOST, Measure of Ovarian Symptoms and Treatment concerns
OC, Ovarian Cancer
OCA, Ovarian Cancer Australia
OVAQOL, OVARian cancer health related Quality of Life scale
PROs, Patient-Reported Outcomes
PROMs, Patient-Reported Outcome Measures
QOL, Quality of Life
SPIRIT-PRO, Standard Protocol Items: Recommendations for Interventional Trials- Patient Reported Outcome
UNDA, University of Notre Dame Australia
VBHC, Value-Based Health Care
Abstract

Ovarian cancer is the second most common gynaecological cancer and the eighth-most common cause of death in Australian women with a five-year relative survival of 46%. Using a ‘ground-up approach’ and patient involvement, this research project implemented a sequential mixed methods approach to develop a health-related quality of life outcome measure across the disease trajectory.

The six key themes identified from initial qualitative data highlighted treatment-related and psychosocial challenges alongside financial issues, relationships with health professionals, and patient coping strategies. This informed the generation of items necessary to develop a draft health-related quality of life tool. A cognitive interviewing technique established the content validity of the draft items. The final draft scale comprised 38 health-related quality of life items across three domains: physical health/functioning wellbeing, emotional wellbeing, and social wellbeing; each rated on a five-point frequency response scale. Field testing and evaluation of psychometric properties could be the focus of a future study.
List of manuscripts submitted for journal review

1. “Women diagnosed with ovarian cancer: Patient and carer experiences and perspectives”

Work was submitted to Patient Related Outcome Measures on 18 July 2020 and was accepted for publication on 15 December 2020.

2. “Employing cognitive interviewing to evaluate, improve and validate items for measuring the health-related quality of life of women diagnosed with ovarian cancer”

Submission of work to Patient Related Outcome Measures on 24 November 2020, whereby the first peer reviewer report has been returned.
Statement of Contributions

Sharolin Boban is the sole author of the thesis. Sharolin developed and implemented the research study; collected, reviewed and evaluated the data; and was the primary author of the manuscripts submitted for publication.

Professor Caroline Bulsara is the senior author of one of the work publications and has supervised Miss Sharolin Boban through her expertise in qualitative research. She has made a substantial contribution to the development, preparation and execution of community group participatory approaches and has supported the revision of various iterations of the work completed.

Professor Jim Codde has supervised the research candidate through all stages of the projects, has engaged in critical review of the manuscripts as they were prepared for publication and is a co-author of the work publications.

Dr. Jenny Downs has extensive knowledge in the field of qualitative study design and developing quality of life measures. She has contributed significantly to the development of the measure and thesis. Given her expertise, Dr. Downs is the senior author of one of the work submitted for publication.

Dr. Paul Cohen, a Gynaecologist, has considerable clinical expertise in gynaecological oncology, including qualitative research. Dr. Cohen is a co-author of the work publications and has made a substantial contribution to the development of this research as well as to the writing of the two manuscripts.

A signed written statement from each of the co-authors to be provided in Appendix 11.
Acknowledgements

This study was carried out with the funding of a grant from the Cancer Research Trust and is part of the CIC Cancer Program, a multi-institutional research organization that seeks to deliver value-based healthcare to clinical settings in Western Australia. In addition, I acknowledge the support of the Australian Government through the Research Training Program (RTP) scheme.

With great pleasure, I would like to take this occasion to sincerely thank those who have been with me during my journey in this field of research. Nothing would have been possible without their assistance.

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A huge thank you to Paul for all the generous support, even though you were busy with your clinics and other projects. Working with such a talented clinician expert was a pleasant
experience. I learned so much from you. Thank you so much for your tremendous contribution to the structuring of my literary works and continuing guidance. Thank you for being such a great mentor.

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Chapter 1: Introduction
Introduction

The primary objective of this thesis was to define and develop a meaningful health-related quality of life (HRQOL) patient-reported outcome measure (PROM) for patients with ovarian cancer (OC). This work formed part of a larger research initiative titled ‘The Continuous Improvement in Care – Cancer (CIC Cancer) Project’. The CIC Cancer project aims to offer value-based health care (VBHC) in clinical oncology settings in Western Australia including OC. The main objective of this larger project is to engage and involve patients, their carers and clinicians to identify and establish an agreed set of outcome measures pertaining to OC.

This chapter provides a background to OC and clinical care with a focus on the quality of care and patient involvement. The purpose, scope and relevance of the research are also discussed in this chapter.

Research Background

Cancer-global and national trends

Cancer, now classified as a chronic illness, is ranked the second leading cause of death worldwide and causes 1 in every 6 deaths. According to a 2018 report by the International Agency for Research on Cancer, it was estimated there were 17 million new cases worldwide and 9.5 million cancer deaths and this is predicted to rise to 27.5 million new cases and 16.3 million deaths within the next 20 years (American Cancer Society, 2018).

Following a global trend, a recent report by the Australian Institute of Health and Welfare has found that 1 in 2 Australian men and women will be diagnosed with cancer by the age of 85 with an estimated 150,000 new cases to be diagnosed by 2020 (Australian Institute of Health and Welfare, 2019). In addition, the cancer data report by the Australian Institute of Health and Welfare for the period 1982-2020 shows that the estimated incidence with all cancers combined has increased from 47,468 to 145,483 whereas actual mortality in persons increased from 24,915 to 48,099 (Australian Institute of Health and Welfare, 2020). The growth in the number of cases has impacted hospital expenditure where a recent report marked that there has been an increase in the hospital-based expenditure for cancer care in
Australia from approximately $4.5 billion in 2008-09 to around $6.3 billion for patients diagnosed during 2009–2013 (Goldsbury et al., 2018). Moreover, continued upward pressure on hospital costs is expected, in part due to improvements in cancer survival rates within Australia and to early detection and better treatment. The number of people living with a cancer diagnosis is predicted to double in less than two decades from 350,000 to more than one million individuals, and double again by 2030 (Fitzmaurice et al., 2019; Wang et al., 2016).

**Cancer care**

With more people living longer following a cancer diagnosis, there has been an international focus in the domain of cancer control and management (Jones et al., 2018) as cancer survivors often develop a range of post-treatment late-onset side effects (pain, anxiety, fatigue) and are at an increased risk of disease recurrence (Jones et al., 2018). The quality of cancer care was first discussed by the Institute of Medicine in 1990 (Lohr et al., 1990). The study committee of the institute defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Lohr et al., 1990, pp. 128-129). However, the increasing need for cancer services, coupled with the complexities of the disease and its management and rising costs, forms a gap in the delivery of cancer care (Levit et al., 2013). Reports indicate that lack of patient involvement including patient-clinician communicational challenges and lack of evidence-based care are barriers in the delivery of effective cancer care and highlight a need for the development and implementation of new strategies to improve the quality of cancer care (Miqueu et al., 2019; Walsh et al., 2010).

**Patient involvement.**

Lack of patient involvement in decision-making and treatment goals with the clinicians has resulted in fragmented medical care which in turn leads to the current prioritising of disease-focused treatments (Saini et al., 2017). Patient involvement is vital in clinical care such as to make informed treatment decisions and participate in healthcare improvements (McDonald et al., 2013), where a recent study pointed to the significance of patient-clinician communication as it provides patients the platform to raise and discuss issues with clinicians thereby forming the shape in subsequent clinical care processes and outcomes (Greenhalgh et al., 2018). Finally, the lack of a standardised dataset for patient-
reported outcomes (PROs) that measures changes in patient outcomes over time has made it
difficult to compare and promote treatments in an evidence-based manner. The recognition
for a standardised data set of PROMs that complement the normal clinical measures has been
moved forward under the growing interest in VBHC.

For an effective provision of oncology care, there has been a shift in the healthcare
delivery model from volume to value-based care (Johansen & Saunders, 2017). Implementation of VBHC into clinical settings uses a patient-centred care approach, whereby
this model promotes better patient health outcomes in an evidence-based manner by reducing
healthcare costs (Porter & Teisberg, 2006). The VBHC design results are reported by both
the care provider through hospitalisation rate and PROs (Porter, 2010). Innately, these
outcomes include tracking patient’s health across the clinical journey and improve HRQOL
in an evidence-based manner (Porter, 2010; Porter & Lee, 2013; Waldrop et al., 2019).

In addition, the involvement of patients with their health care team strengthens and
increases the provision of patient-centred care and thus potentially aid cancer control
(Lavallee et al., 2016). Recent research has noted that this can be achieved by including
PROs in clinical settings that could enhance the delivery of health care (Lavallee et al., 2016;
Tzelepis et al., 2015; Zucca et al., 2014). PROs are patient self-reports that measure health
status and conditions (Basch, 2017) and are about their health and quality of life (QOL),
health care, or treatment related functional status. Patient-reported outcome measures
(PROMs) are the tools used to measure PROs (Kingsley & Patel, 2017). A study at the
Martini Klinik in Hamburg Germany reported that the inclusion of patient-derived
information resulted in significant improvement in patient outcomes for CONDITION (Porter
et al., 2014). The use of PROs is less well incorporated into routine practice in clinical
settings within Australia (Lavallee et al., 2016). As well as needing improved evidence to
support better survival and functional outcomes, clinical care should select validated PROs to
more accurately guide and monitor strategies of clinical care and support.

To help address the need for standardised and meaningful measurement of clinical
and patient-orientated outcomes, the International Consortium for Health Outcome Measures
(ICHOM) has developed numerous standardised datasets for a large number of health
conditions and diseases, including various cancers (Ong et al., 2017; Zerillo et al., 2017).
Implementation of a standardised dataset can provide a platform for comparison of outcomes across health care providers and patients for effectiveness and cost-benefit (Ohno-Machado, 2014). ICHOM datasets have already been developed for several cancer types that consist of colorectal, lung, breast and prostate (Mak et al., 2016; Morgans et al., 2015; Ong et al., 2017; Zerillo et al., 2017). Unfortunately, there are currently no internationally agreed datasets for OC.

**Purpose of the Study**

The primary aim of this study is to address this current lack of a PROM tool designed for OC. While a number of survey instruments have been previously developed to measure signs and symptoms and overall HRQOL in women with OC, most were not developed in consultation with cancer patients and their carers and/or were designed for monitoring patients just through their chemotherapy phase of treatment rather than the whole patient journey and are as follows:

- European Organization for Research and Treatment of Cancer Quality of Life Questionnaire- Ovarian Cancer Module 28 (EORTC QLQ-OV28) (European Organisation for Research and Treatment of Cancer Quality of Life, 2019)
- Functional Assessment of Cancer Therapy Ovarian Cancer (FACT-O) (FACIT.org, 2019)
- FACT ovarian cancer symptom index (FOSI) (FACIT.org, 2020b)
- Measure of Ovarian Symptoms and Treatment concerns (MOST) (King et al., 2018)

Thus, this study utilised patients with OC to identify an agreed specific set of PROM using a sequential mixed methods approach through a holistic research process via semi-structured telephone interviews and focus groups and cognitive interviewing (CI) using the ‘think aloud’ technique to reach consensus on the initial development of HRQOL PROM using both consumer and clinician input. Findings from interviews and focus groups formed the basis of the CI phase. The CI process outcomes informed a drafted outcome measure. In the future, identification and content prioritisation of the developed PROM will then be piloted to measure its psychometric properties and later on will then be piloted anonymously in patients for validation. Together with other newly developed outcomes, this will help
determine what is important to patients in order to directly improve the lives of those diagnosed with OC.

**Overarching aim**

This study aimed to develop a meaningful OC-specific HRQOL PROM through patient involvement.

**Research Questions**

The overarching question for this study was “What are the key outcomes associated with the disease and treatment for patients with OC that can be self-reported and utilised in both clinical trials and clinical practices?” with the following specific research questions being:

1. What are the key outcome priorities identified and described by women with OC?
2. From the comprehensive consumer-driven and identified list of outcomes, what specific outcomes contribute to accurately measuring the HRQOL of women diagnosed with OC?
3. Are the key outcomes identified through these processes different from existing tools and if so, how are they different?

**Significance**

Western Australia Cancer Plan 2020-2025 is a five-year plan that lays out a strategy for providing the best possible cancer care to the people of Western Australia. According to the report, Western Australia outperformed the rest of Australia, having the highest five-year survival rates for several cancers, including ovarian cancer (Government of Western Australia Department of Health, 2020).

It is anticipated that this study will contribute to improvements in the treatment and management of patients with OC and help develop better information about the types and impact of PROs with this disease. This study involved patients throughout all phases of the development of the HRQOL PROM tool. It will enable patients to provide detailed information regarding aspects of OC-related diagnosis/treatments/disease progression/recurrence that are important to them and to their health care providers in a timely and effective manner. Through further validation, it is envisaged that the standard set
of PROMs developed from this study will enable comparisons of OC treatments and facilitate long-term improvement in OC care both within and outside individual clinics.

**Thesis structure**

The structure of the thesis is as follows:

- **Chapter One** provides an overview of cancer and the quality of care provided to the patients. This chapter also summarises the challenges in improving the standard of treatment by transitioning to value-based care and engaging patients with their health team.

- **Chapter Two** presents a comprehensive literature review of OC and four existing OC-specific PROM tools. This chapter also discusses the limitations of each tool and argues that patient involvement is essential in the development of a PROM tool because patient experiences and perspectives are needed to incorporate outcomes that matter most to patients.

- **Chapter Three** details the study methodologies utilised in this thesis.

- **Chapter Four** reports on a qualitative study on patient and career perspectives on their clinical journey as published in *Patient Related Outcome Measures* (2020).

- **Chapter Five** reports the initial development of an OC-specific HRQOL PROM through the utilisation of cognitive interviewing as a manuscript submitted to *Patient Related Outcome Measures* which is under peer review.

- **Chapter Six** the final chapter, comprises a discussion that addresses the research questions, conclusions and recommendations for future research, from the qualitative work conducted in this thesis.

The reference list of chapters four and five are listed in compliance with each chapter as they are presented in a manuscript format. However, a compiled full reference list is provided at the end of this thesis for the remaining chapters.
Chapter Two: Review of literature
Introduction

This chapter provides a comprehensive literature review regarding OC, the use of existing OC specific PROM tools and their limitations are discussed in this chapter. The chapter commences with an overview of OC and how factors like symptomatology and treatment influence the survival course of patients diagnosed with OC. HRQOL is then discussed, accompanied by a brief definition of QOL. The chapter explains the four tools developed specifically for OC-diagnosed patients. Finally, the chapter discusses the limitations and gaps of these four tools, showing that the development of an OC specific tool is necessary which is discussed in chapters three and four.

Ovarian cancer

Although the incidence of OC is low compared to other female cancers, the morbidity and mortality rates are relatively high (Chase & Wenzel, 2011). In Australia, OC is the eighth most commonly diagnosed cancer among women with 1532 new cases diagnosed in 2020 and the second most common cause of death due to gynaecological cancers with an estimation of 1068 deaths from OC in 2020 (Cancer Australia, 2021). In Western Australia, 115 cases are being diagnosed every year, with an average five-year survival rate of less than 50% (Department of Health Western Australia, 2017). Prognosis depends on factors such as age, genetic factors, general health, tumour stage, response to treatments and macroscopic residual disease at the completion of surgery (Burges & Schmalfeldt, 2011).

Factors Impacting Clinical Diagnosis and Survival

Symptomatology

Ovarian cancer affects women of all ages but is most commonly diagnosed after menopause with major risk factors including advancing age and a family history of ovarian and breast cancer (Doubeni et al., 2016). Women with early-stage disease are often asymptomatic. Around 75% of women are diagnosed with an advanced tumour where symptoms may be nonspecific (Doubeni et al., 2016). The United Kingdom Collaborative Trial of Ovarian Cancer Screening did not demonstrate a significant decrease in OC mortality with screening and there is currently no effective population-level screening test for OC (Henderson et al., 2018; Jacobs et al., 2016; Natarajan et al., 2018).
The four groups of symptoms that have been found in retrospective studies to be more commonly associated with OC are abdominal/pelvic pain, bloating/abdominal distension, bladder irritability (frequency, urgency and nocturia) and early satiety (early fullness when eating) (Ebell et al., 2016; Goff et al., 2007; Goff et al., 2004). As many of these symptoms are indicators of other diseases, such as gastrointestinal disease (Bankhead et al., 2008), the presence of OC is often resulting in misdiagnosis or delayed diagnosis (Robinson et al., 2012).

**Diagnosis**

In the absence of screening tools and specific symptoms, diagnosis of OC relies on pelvic examination, various imaging investigations and measurement of the tumour specific blood marker, CA125 (Badgwell & Bast, 2007). Unfortunately, circulating levels of CA125 vary by disease stage (Badgwell & Bast, 2007) and associations with other health conditions like pregnancy, menstruation, pelvic inflammation make it inefficient as a screening strategy (Fritsche & Bast, 1998; Gupta & Lis, 2009). Recent outcomes from the largest OC screening trial to date, the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS), reported annual multimodal screening using the longitudinal CA125 Risk of Ovarian Cancer Algorithm and pelvic ultrasound failed to reduce mortality rates in the screened population compared with no screening, suggesting more productive outcomes may come from screening high-risk women (family history or with BRAC1/2 mutations) or further exploration of OC tumour DNA biomarkers (Jacobs et al., 2016; Menon et al., 2018).

In the absence of an effective screening tool or specific symptoms, the majority of cases of OC are diagnosed at advanced stages (III & IV) (Miranda & Ahmed, 2016) often resulting in adverse disease outcomes (Buys et al., 2011). While there is an urgent need to develop new strategies for screening and early detection, other studies have demonstrated that routine review following treatment is not effective in improving survival, quality of care and relieving anxiety due to lack of high-quality evidence for follow-up care (Cancer Australia, 2012; Le et al., 2016).
Clinical management

Whilst OC has multiple cellular origins (Cardenas et al., 2016), 80% are epithelial (Natarajan et al., 2018). Treatment of epithelial ovarian cancer is a combination of both surgery and chemotherapy. While fertility-preserving surgery with unilateral salpingo-oophorectomy may be offered to younger women with unilateral non-metastatic cancer (Stage 1A), those with more advanced cancer undergo radical surgery that may include total hysterectomy, bilateral salpingo-oophorectomy, omentectomy, splenectomy, diaphragmatic resection, pelvic peritonectomy, bowel resection and colostomy. Disease deemed non-resectable, or patients did not fit for surgery due to poor performance status, comorbidities and/or malnutrition, are treated by neoadjuvant chemotherapy followed by an interval cytoreductive surgery after 3-4 chemotherapy cycles (Natarajan et al., 2018).

Standard first-line chemotherapy for epithelial ovarian cancer involves six, three-weekly cycles of intravenous or intraperitoneal administration of a platinum-based drug such as carboplatin, with a taxane, usually paclitaxel (Cristea et al., 2010; Schwab et al., 2014). Patients undergoing chemotherapy often experience nausea, vomiting, hair loss, cognitive dysfunction, fatigue, changes in sexual functioning, peripheral neuropathy and reduced QOL (Kayl & Meyers, 2006).

Although there has been some improvement in OC control in the last two decades that has resulted in increased survival (Arnold et al., 2019). Approximately 80% of women with advanced OC relapse (median time to first recurrence 18 months) which is usually eventually fatal due to the emergence of drug resistance (Liu et al., 2018; Lloyd et al., 2015).

While platinum-based therapy continues to be the principal regimen used to treat tumours that recur at least 6 months after prior therapy, the response typically persists for just a few months and with each additional course of therapy, the treatment-free period usually grows shorter before the tumour is considered ‘platinum resistant’ (Luvero et al., 2014). The sequential use of chemotherapy regimens and the incorporation of molecularly targeted treatments have been shown to extend the median survival time of patients with OC and palliate symptoms to several months, but it is rarely curative (Luvero et al., 2014).
Clinical trajectory: patient concerns

While clinical management of cancer patients routinely addresses pain (Jacox et al., 1994) and the side-effects associated with chemotherapy (Cassidy & Misset, 2002), cancer patients have also been shown to have nearly twice the level of psychological distress of the general population (Hinz et al., 2010) exhibiting severe emotional distress particularly during diagnosis and the initial treatment period (Andersen et al., 1989; Zenger et al., 2010). Similar observations have been made in women with OC (Bodurka-Bevers et al., 2000) with another study reporting greater levels of psychological distress occurred in younger patients, patients who had more recently been diagnosed with ovarian cancer and those with more advanced or recurrent disease (Norton et al., 2004). OC patients are faced with additional difficulties with their physical and social wellbeing, fatigue and pain (Osoba et al., 1994). Similarly, in patients with advanced cancer, distress levels are often exacerbated by feelings of being a burden to others (Engelmann et al., 2016), fear of recurrence (Crist & Grunfeld, 2013) and/or death (Bachner et al., 2011).

Many new cancer treatments are being evaluated solely based on increased survival and without evaluating details on other benefits and shortcomings of these treatments. As such, there has been a call for clinical trials to measure QOL and other PROs to create a more comprehensive assessment of the treatment protocol and provide patients with greater knowledge of potential impacts (Thomas, 2016; Wilson et al., 2018). Similarly, the importance of monitoring QOL symptoms in patients with advanced cancer as part of clinical management has been shown to result in fewer emergency department visits and hospital admissions, longer duration of palliative chemotherapy and superior quality-adjusted survival than patients receiving usual care (Basch et al., 2016).

Quality of Life Measures

Whilst functional status had been used in the social sciences literature since the early 1900s, new measures that provided a level of objective scoring for use in health disciplines did not appear until around the middle of the century (Prutkin, 2002). These measures became more popular from the 1970s and became known as QOL (Pennacchini et al., 2011). Within the health domain, QOL often reflects a multidimensional aspect of physical, psychological, functional and social wellbeing amongst patients (Gotay, 1996) while other dimensions such as spirituality, sexuality, treatment satisfaction can also be important (Cella
& Tulsky, 1990). These dimensions are interrelated as a recent study finding suggests that alterations in one QOL dimension can impact expectations in other dimensions too (Jitender et al., 2018).

QOL measures are used in multiple ways in health care. These include (Fitzpatrick et al., 1992):

- Screening and monitoring for psychological problems in individual patient care;
- Measuring outcomes in health services and/or research;
- Clinical trials;
- Assessment of cost-utility;
- Medical audits;
- Population surveys of perceived health problems.

The COVID-19 coronavirus pandemic remains our largest public health threat in decades, influencing all dimensions of everyday life (Liang et al., 2020). Although we are seeking to defeat coronavirus with collaborative management procedures, minority communities such as those afflicted with cancer should have special focus and importance as they are faced with bigger challenges such as disease progression and lack of treatment choice due to self-isolation protocols (The Lancet, 2020). Thus, it is important to evaluate their QOL. In fact, a recent study found that due to COVID-19, financial challenges, altered family and social life impacted the QOL of cancer patients. In addition, these challenges were associated with a considerable decline in the welfare and functioning ability of the patients (Ciążyńska et al., 2020).

Health-related quality of life (HRQOL)

While the term, QOL, is still used within the social sciences literature based on constructs such as economic performance and social progress, new measures that pertain to general health well-being or outcomes surrounding a specific disease, often called HRQOL, are today common within the health sciences literature (Post, 2014). Multiple definitions exist. In essence, HRQOL primarily focuses on the impact that a disease and its treatment have on various aspects of patients’ lives including physical, functional, psychological and social (Šumskienė et al., 2015).
One essential purpose for measuring HRQOL is to improve and broaden knowledge on the spectrum of patient issues. HRQOL instruments are designed as general PROMs such as the Short Form Survey (SF-36) (Ware & Gandek, 1998) which can be used within broad disease groups (Bousquet et al., 1994; Kemmler et al., 1999), or PROMs that are limited to those with specific diseases such as breast cancer and gynaecological cancers (Diaz-Buxo et al., 2000) and/or symptoms (Zigmond & Snaith, 1983). Research shows that the joint administration of standardised and disease-specific tools will lead to better evaluation of both global and specific HRQOL attributes (Loria et al., 2012; Šumskienė et al., 2015).

With a plethora of HRQOL instruments now available, concerns have been raised about the reliability, validity, reproducibility, cross-cultural applicability, sensitivity to change, and interpretability of these tools (Naughton & Wiklund, 1993; Okamoto et al., 2003; Soni et al., 2002). At present, most HRQOL measures are limited to use within clinical trials and formal evaluation studies where they are used alongside other demographic and clinical information, but there is increasing interest to incorporate these tools into routine clinical management (Basch et al., 2016; Testa & Simonson, 1996).

In addition to aiding the decisions around treatment options, HRQOL and symptom measures can be useful in assisting with end-of-life decisions being made by clinicians in consultation with their patients. Price et al showed that HRQOL declined sharply in women with OC from six months prior to death with anorexia, nausea and pain increasing towards the end of life (Price et al., 2013). This provides a valuable example of how HRQOL PROs could shift treatment goals towards symptom palliation. In addition, studies also highlight that it is also important to carefully monitor the HRQOL of advanced cancer patients in clinical settings due to the potential problem of fearing death. (Detmar et al., 2000; Edwards et al., 2010; Saeteren et al., 2011; van Roij et al., 2018). Moreover, measuring HRQOL when treating advanced cancer is vital, as it increases health professionals’ understanding of patients’ changing priorities and would enhance treatment outcomes such as fewer emergency/hospital visits and improved survivorship (Basch et al., 2016; Etkind et al., 2015).
Patient-Reported Measures and Outcomes (PROMs)

The role of the patient in providing information and participating in clinical decisions has become increasingly clear in the last decade or two. Information provided by the patient without clinician modification and/or interpretation is termed a patient-reported outcome measure (PROM) (Meadows, 2011). These measures can be general or disease specific and are defined as information that is directly reported by the patient without interpretation of the patient’s response (Meadows, 2011) and pertains to the patient’s health, QOL, or functional status associated with health care or treatment (Moss & Havrilesky, 2018; Weldring & Smith, 2013). All PROM instruments need a number of attributes that include validity, reliability, minimal administrative and respondent burden, and appropriate language and cultural adaptations (Lipscomb et al., 2007). They should be short enough for patients to complete within 15 minutes and be easily comprehended (Basch et al., 2012).

It has been noted that many researchers use the term HRQOL to describe any phenomenon or latent trait that has been developed directly from patients (U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research, 2006), and others see this as “patient reported” but question whether this is of direct concern to the patient (Doward & McKenna, 2004). And herein, lies an important distinction – does the collected information actually have importance or concern to the patient? While this distinction is acknowledged in a paper by Friedlander and King (Friedlander & King, 2013), they also argue for the importance of consistency in using HRQOL/PRO measurements, their analysis and reporting in OC trials through the establishment of guidelines such as CONSORT-PRO & SPIRIT-PRO (Calvert et al., 2018; Joly et al., 2017). These guidelines recommend six checklist items be considered for randomised, clinical trials where PROs are the primary or secondary endpoints. These include: that the PRO be identified as a primary or secondary outcome(s) in the abstract; a description of the hypothesis of the pros and relevant domains is provided; evidence for the quality and efficacy of the instrument(s) must be provided; a methodological method for working with incomplete data must be specifically stated; and generalizability of findings to other communities and clinical experience must be addressed. In further, the 16-items recommended by the SPIRIT-PRO guidelines need to be addressed and included in clinical trial protocols (Calvert et al., 2013; Calvert et al., 2018).
Importance of patient involvement in PROM development.

Patient involvement has a profound impact on the development of PROM tools as it is only the patients who can determine outcome relevance and comprehensibility of the tool (Staniszewska et al., 2011; Trujols et al., 2013). In addition, research shows lack of patient involvement affects the sensitivity, validity and response of the tool (Fossey & Harvey, 2001; Meadows, 2011). Thus, patient involvement is a key factor when developing a new tool to measure PROs. As PROMs are developed to reflect upon patient perspective, it is essential to involve patients throughout the development processes (Kirwan et al., 2011; Wiering et al., 2017). As reported in a recent review of 189 studies that described the development of 193 PROMS, over a quarter had no patient involvement at all, while some patient involvement took place in the development of most PROMs, but only 6.7% of patients were involved in all aspects of the development. In addition, patient involvement did not increase in PROM development studies over time (Wiering et al., 2017). Even though certain limitations exist such as the availability of resources including time and money, PROMs developers agree that it is a necessity to involve patients during PROM development (Wiering et al., 2017).

Cancer Specific PROMs

Although clinical trials involving cancer patients utilise a number of general PRO tools, (such as the hospital anxiety and depression scale (HADS), NCI PRO-Common Terminology Criteria for Adverse Events (CTCAE), Rotterdam symptom checklist, Depression, anxiety and stress scale 21 (DASS-21), Patient-reported outcomes measurement information system (PROMIS) and Medical outcomes study (MOS) short form survey 36 (SF-36)), several validated tools exist for cancer-patients (Moss & Havrilesky, 2018). Within these, some are designed for patients with specific cancer types, including gynaecologic cancers (Moss & Havrilesky, 2018).

Ovarian Cancer specific PROMs for HRQOL

European Organization for Research and Treatment of Cancer (EORTC).

An international non-profit organisation for cancer research was established in 1962 under Belgian legislation as the Groupe Européen de Chimiothérapie Anticancéreuse (European Organisation for Research and Treatment of Cancer, 2020). The foundation seeks to enhance the survival and quality of life of patients diagnosed with cancer. Over five
decades, substantial progress has been made in clinical science from the treatment and control of cancer to the evaluation of patient QOL. The EORTC developed a tool called the EORTC Quality of Life Questionnaire for Cancer Patients (EORTC QLQ-C30), one of the widely used cancer-specific QOL questionnaires (Moss & Havrilesky, 2018). The questionnaire comprises 30 items describing five functional scales: physical, role, emotional, social and cognitive; overall assessment of general health and QOL; and nine cancer symptom subscales (pain, fatigue, nausea, vomiting, constipation, diarrhoea, dyspnoea, problems with sleep, appetite) (Aaronson et al., 1993). The EORTC further developed a specific ovarian cancer module, QLQ-OV28, which is supplemented with QLQ-C30. QLQ-OV28 contains 28 items that assess body image, sexuality and attitude to disease/treatment, abdominal/gastrointestinal symptoms, peripheral neuropathy, hormonal/menopausal symptoms and other chemotherapy side-effects (European Organisation for Research and Treatment of Cancer Quality of Life, 2019).

Functional Assessment of Chronic Illness Therapy.

Functional Assessment of Chronic Illness Therapy (FACIT), formerly known as Functional Assessment of Cancer Therapy (FACT), was introduced in the 1980s. The FACT-G (Functional Assessment of Cancer Therapy – General) was the original questionnaire leading to the creation of the broader quality of life instruments, FACIT (FACIT.org, 2020a). The FACT-G is another commonly used HRQOL tool among cancer patients that can be augmented by site- and/or treatment-specific modules (Moss & Havrilesky, 2018). This survey evaluates the effects of cancer treatment in four domains: physical, social/family, emotional and functional. Likewise, EORTC, FACIT have developed ovarian cancer-specific modules (FACT-O and FACT-Ovarian Symptom Index (FOSI)), whereby these modules are offered with FACT-G items measuring QOL factors (Friedlander & King, 2013). The FACT-O questionnaire utilises the 27 items of FACT-G that measure four core domains, additional 12 items (body image, sexuality, abdominal/bowel symptoms) specific to ovarian cancer (FACIT.org, 2019). Derived from the FACT-O, FOSI is a brief index, containing eight items that measure the symptom response to OC care (FACIT.org, 2020b).

Measure of Ovarian Symptoms and Treatment concerns.

A new tool that assesses patient-reported advantages and disadvantages has recently been introduced to assess the effectiveness of chemotherapy as a palliative treatment in
women with symptomatic ovarian cancer (Friedlander et al., 2014; King et al., 2014). In their study, 126 patients receiving palliative chemotherapy completed 5 validated health-related quality-of-life questionnaires (EORTC QLQ-C30, QLQ-OV28, FACT-O, FOSI and gynaecologic cancer-specific Symptom Representation Questionnaire) before starting treatment and before each treatment cycle. Through a mix of study participant interviews and statistical analysis, they identified a new tool known as the Measure of Ovarian Symptoms and Treatment (MOST), which has three versions. MOST-T35(v1) consisted of 35 items of which 15 assess disease symptoms, 17 assess adverse effects of treatment, and 3 assess well-being (physical, emotional and overall). This tool underwent further development which reduced it to 24 items, MOST-T24(v2), comprising five subscales describing abdominal symptoms (MOST-Abdo), disease or treatment-related symptoms (MOST-DorT), chemotherapy-related symptoms (MOST-Chemo), psychological symptoms (MOST-Psych), and MOST-Well-being (King et al., 2018). The third version, MOST-S27, advised to be used to monitor patients undergoing therapy with the first-line treatment contains 27 items in which 17 items assess disease symptoms, 3 items assess well-being, 5 items assess treatment difficulties, and two items aimed to identify and assess additional symptoms (Gynecologic Cancer Intergroup, 2020).

**Limitations of ovarian cancer specific PROMs for HRQOL**

The two core instruments and their OC modules pose several limitations with all four tools methodologically distinct. EORTC and FACT are generic tools used in cancer patients. A study that compared EORTC QLQ-C30 and FACT-G found that the scales overlapped considerably (Kemmler et al., 1999). Despite the major overlap, previous studies have however shown that social dimensions of HRQOL are distinct from both instruments (Blazeby et al., 2005; Holzner et al., 2006; Luckett et al., 2011) A recent study indicated that the EORTC QLQ-C30 assesses the relationship of physical disabilities with family and social life, while the social domain of FACT-G measures family and friends’ social support and found that the overall quality of life measurement varied between the two instruments (Darling et al., 2020). Since EORTC QLQ C-30 and FACIT-G are administered in patients with various types and stages of cancer, these measures are not considered applicable to patients receiving palliative care. Because the spiritual domain is particularly relevant at the
terminal phase, this domain is not included in these current measuring instruments, challenging its measurement properties (Albers et al., 2009).

Recent research investigated the incorporation of EORTC measures into clinical practice and found that the EORTC QLQ-C30 has its own challenges such as duration, frequency and the evaluation of scores by health professionals (Wintner et al., 2016). Moreover, a recent study evaluated the psychometric properties of 39 self-administered HRQOL tools with advanced cancer patients. The study results revealed that EORTC QLQ-C30 had good content and construct validity. However, psychometric properties of the EORTC QLQ-C30 such as reliability, internal consistency, responsiveness and interpretability were unclear and the psychometric properties of FACIT-G were incomplete as they were inadequately evaluated on the study participants (van Roij et al., 2018).

The accuracy of measuring patient HRQOL using current validated instruments is potentially challenged if OC patients are to be administered with these instruments, as this may not truly represent the challenges and complexities experienced by women with OC during the clinical trajectory. A 2005 study indicated that although these instruments have similarities, they cover various aspects of the QOL of a cancer patient. The study emphasised that the choice of instrument, therefore, depends on the nature of the individual study (Blazeby et al., 2005).

Moreover, there was only minimal or no patient participation during the development (Aaronson et al., 1993). For example, during the development of QOL domains of FACT-O, patient involvement only occurred during the initial stages of development by conducting open-ended interviews and later in the first validation process. It is to be noted that participated patients had mixed cancer diagnoses (Cella et al., 1993) wherein it could be a problem of not being designed for a specific cancer type.

The identified limitations of the existing tools relating to the questionnaire content and its psychometric properties denote that the development of this OC-specific tool is necessary as it will be unique in its methodology.
Conclusion

The potential of HRQOL PROMs to improve the care of cancer survivors is increasingly recognised because they allow accurate measurement of a range of outcomes throughout a patient’s clinical trajectory. Research has demonstrated that involving patients during each stage of PROM development can yield a PROM instrument that is valid and comprehensible to patients. Further, the implementation of these measurement tools into both clinical care and research serves as a key component in delivering value-based patient-centred care (Johansen & Saunders, 2017). While validated ovarian cancer PROM instruments do exist, they are few and may not adequately cover associated symptoms during the whole disease trajectory (European Organisation for Research and Treatment of Cancer Quality of Life, 2019; FACIT.org, 2019, 2020b; King et al., 2018). These tools have only incorporated minimal patient involvement during their developmental stages which are vital for a PROM development (Wiering et al., 2017). Measuring patient experiences such as disease and treatment related symptoms (frequency, severity and duration) and HRQOL, can aid in assessing individual treatment progress and disease recurrence.

This thesis sought to address these gaps by undertaking a “ground-up” approach to PROM development by engaging with ovarian cancer patients, and their carers and clinicians, to identify a set of relevant and meaningful measures that have both personal and clinical significance. The aim of this research was to enhance our understanding of the outcomes that matter most to women with ovarian cancer and to ultimately develop a PROM tool that will enable better identification and earlier treatment of symptoms during the entire course of the disease.

Chapter summary

This chapter provided a comprehensive literature review of existing OC-specific PROM tools. Limitations in methodological approaches, including lack of validation of psychometric properties and patient involvement in their development, were discussed. These identified gaps underlined the need to establish an OC-specific HRQOL PROM tool through patient involvement which is addressed in the primary (chapter four) and secondary (chapter five) research of this thesis.
Chapter Three: Methodology
Introduction

This chapter describes the three qualitative approaches used in the two studies conducted. As this thesis employed a sequential mixed methods approach, the findings of the primary piece of research paved the way to the development of the construction of the secondary piece of research. The two studies have been submitted for publication, details about how each study was undertaken are primarily described in Chapters 4 and 5 so this Chapter provides an overview.

Design and Methodology

The overarching methodology for this study is sequential mixed methods. A sequential mixed methods approach involves conducting a sequence of phases of either quantitative or qualitative data collection or analysis, followed by the analysis of the second and subsequent phase (Berman & Tufts, 2017). The findings of the preceding phase inform the development and conduct of the second and subsequent phases of the study. The triangulation of data in each phase ensures that the study findings are validated through the convergence of information from the qualitative data. Triangulation in qualitative research enables the development of a comprehensive and broader understanding of phenomena (Patton, 1999). This approach can be used as data source triangulation when applied to qualitative analysis. Data source triangulation requires data collection from people, organisations, or families to obtain different viewpoints and data validation (Carter et al., 2014).

The process followed by the candidate is best practice in scale development (Boateng et al., 2018) whereby item generation as the first step includes both deductive and inductive methods. Deductive includes a scoping exercise of existing scales as well as an extensive literature review. Inductive include qualitative data collection, which when combined with the literature review, provides a comprehensive list of items for inclusion in the pilot scale. Best practice in scale development will include both inductive and deductive methods. Researchers developing PROMS have employed similar qualitative approaches such as community conversation as part of field notes, qualitative interviews, focus groups, cognitive interviewing for their scale development (Chhina et al., 2021; Fenwick et al., 2013; Lessard et al., 2019; Wright et al., 2021).
Thus, an integration of various qualitative approaches into this research was beneficial as it can provide great depth of knowledge and enable to investigate identified issues as a whole (Almalki, 2016). As this study utilised a sequential approach, it was conducted in two distinctive phases. Collection and analysis of data were conducted at several stages. As noted earlier, each phase was dependent on the previous phase to inform the choice of how to proceed to the next subsequent phases, data collection at various stages was essential. The study design is visually represented in Figure 1.
Figure 1
Developmental stages of HRQOL PROM tool for patients diagnosed with OC

Comprehensive Literature review
Articles with PROMS to be identified through PubMed

Phase One:
[Preliminary work]
Community conversation
(15 women with OC, two consumer advocates and a

Phase Two:
Cognitive interview [Concurrent Think-aloud procedure]
14 women diagnosed with OC

Qualitative analysis
Item refinement & validity

Phase One:
Semi-structured interviews
13 women with OC

Phase One:
Focus groups
13 women with OC
and two consumer advocates

Phase One:
Focus groups
13 women with OC
and two consumer advocates

Qualitative analysis
Item generation for PROM tool
Phase One- Qualitative Interviews and Focus Groups

Drawing on the findings from the literature review, Phase One directly engaged with patients with OC, their carers and a clinician through a community conversation event, semi-structured telephone interviews and focus group discussions. These processes sought to hear the “patient’s voice” and identify their view of the health symptoms and outcomes that matter most to them as they traverse their disease pathway. Combined with an extensive literature review and existing cancer specific tools, this phase aimed to generate and compile items necessary for the PROM tool development using three qualitative approaches. Ethics approval for this study was granted by the Human Research Ethics Committee at UNDA (Appendix 1).

Community Conversation

Phase One commenced by performing ‘grass-roots’ work within the community of OC patients through community conversation to promote community mobilisation. The key purpose of this initial step was to listen to the community’s needs attentively and most importantly, encourage members to think, discuss and explore the main causes and underlying issues behind their health problems.

While not a formalised research methodology, community conversation is used as a qualitative research tool for communicating and engaging key stakeholders in identifying various dynamics of the type that is fundamental to the qualitative study (Trainor, 2018)(McKenzie & Hanley, 2014). It also allows the researcher to investigate and highlight viewpoints and perceptions of a given population (Patton, 2015). To provide an insight into the range of issues expected to be divulged through the interview and focus group sessions, and to help ensure these events are developed and conducted in a manner that is both welcoming, safe and supportive for these patients, an initial “community conversation” was held with a small number of 15 women with ovarian cancer, two consumer advocates and a clinician. The event was facilitated by an independent consumer representative group and a gynaecologist with experience in this area of gynaecological cancers to explore some of the key issues of personal importance to these key stakeholder groups that were used to inform the subsequent steps in this phase of the work.
**Semi-structured Interviews**

Phase One then comprised engaging with women who have been diagnosed with OC using a semi-structured interview approach, with the purpose of gaining a comprehensive understanding of their health concerns at a personal level as the first step in identifying the specific items the developed PROM will utilise. Upon recruitment, participants were provided with a participant information sheet (Appendix 2) and consent form (Appendix 4) that required to be signed and returned prior to the scheduled interview.

Semi-structured interviews are one of the most widely used qualitative data collection approaches that aim to obtain rich information and explore the "insider perspective" of a participant (Brinkmann, 2013). One characteristic advantage of this method is that it allows participants to speak freely and provides the opportunity to obtain new and novel information. Another advantage is that interviewer has the flexibility to focus the conversation on issues relating to the study raised by the interviewees (Brinkmann, 2013). Thirdly, questions can be prepared in advance so that the interviewer demonstrates competence and knowledge about the subject matter during the interview, thereby allowing two-way communication between interviewer and interviewee. Moreover, information-rich data can be collected in a time- and resource-efficient manner thereby producing analogous and reliable qualitative data (Barrett & Twycross, 2018).

**Focus groups**

Following the individual interviews, women with OC and their carers were invited to participate in two focus groups to further discuss and validate the findings from the interview process and to explore a broader understanding of health-related outcomes in this context. A secondary approach is especially vital for this qualitative research as it provides data triangulation and a balance across the disease spectrum that may not be fully explored in a one-on-one, face-to-face interview. Recruited participants were provided with a participant information sheet (Appendix 3) and ensured that the signed consent form (Appendix 5) was returned prior to the task commencement.

Focus groups are a useful data collection tool in qualitative research as they enable in-depth discussions of sensitive issues and provide a platform for sensitive topics to be raised (Jordan et al., 2007). Focus groups will allow those affected by OC to share their experiences
or views similar to others (Liamputtong, 2013). Interaction amongst participants is a significant feature of focus groups and is useful in providing a platform for an open conversation, where discussions and topics are free-flowing and the comments among participants stimulate recall in others. Another advantage of focus groups is that they eliminate the chance of misunderstanding the research questions asked, as participants have the opportunity to raise any query during the meeting (Liamputtong, 2013). Having no prior knowledge about the participants, this research tool is particularly useful for this study to explore and examine their knowledge and experience.

By using these qualitative approaches, the identified outcomes were then analysed and categorised in accordance with the major themes which contributed to the construction of an initial draft set of items to be administered with women diagnosed with OC using CI in Phase Two.

**Phase Two - Cognitive Interviewing**

To be used routinely in a clinical setting, any PROM information needs to be standardised and validated. Using a cognitive interviewing (CI) approach, the purpose of this phase of the study was to refine and validate the wording of the items developed from the information collected during Phase One. Common themes identified from all consumer consultation procedures (including the initial pilot project patient interviews) and the literature relating to coping with cancer were collated. Also, more domains and items were generated during CI. The identified themes were refined and operationalised into statements corresponding to each theme. The study was granted ethics approval by the Human Research Ethics Committee at UNDA (Appendix 6). Participant information sheet (Appendix 7), consent form (Appendix 7) and a draft set of statements for the CI (Appendix 9) were individually sent to recruited participants and the researcher ensured that the signed consent forms were received prior to the scheduled interviews.

CI is a method where items and contents and response processes can be assessed and validated (Ryan et al., 2012). For this study, CI was conducted through the concurrent think-aloud (CTA) procedure, a method that provides an opportunity for the respondents to speak aloud about their thoughts (Charters, 2003). The role of the interviewer is predominately to listen to the respondents while respondents are encouraged to speak aloud their thought process either as they answer each question or after they complete the task. Unlike qualitative
interviews which aim to identify the meaning of a phenomenon (Evans, 2017), the distinctive characteristic of CI is that it aids to identify tool items where respondent interpretation and the developer’s intentions are asymmetrical and to identify ways in which those items can be modified based on the responses given (Charters, 2003; Peterson et al., 2017).

The CI process entails determining item intent, collecting data, analysing it, and comparing respondent interpretation to the original meaning (Castillo-Díaz & Padilla, 2013). It is to note that a process of defining the construct, identifying the measurement scale, and developing items are required in the early stages. CI expands on this by utilising these connections to determine item intent (Fortune-Greeley et al., 2009; Ryan et al., 2012). Item intent is directly related to the aspect of the construct that the item is intended to leverage (Dumas et al., 2008). Importantly, before the CI Phase, the scale developer/s should document the intent of each item. The interpretations of item intent and the corresponding scale construct serve as a foundation for determining whether there is a mismatch between respondents' interpretations and responses and interprets the item and what it is designed to measure (Knafl et al., 2007; Peterson et al., 2017).

As the outcomes collected in Phase One led to the development of Phase Two, the researcher conducted an extensive literature review to understand the similarities and differences between the concepts of QOL, HRQOL, well-being and patient satisfaction. This was conducted to ensure that refinement of the tool and its items was conducted consistently. In addition, the CTA procedure allowed the researcher to recognise the issues and errors both with item comprehension and with the overall questionnaire structure. The in-depth and rich information collected through the CTA procedure also allowed the researcher to identify and determine some additional HRQOL items.

Chapter summary

In summary, this chapter addressed the initial stages in the development of an OC-specific HRQOL PROM tool using patient involvement. The chapter detailed the qualitative approaches used in the development of a HRQOL PROM tool that captures the ‘patient voice’ through a grass-roots approach. Each method served a unique purpose for the tool development. The qualitative techniques employed in this thesis included:
- Phase One: Community conversation as a preliminary work, followed by semi-structured telephone interviews and focus groups.
  
  **Purpose:** To gather baseline evidence for the later creation of a PROM that defines HRQOL for women diagnosed with OC.

- Phase Two: Utilisation of CI through CTA procedure.
  
  **Purpose:** To refine and validate the items collected from the preceding qualitative dataset.

The following two chapters detail the sequential phases in the format of journal articles that have been submitted to *Patient Related Outcome Measures*. The first article has been accepted for publication and the second article has received comments from the first reviewer. These chapters provide a detailed description of the data collected and analysed using respective qualitative methods.
Chapter Four: Results (Phase One)

Women diagnosed with ovarian cancer: Patient and carer experiences and perspectives
Introduction

This chapter explores the processes associated with the initial stage of a patient led development of HRQOL PROM. The purpose of this qualitative phase is to seek and hear “patient voice” and to identify the patient views of the health symptoms and outcomes that matter most to them as they traverse their disease pathway. While the following information has been presented in the format of a journal article, the contents describe all aspects, from the recruitment process to data analysis and interpretation, with the identification of the study limitations.

This manuscript was submitted to and accepted by the journal *Patient Related Outcome Measures*. The format therefore follows the journal requirements and has completed two rounds of blind peer review.
Women diagnosed with ovarian cancer: Patient and carer experiences and perspectives

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Abstract

**Purpose:** By directly engaging with women diagnosed with ovarian cancer, this study aimed to explore and identify their view of the health symptoms and outcomes that matter most to them as they traverse their disease pathway.

**Background:** Patient reported outcome measures in ovarian cancer have tended to focus on physical symptoms rather than the more complex psychosocial aspects of living with the disease. Using a ‘ground-up approach’, this study sought to comprehensively understand the health concerns that matter most to women with ovarian cancer as a first step in generating items for development into an ovarian cancer specific patient reported outcome measure.

**Patients and methods:** Following an extensive literature review, we sought to capture the “patient voice” through a qualitative descriptive approach including a community conversation with ovarian cancer patients, their carers and clinicians, and interviews and focus groups with women with ovarian cancer. Thirteen women were interviewed individually, and two focus groups were conducted. A template thematic analysis was used to analyze the data.

**Results:** Key themes included challenges related to clinical diagnosis, treatment phase, altered relationships with family/friends, financial issues, relationships with health professionals and coping strategies. Within each key theme, several sub themes emerged that were identified as various challenges experienced by participants. Diagnostic delay, chemotherapy and surgery-related challenges, negative impact of sexual well-being on partner relationship, communicational challenges with health professionals were among the few issues identified. In addition, self-empowerment was identified as a coping mechanism among participants.

**Conclusions:** By identifying priorities for women diagnosed with ovarian cancer we have highlighted the need for strategies to reduce diagnostic delays and improve quality of life for these women. Data will inform the development of an ovarian cancer specific patient reported outcome measure.

**Keywords:** Focus Groups; Health-Related Quality of Life; Qualitative Descriptive; Patient-Reported Outcome Measures; Semi-Structured Interviews
**Introduction**

Ovarian cancer (OC) affects women of all ages but is most commonly diagnosed after menopause. More than 75% of affected women are diagnosed at an advanced stage because early-stage disease is usually asymptomatic, and symptoms of late-stage disease are nonspecific. The strongest risk factors are advancing age and family history of ovarian and breast cancer.\(^1\) Currently there is no effective population-level screening test for OC.\(^2,3\) Treatment usually involves radical surgery and chemotherapy with subsequent lines of chemotherapy for disease recurrence.\(^4\) Treatments can impair health-related quality of life (HRQOL), a concept that pertains to general well-being or outcomes surrounding a specific disease.\(^5,6\)

Over the previous two decades, patients have had increasing roles in providing information and participating in clinical decisions for managing their cancer. Structured patient provided information without clinician modification and/or interpretation is termed a patient-reported outcome measure (PROM).\(^7\) PROMs can be either generic tools such as the hospital anxiety and depression scale or disease specific tools designed for specific groups of patients such as those with gynecologic cancers.\(^8\) Patient involvement has a profound impact on PROM development as it is only the patients who can determine item relevance and comprehensibility of the tool.\(^9,10\)

Currently, four validated OC specific PROMs have been developed to measure HRQOL of the patients: The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire of Cancer Patients - Ovarian Cancer module (EORTC QLQ-OV28), Functional Assessment of Cancer Therapy Ovarian Cancer (FACT-O), FACT Ovarian Symptom Index (FOSI) and Measure of Ovarian Symptoms and Treatment Concerns (MOST).\(^11-13\) However, these tools do not identify all aspects of HRQOL and differences exist in the level of patient involvement in the development of these PROMs, which is vital for PROM development.\(^14\)

This study is affiliated with an overarching project, Patients First: Continuous Improvement in Care-Cancer (‘CIC’ Cancer), that aims to develop an OC PROM to measure HRQOL, through a ‘ground-up approach’ that includes meaningful patient involvement. As an initial step, this phase of the study involved the collection and analysis of qualitative data to inform
the subsequent generation of items necessary for the development of an ovarian cancer specific HRQOL tool.

**Material and Methods**

**Study design**

Based on an extensive literature review and assessment of the content of existing cancer PROMs, this study utilized a qualitative descriptive approach. A qualitative descriptive approach enables the researcher to obtain comprehensive details of personal events as experienced by individuals, and is appropriate for health science researchers as it provides rich and descriptive information from the participant’s perspective.15 This study employed a community conversation for women with OC, their carers and a clinician (PAC) to shape the subsequent semi-structured interviews and focus groups.

**Participants**

Purposive sampling (non-probability) using a maximum variation sampling strategy was used to identify participants. Purposive sampling enables the researcher to intentionally select participants who have in depth personal knowledge of the topic which will contribute to the study in alignment with the research aims.16 The participant inclusion criteria were women diagnosed with OC aged above 18 years, who were living in Western Australia and fluent in English. Carers of participants were also invited to participate in the study. Participants were recruited at various time-points from their diagnosis.17

**Recruitment procedure**

Community conversation, interview and focus group participants were recruited through an advertisement distributed through the media and relevant agencies including Cancer Council Western Australia (CCWA) and Ovarian Cancer Australia (OCA). Interested participants were asked to contact the researcher(s) and/or CCWA & OCA directly. Thereafter, the participants were contacted by the researchers (CB, SB) who provided them with the choice to participate in either interviews or focus groups. Details of date and time along with venue for the community conversations, interviews and focus groups were sent out by e-mails to
participants through both the CCWA member database and the OCA networks along with the CCWA regional support coordinator. The initial “community conversation” facilitated by a qualitative research expert (CB) was held with fifteen women with OC (different to those who participated in the interview and focus groups), two consumer advocates and a gynecologist with experience in gynecological oncology (PAC) to explore some of the key issues of personal importance to key stakeholder groups.

**Data collection**

Ethics approval for this study was granted by the Human Research Ethics Committee at University of Notre Dame Australia (018158F) and conforms to Australian ‘2018 Update of the National Statement on Ethical Conduct in Human Research’. The participant information sheet and consent form were provided to participants and the signed consent form was obtained from the participants prior to data collection. All participants provided consent for their de-identified data to be published. Guided by the literature review and the field notes during community conversation, similar question format were formulated for both interviews and focus groups, Figure 1. In addition, our study processes complied with the Declaration of Helsinki.
Figure 1 Question format used during semi-structured telephone interviews and focus groups.

Along with the qualitative research expert, the student researcher (SB) independently conducted individual telephone interviews of approximately 30 minutes duration with thirteen OC patients at their place of convenience. The research team (CB, SB) then conducted two focus groups in metropolitan Perth, Western Australia. A total of 13 participants attended one of the two focus groups, each lasting approximately 90 minutes, with participation of three carers in the second focus group. Participants varied in their age. Most participants were employed and were married/defacto. Four participants were over five years since diagnosis, but one participant had received a diagnosis less than six months at time of the interview. Disease status of the participants at the time of the interview was obtained. Six participants were undergoing active treatment, with a completion of at least two full cycles of chemotherapy. The remaining participants confirmed that they were in remission or awaiting treatment. The number of cases of OC in Western Australia is small compared to some other cancers (e.g. breast, prostate) and it was important to recruit as many
women with OC across the disease trajectory as possible. Thus, the focus of this study was the importance of the different experiences of the participants.

**Analysis**

Data saturation was achieved and collected data was audio-recorded and transcribed verbatim by the student researcher (SB). Template thematic analysis was performed which included open and axial coding using the qualitative data management program, QSR NVivo (version 12), Figure 2. Template analysis is defined as a method for identifying, analysing and reporting themes in the data based on the task question format. It enables the researcher to identify emerging themes in understanding a phenomenon or event. Key themes identified were categorized as core themes and further emerging themes then became the categorical sub themes for analysis.

Member checking also included sending the summary of coding and themes back to four participants who had indicated that they were willing to receive this summary via the CCWA and OCA support group coordinators.

**Results**

Six key themes emerged regarding various aspects of illness and treatment experiences described by the women and their carers (Figure 3). Within each key theme, several sub themes and relative sub themes emerged that were identified as various challenges experienced by participants as detailed below.
Figure 3 Representation of key themes emerged from interviews and focus groups.

**Diagnosis, treatment and related issues**

Four factors were identified in relation to the symptomatic presentation pertaining to the disease and are shown in Table 1. Participants experienced pre-diagnostic symptoms including abdominal/bowel discomfort and pain, urinary urgency, fatigue, weight gain, abnormal menstrual bleeding and/or menopausal symptoms. Lack of awareness of disease symptoms by both patients and health professionals (HPs) was a related issue. Due to work and family commitments, several participants intentionally ignored their symptoms. In further, majority of the participants expressed diagnostic delay as another challenge faced during their clinical diagnosis phase.

Table 1 Percentage of participants with symptoms and presentation

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Percentage of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal discomfort</td>
<td>19.2</td>
</tr>
<tr>
<td>Bloating</td>
<td>11.5</td>
</tr>
<tr>
<td>Bowel movement pain</td>
<td>7.7</td>
</tr>
<tr>
<td>Constipation</td>
<td>3.8</td>
</tr>
<tr>
<td>Eye issues</td>
<td>3.8</td>
</tr>
<tr>
<td>Fatigue</td>
<td>7.7</td>
</tr>
<tr>
<td>Joint pain</td>
<td>3.8</td>
</tr>
<tr>
<td>Menopause symptoms</td>
<td>11.5</td>
</tr>
<tr>
<td>Perineal pain</td>
<td>3.8</td>
</tr>
<tr>
<td>Urinary urgency</td>
<td>19.2</td>
</tr>
<tr>
<td>----------------</td>
<td>------</td>
</tr>
<tr>
<td>Weight gain</td>
<td>7.7</td>
</tr>
<tr>
<td><strong>Symptom presentation</strong></td>
<td></td>
</tr>
<tr>
<td>Lack of disease symptoms awareness</td>
<td>42.3</td>
</tr>
<tr>
<td>Asymptomatic presentation</td>
<td>19.2</td>
</tr>
<tr>
<td>Self-monitoring of symptoms</td>
<td>7.7</td>
</tr>
</tbody>
</table>

**Note:** The percentage for each symptom/symptom presentation is calculated as per the number of interview/focus groups participants reporting it. Thus, for total number of participants (n=26), the total percentage of symptoms/symptom presentation does not equate to 100 percentage.

Challenges related to receiving treatments were highlighted with at least half of the participants feeling vulnerable at times since receiving their diagnosis. Most of the participants were challenged by side-effects. Fatigue, nausea, neuropathy, memory loss and loss of appetite were the most common side-effects identified, with less common side-effects such as mucositis and organ failure also described. Support of family and friends provided strength for the majority of the participants. Some women indicated having to modify their usual diet, lifestyle and physical activity during treatment. Activities such as meditation, cycling, gardening and yoga helped them cope during and after treatment. However, some participants also mentioned how empowering themselves during treatment was vital. Maintaining and having a relaxed mind, a positive attitude and a sense of humor were practiced by a few, despite the situations they were facing at that time.

Another participant spoke of how she had lost the chance of experiencing motherhood. Rurally located participants faced further travel challenges of time and distance. And furthermore, two participants highlighted issues around having lack of treatment options while travelling, either it be a rural destination or an interstate travel.

**Living with the OC trajectory**

Other key themes related to living with a diagnosis of OC across the disease trajectory.

**Relationships and support.**

All participants agreed that relationships with their family and friends influenced their lives. Some participants spoke of experiencing lack of support with unpredictable reactions and withdrawal of family and/or friends. Other participants spoke of being avoided and noticed that people around them “react differently” which then created emotional reactions such as
upset and insecurity. Furthermore, sexual relations and a changed level of intimacy with a partner/spouse were identified as an important subtheme in their lives. Many participants described how a lack of intimacy had put pressure on their partner/spouse relationship and affected their emotional well-being. A few participants described their sexual relationship as ‘non-existent’ and that a counsellor had been consulted.

Most of the participants agreed and acknowledged having support from family and/or friends had a profound impact on their lives. A positive relationship with close family boosted their journey particularly following the diagnosis and during treatment. Participants described drawing strength and emotional support, and an increased interpersonal relationship bond with family and friends.

**Financial issues.**
Almost all participants reported having financial issues such as out-of-pocket expenses for scans, surgery and other practical issues including hospital parking and medication costs. Several participants reported lack of information about accessing health services. Some mentioned the financial toxicity associated with their illness and that they lacked knowledge of how to access support services such as paying the bills without going into debt and having to access their superannuation funds for urgent and necessary expenses.

“I guess it was not even initially when I wasn’t told about certain things I could access like my super. I had to find out I think two years down the track or something. So it wasn’t, nobody even gave me that sort of information”.

Some participants had to stop work during treatment and others had to reduce their workload to cope with the challenges and issues faced during their clinical journey.

**Interaction with Health Professionals.**
Participants spoke of their relationships and experiences with their respective HPs. In general, most participants acknowledged having a positive relation with HPs including general practitioners (GPs), gynecological oncology and medical oncology providers in terms of the support and medical treatment provided to them. The advice received by the oncology team was described by one participant as “absolutely phenomenal…(they) answered any questions with patience and understanding”.
Meanwhile, some participants spoke of a perceived negative relationship with their HPs. Overall, many participants felt there were communication gaps in the healthcare system, particularly during treatment, and participants experienced various forms of communication challenges either with or between oncologists and GPs and specialist departments.

“Because of my complex medical problem, I’ve been out for a few months affected by surgery and by several treatments. So, I found that (hospital’s) communication between the different departments just wasn’t there”.

Furthermore, issues around clinician lack of empathy and compassion, and providing inconsistent information about prognosis negatively impacted the emotional well-being of many participants. A majority had a less than satisfactory relationship with GPs. Half of the participants described the excessive length of time for their symptoms to be investigated leading to a delay in their diagnosis. Some perceived being ignored or that GPs were “pretty dismissive” about their symptoms thinking they were due to a urinary tract infection or perimenopause and no further action was taken. Furthermore, participants mentioned having difficulties requesting tests such as ultrasound scans and pressed for these.

Insufficient provision of information was one of the key issues in relation to treatment and participants complained that oncologists, did not fully explain the side effects of the prescribed medications. Some participants also reported a lack of involvement in decisions about their treatment and not being provided with treatment options including at disease recurrence.

Coping strategies.
Participants were asked to share their experiences on how they coped with difficult situations through their clinical journey. They described support from family and friends, lifestyle and physical activity assisted them to cope with difficult situations and kept them moving forward. Walking, listening to music, meditation, nutrition and crafts were some examples. Two participants mentioned how making time for themselves was important for both their mind and body. Several participants sought help from support group organisations through which telephone support services, information booklets and complementary services such as yoga were provided.
Self-Empowerment
Some participants emphasized that taking control of their own lives was their one main strengths. Identified factors were being able to look forward, having an attitude of not giving up and learning how to ‘stick up’ for oneself. Participants expressed that by being independent and knowing their innermost selves provided them motivation and strength throughout their lives. In addition, providing self-encouragement through positive attitude and feeling gratitude helped them.

“I do need and want to practice gratitude every day. I am grateful for what I’ve got. And I’m much more in tune with the little things in life”.

Further to this, having a strong spiritual belief system helped to calm them and became a source of comfort explicitly during chemotherapy. In addition, having spiritual belief helped not only the participants, but also their families to gain strength in order to cope with difficult situations.

Discussion
In this study women with OC were able to express their own voices based on their individual experiences. Therefore, the six themes identified describe both HRQOL and contextual themes. Post diagnosis and treatment-related issues, relationships and supports with family and friends, financial issues, relationships with healthcare providers and self-perceived coping strategies were the key themes identified. Each theme had a number of overlapping sub themes that were identified as priorities for the women. In particular, challenges related to relationships, financial issues, relationships with healthcare providers and coping strategies were experienced during and after diagnosis and treatment.

Diagnostic delay was a key concern and our data suggested that lack of early symptom awareness due to insufficient OC knowledge and symptom recognition by participants and HPs contributed to the delay. This is consistent with studies that have low levels of OC symptom awareness are associated with delayed diagnosis.22-24 While, lack of cancer detection and inexpedient referral patterns influenced incorrect diagnosis by the physicians,25 and greater public education to increase knowledge of disease symptoms could be helpful.26,27
Most participants received a combination of surgery and chemotherapy. Treatments adversely affected physical well-being with prevalent symptoms such as fatigue, nausea and neuropathy. Research is now focusing on symptom management interventions guided by the implementation of PROMs into clinical settings and trials. Several surgery-related outcomes including change in body image, premature and sudden onset of menopause, and loss of reproductive function may affect psychological well-being. The possible loss of fertility during treatment with cancer can be more distressing than cancer itself, according to recent reports where efforts to maintain fertility through techniques such as fertility-sparing surgery are essential in younger women diagnosed with gynecological cancers as they could lead to an improvement in quality of life. Another recent study indicated high levels of psychological distress when diagnosed women reach childbearing age as menstrual function and fertility were lost. It is therefore important to monitor the progression of cancer but should also provide appropriate fertility preservation counselling. This has potential to alleviate stress, anxiety and depression and a smaller negative effect on the quality of life. Consistent with our findings, a past study showed that those who underwent surgery have experienced psychological distress such as lack of self-esteem, self-worth and loss of femininity.

Survivorship is important in cancer care and recent improvements in treatment have resulted in an increased number of survivors. However, our findings highlighted the need for patient-centered care. Patient involvement is vital in clinical care, where a recent study pointed to the significance of patient-clinician communication. This communication style provides patients with the platform to raise and discuss issues with clinicians thereby shaping subsequent clinical care processes and outcomes.

One of the contextual themes of HRQOL identified was perceived lack of provision of adequate information and services. Studies show that educating and communicating patients and their families regarding treatment options and its underlying side-effects will prepare patients to realize the likely outcome of treatment and will assist them in facing upcoming challenges. Inadequate services such as counselling were identified. Studies show that psychological and other supports are essential in these women’s lives, focusing on psychological well-being as well as counselling related to financial and nutritional needs.
Further, our findings illustrated some communication gaps between the women and their healthcare providers. Research shows that engagement of patients with their healthcare team strengthens and increases the provision of patient-centered care and thus potentially aids cancer control. A 2013 study described that patient-clinician communication may assist adherence and agreement to treatment, where for example, two-way communication on treatment-based symptoms could aid in symptom management. A recent study which focused on the sexual function of women diagnosed with OC reported that not only was there a communication gap between patient and clinicians, the clinicians expected patients to have disease related sexual problems and waited until patients spoke about their concerns. Improving survival, functional recovery and quality of life while minimizing long term side-effects are key priorities in cancer care.

Social well-being is consistent with the concept of HRQOL. The importance of being supported by family and friends, especially partners/spouses, was a critical factor for well-being. Some participants experienced changes in their relationships. Time spent with family was reduced due to treatment demands and withdrawal of loved ones from them. Previous studies have reported that women have felt displeasure from their friends and were unwilling to discuss about the disease.

Overall, participants experienced highly compromised HRQOL, around the time of diagnosis and during treatment. There is an urgent need to develop new strategies for early detection and screening, as diagnostic delay was associated with psychological distress such as anxiety, fear of death, parental stress and uncertainty in the current study and has also been previously reported. Additionally, participants experienced challenge in obtaining appropriate information to access and benefit from the healthcare system post diagnosis. Multiple studies have found that unreliable provision of knowledge and information is a driver of poor medical care in many high-income countries, including Australia. Involvement of patients in decision making and public engagement could improve the evidence based value of their healthcare.

Emotional domain is another aspect of HRQOL. Emotional distress was experienced particularly during treatment phase. Fear of recurrence was a source of emotional distress. Previous studies related to gynecological and OC research shows that women have fear of disease recurrence during the treatment and post treatment phases and that these fears are
poorly understood. Frustration was also of concern with almost all women frustrated due to their treatment side-effects and symptoms. A 2020 qualitative study that investigated life experiences of women diagnosed with OC found similar results on how women fall into frustration following treatment completion.

Understanding and measuring HRQOL outcomes related to the sexual well-being of women diagnosed with OC is vital. Half of participants had poorer sexual function impacting their overall health and well-being. Changes to body image, sudden onset of menopause, infertility and lack of intimacy were identified and negatively impact emotional well-being with a sense of losing feminine identity. It has also been found that difficulties with body image and lack of intimacy are associated with impaired quality of life.

Not only do individuals diagnosed with cancer have detrimental impacts on their sexual functioning, it often influences their partners. Studies suggest that cancer partners may suffer equal or even higher levels of distress relative to their sick spouses. Partners of cancer survivors do not often have the resources to offer sufficient care to their female partners. Findings from a 2009 study indicate that the sexual perceptions of the partners were influenced by loss of interest in the individual with cancer and tension and fatigue correlated with care tasks. Carers agreed that reduced happiness with the partnership could be followed by poorer quality of life as well as higher levels of anxiety and depression.

Financial aspects were described, and this influenced participant wellbeing. Due to the amount of time required to spend in treatments, some participants had lost their income stability either due to change to their employment status or being unable to continue in the workforce, impairing their emotional well-being and overall HRQOL. Some issues might appear to be more minor, such as related to the lack of car parking availability at respective clinical settings, but when needed on multiple occasions, this was a more major concern. Studies in women with OC found that disease and treatment related burdens create several issues including social and financial effects on their lives.

Participants also described current strategies they used in daily life. Participants utilized numerous coping strategies such as modified diet and lifestyle, which could be considered as a contextual factor that could influence HRQOL. Family and friend support was another major help sought by these women, which in turn helped improve and maintain their quality
of life. Self-empowerment techniques such as ability to look to the future, having positive attitude and sense of humor were a few techniques employed by the participants. Recent studies also show similar coping strategies used by women and how changed views and adding humor to their personal experiences was a means of self-healing. Overall, the participants were able to maintain their HRQOL and continue a modified normal life with the implementation of various strategies and self-management techniques into their lives.

**Limitations and strengths of this study**

There are approximately 115 new diagnoses of OC per year in Western Australia, potentially compromising data collection using a small sample size. However, maximum variability and data saturation were achieved using small sample size and thus should not be considered as a limitation but a strength. While the study sought to explore patient outcomes across the clinical trajectory, participants might not have accurately recalled their perspectives, constituting to another limitation.

Moreover, rich and descriptive data were obtained using the qualitative methods where intentionality of the participants and their carers were explored. In addition, utilizing a qualitative approach has enabled a holistic understanding of patients’ and carers’ lived experiences. The ‘bottom up’ approach of involving patients from commencement and throughout the study will ensure that going forward, priorities are clearly identified by the consumers (women with OC themselves) in consultation with clinicians. We envisage that the proposed OC specific PROM to be developed in a future study would be used in clinical settings to identify and measure specific problems that patients encounter that needed to be discussed.

**Conclusion**

By identifying key priorities for women with OC using a ‘ground-up community based approach’, we have highlighted the need for strategies to reduce diagnostic delays, assist patients in navigating the healthcare system, and improve their HRQOL and potentially develop a OC specific PROM that will enable better identification and earlier treatment of symptoms during the entire course of the disease.
Abbreviations
CCWA, Cancer Council Western Australia; CIC Cancer Project, Continuous Improvement in Care-Cancer Project; GPs, General Practitioners; HPs, Health Professionals; HRQOL, Health-Related Quality of Life; OC, Ovarian Cancer; OCA, Ovarian Cancer Australia; PROMs, Patient Reported Outcome Measures.

Acknowledgements
We are thankful for the generous involvement of participants, and their carers for sharing their experiences with us.

Author Contributions
All authors made significant contributions to the study conception and design, execution, performance of the research, data acquisition, analysis and interpretation of data, took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

Disclosure

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Conflict of interest
The author reports no conflicts of interest in this work.
References


Chapter summary

As this study aimed to develop an OC-specific tool though ‘grass-roots’ or ‘ground-up’ approach, the qualitative methods have captured rich information from patients’ perspective and the qualitative analysis conducted has gathered baseline data for the later creation of a PROM that defines HRQOL for women diagnosed with OC. Through semi-structured interviews and focus groups, we sought to gain a comprehensive understanding of their health concerns at a personal level as the first step in identifying the specific items for a new HR-QOL measure.

Further, the lived experience, as described by the participants, included data identifying various qualitative variables. As an initial developmental stage, identifying and reporting on processes and outcomes from qualitative data is also important. We also believe that by documenting the perspectives of women with OC that extend beyond symptomology and clinical outcomes that we provide an insight into the key priority areas for the women in terms of better managing their illness.

The six major themes identified in this study forms the domains of the measure that are yet to be developed in the next phase, Phase Two. Through the implementation of CI, the subsequent phase is elaborated in the following chapter.
Chapter Five: Results (Phase Two)

Employing cognitive interviewing to evaluate, improve and validate items for measuring the health-related quality of life of women diagnosed with ovarian cancer
Introduction

This chapter describes the refinement and validation of the wording of the items developed from the qualitative information collected in the preceding study phase (provide chapter number here in the brackets). This chapter reports the ways in which the CI technique enables to mould the items into statements that can be integrated into a disease-specific PROM through the participation of women diagnosed with OC. In addition, the study also highlights the purpose of employing CI in qualitative research.

The following manuscript is submitted to Patient Related Outcome Measures on 24 November 2020, whereby the first peer reviewer report has been returned. The manuscript has been assembled in a journal article format, by detailing the qualitative approach used. This chapter also illustrates the need to further validate the tool to perform further research studies in field tests and to confirm its psychometric properties.
Employing cognitive interviewing to evaluate, improve and validate items for measuring the health-related quality of life of women diagnosed with ovarian cancer

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Abstract

Purpose: This study investigated the content validity of items for inclusion in a new health-related quality of life measure suitable for patients with ovarian cancer.

Background: Patient-reported outcome are self-reports of patients by using tools and/or instruments called patient-reported outcome measures. Use of patient-reported outcome measures in clinical settings facilitate the delivery of better health care to improve patient health outcomes.

Patients and Methods: This study used cognitive interviewing techniques with fourteen women diagnosed with ovarian cancer and at different times since diagnosis, to evaluate items derived from a previously collected qualitative dataset. A set of draft items was administered via telephone, Zoom and WhatsApp app together with questions on item meaning and wording. Interviews were transcribed and thematically analysed.

Results: Four broad themes emerged in relation to the questionnaire construct and comprehension of items: intent and clarity, wording, relevance and context, and overall questionnaire construct. All draft items were adjusted based on the interview findings. The final set of 38 health-related quality of life items comprised 7 items describing physical health and functioning, 21 describing emotional wellbeing and 10 items describing social wellbeing; each rated on a five-point frequency response scale.

Conclusion: The items reflected a range of personal experiences associated with the patient clinical journey, creating a health-related quality of life tool specific to women diagnosed with ovarian cancer. The cognitive interviewing process established content validity for the tool, thereby, preparing it for field testing and evaluation of its psychometric properties. This study highlighted the fundamental role of cognitive interviewing during health-related quality of life questionnaire development to ensure that item content is grounded in patient feelings, functioning and meaning.

Keywords: Cognitive interviewing; Health-related quality of life; Ovarian cancer; Patient reported outcome measures

Introduction

Ovarian cancer (OC) is the most lethal gynaecological malignancy. Globally, 230 000 women are diagnosed with OC and 150 000 die of the disease each year.1 In Australia, OC is the eighth most commonly diagnosed cancer among women with approximately 1500 new cases diagnosed every year and a five-year relative survival of only 46%.2 OC survivors remain at
high risk of relapse and fear of cancer recurrence which may lead to significant anxiety and psychological morbidity. Many OC survivors report moderate to severe symptoms such as peripheral neuropathy and fatigue two years after completing treatment, and may experience a disease recurrence, or developing a new primary cancer, all of which can influence health-related quality of life (HRQOL).

Patient reported outcomes are defined as “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else”. Patient reported outcomes are collected using tools and/or instruments called patient reported outcome measures (PROMs). Incorporating PROMs into clinical settings is believed to enhance the delivery of health care and achievement of patient health outcomes.

Clinical trials involving cancer patients often utilize general PROMs, (for example, the Short Form Survey 36 (SF-36)) and validated tools for specific cancer types, including gynaecologic cancers. Whilst commonly used in research, PROMs are less often used in routine clinical practice, and important information on functional recovery and HRQOL could be missed.

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer Patients (EORTC QLQ-C30) and Functional Assessment of Chronic Illness Therapy Functional Assessment of Cancer Therapy - General (FACT-FACIT FACT-G) are the two most widely used cancer-specific HRQOL questionnaires and can be augmented by site- and/or treatment-specific modules. Both EORTC and FACT have OC-specific modules including EORTC QLQ-OV28, FACT-O and FACT-ovarian cancer symptom index (FOSI). The EORTC QLQ-C30 questionnaire contains 30 items which assess functioning, global HRQOL, and cancer-related symptoms. It is complemented by a OC module, QLQ-OV28, which contains a further 28 items including body image, abdominal/gastrointestinal symptoms, hormonal/menopausal symptoms. The FACT-O questionnaire comprises 27 items from FACT-G to cover four core domains of wellbeing with an additional 12 items specific to OC. The FOSI is a shorter, more focused subset of the FACT-O items that includes three subscales: disease/treatment-related symptoms and general function/wellbeing. More recently, King et al developed a tool, the Measure of Ovarian Symptoms and Treatment concerns (MOST), to assess patient-reported symptom burden as
an end point in clinical trials. This tool consists of 24 items including abdominal/disease/treatment-related symptoms, psychological symptoms and MOST-Well-being.\textsuperscript{15}

Whilst each of these tools seek to describe experiences of women with OC, each were developed using different methodological approaches and this could explain variations in their content.\textsuperscript{16} For example, the FACT-O was developed to assess symptoms and quality of life and semi-structured interviews were conducted with five health professionals (nurses) and 17 OC patients with varying disease severity. Items were then reviewed by a panel of experts.\textsuperscript{17} Additional to symptoms, the items reflect psychosocial aspects such as “appearance of my body,” “able to feel like a woman”.\textsuperscript{17} Like FACT-O, the QLQ-OV28 focused on measuring symptoms, both general and disease specific symptoms. Unlike MOST which primarily focused on symptom benefit in women with symptomatic OC, neither QLQ-OV28 nor the FACT-O were specifically developed and validated in patients with platinum resistant recurrent OC, where the aim of treatment is symptom benefit and palliation. Similarly, differences exist in the level and stage of patient involvement in the development of PROMs.\textsuperscript{13,14} The importance of this is seen in the work of Kirwan\textsuperscript{18,19} and illustrated by Friedlander who showed clear differences between the level of important of symptoms reported by symptom benefit in women with symptomatic OC.

We previously conducted semi-structured interviews and focus groups with women with OC and identified key experiences and priorities for women diagnosed with OC. Findings included challenges related to diagnosis and treatment, adjustments in their relationships with family and/or friends, financial issues, some difficulties in their relationships with health professionals and comment on useful coping strategies. Through the use of template thematic analysis, these findings were further developed into a set of items that could be useful for the development of a values-based OC PROM (under review).

Establishing content validity is a fundamental first step in establishing whether an outcome measure is fit for purpose.\textsuperscript{20} Using cognitive interviewing (CI), the purpose of this study was to refine, and content validate the items/statements derived from the qualitative data collected in our previous study. We also aimed to examine whether additional items from the dataset could contribute to a broader questionnaire on factors related to HRQOL.
**Material and Methods**

This study employed cognitive interviewing (CI) with the integration of concurrent think-aloud (CTA) procedure. CI is a method whereby items and contents and response processes can be assessed and validated,\(^{21}\) ensuring the content clarity and relevance of the items and response categories.\(^{22,23}\) The CTA procedure is a research method in which respondents speak aloud about their thoughts as they complete each questionnaire item in regard to personal understanding of the items.\(^{24,25}\) Thus, this interview procedure was implemented to identify items where respondent interpretation and the developer’s intentions were dissimilar and to identify ways in which those items can be modified based on the responses given.\(^{22,24}\) This study was granted ethics approval by the Human Research Ethics Committee at University of Notre Dame Australia (UNDA) (2020-010F) and our study complied with the Declaration of Helsinki.

**Recruitment procedures and study population**

Our previous study incorporated input and guidance from relevant community support organisations, primarily Ovarian Cancer Australia (OCA) and Cancer Council Western Australia (CCWA). This study also worked in partnership with CCWA, OCA and the Australia New Zealand Gynaecological Oncology Group-Survivors Teaching Students, in recruiting participants through advertisements distributed through the media and relevant agencies. The recruitment process was slow as it coincided with the COVID-19 pandemic. Additional participants were recruited through King Edward Memorial Hospital and Solaris Cancer Care, a patient support organisation, in Perth, Western Australia. All participants who expressed interest in participating in the study were contacted directly by the UNDA researcher (SB) to schedule an interview at a mutually convenient time.

Recruitment was purposive and utilized a maximum variation strategy, aiming to represent variation in the stage of OC, treatment received, demographic and socioeconomic characteristics. This sampling technique provides insights and in-depth knowledge regarding individuals’ experience in different circumstances.\(^{26}\) Participants were women diagnosed with OC, older than 18 years and were proficient in English.

**Data collection**
Participants were provided with all relevant documents including a consent form, participant information sheet and interview schedule, and signed consent was received prior to interview commencement. Due to the COVID-19 pandemic, interviews were conducted using telephone or video (Zoom/Skype/WhatsApp App) according to the participant’s preference. Identified statements from our previous qualitative study were tested by conducting CI using the CTA procedure (Table 1). The focus of applying CTA was not limited to determining certain words or response categories of the items but also to identify how and why respondents answered each item. Prior to the interview, participants were briefed that they would be asked to share their thoughts and opinions on the statements that were unclear or difficult to comprehend (Charters, 2003). Participants were encouraged to engage with the researcher by reacting to pieces of the document and explain if they found the items and/or content confusing or unfamiliar.

Table 1: Probing questions used during the CTA procedure

<table>
<thead>
<tr>
<th>Context</th>
<th>Question Format</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOW</td>
<td>How did you respond to that statement?</td>
<td>“How would you rate that statement?”</td>
</tr>
<tr>
<td>WHY</td>
<td>Why did you respond in that way?</td>
<td>“Why did you agree but not strongly agree?”</td>
</tr>
<tr>
<td>REWORD</td>
<td>Is there any other way to reword the statement?</td>
<td>“You were confused with that statement. So, would you reword that statement?”</td>
</tr>
</tbody>
</table>

**Data Analysis**

Collected data was audio-recorded and transcribed verbatim and was imported into QSR NVivo version 12 for data management and analysis. In the last five interviews conducted, no new codes or themes were generated and thus saturation of data was achieved. The CI data were analysed in a multistep process. The initial analysis comprised open coding, with the intention of establishing codes based on participant feedback and suggestions. Thereafter, a second analysis involved axial coding to identify patterns in the codes for each item based on participant feedback and to categorise it under broader themes. Data collected via the CTA procedure were thematically analysed using this theme coding approach. Braun & Clarke have defined thematic analysis as a method that aims to achieve an in-depth understanding of the phenomenon and enable identification of emerging themes and patterns across the qualitative data collected. Items generated from all interviews (including the initial patient interviews) and the literature relating to coping with cancer were collated into the interview
statements. Additional items were also generated based on emerging themes identified during the CI data analysis. The identified themes were then refined and operationalised into statements corresponding to each theme.

**Investigative team**

During multiple sittings, the supervisory team from clinical and research backgrounds, reviewed the modified statements to establish a final set of items. A qualitative researcher who had collaborated closely with community groups, a health researcher with research expertise in qualitative study designs and had expertise in developing quality of life measures, a health researcher whose expertise lies in the areas of health service redesign and translation, a gynaecologist and a higher degree research student. Team meetings formed a fundamental part of the questionnaire development phase. In compliance with all collective feedback and suggestions, supervisory team meetings were held to determine necessary changes and achieve a consensus on the modifications.

**Results**

**Participants**

Fourteen participants took part in individual telephone or video interviews with a mean duration of one hour and fifteen minutes (range 30 minutes to one hour 50 minutes). Interviews for one participant were completed over two occasions for their convenience, and the initial interview which provided pilot data was also incorporated into the dataset. Feedback collected from the pilot interview informed modification of the statements’ response scale to be used in the subsequent interviews. Participants varied in age, employment and marital status but all lived in a metropolitan setting. Seven participants had been diagnosed over five years previously and two participants had received their diagnosis within a year of the interview. Among the 14 interviewees, five participants were undergoing active treatment because of recurrence of their cancer (Table 2).
Table 2: Description of study participants (n=14)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No: of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Group (years)</strong></td>
<td></td>
</tr>
<tr>
<td>50 to 59</td>
<td>5</td>
</tr>
<tr>
<td>60 to 69</td>
<td>5</td>
</tr>
<tr>
<td>70 to 79</td>
<td>4</td>
</tr>
<tr>
<td><strong>Current Employment Status</strong></td>
<td></td>
</tr>
<tr>
<td>Currently looking for work</td>
<td>1</td>
</tr>
<tr>
<td>Employed (Casual, Part-time, Full-time, Self-employed)</td>
<td>5</td>
</tr>
<tr>
<td>Home duties</td>
<td>1</td>
</tr>
<tr>
<td>Retired</td>
<td>7</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>5</td>
</tr>
<tr>
<td>TAFE certificate</td>
<td>4</td>
</tr>
<tr>
<td>University degree (undergraduate/postgraduate)</td>
<td>5</td>
</tr>
<tr>
<td><strong>Employment Status before diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Employed (Casual, Part-time, Full-time, Self-employed)</td>
<td>10</td>
</tr>
<tr>
<td>Home duties</td>
<td>2</td>
</tr>
<tr>
<td>Retired</td>
<td>2</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Married or de facto</td>
<td>8</td>
</tr>
<tr>
<td>Separate or Divorced</td>
<td>4</td>
</tr>
<tr>
<td>Single/Never married</td>
<td>1</td>
</tr>
<tr>
<td>Widowed</td>
<td>1</td>
</tr>
<tr>
<td><strong>Treatment Status</strong></td>
<td></td>
</tr>
<tr>
<td>Not on treatment</td>
<td>9</td>
</tr>
<tr>
<td>Currently on Treatment</td>
<td>5</td>
</tr>
<tr>
<td><strong>Length of time since diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>6 months – 1 year</td>
<td>2</td>
</tr>
<tr>
<td>2-4 years</td>
<td>5</td>
</tr>
<tr>
<td>&gt;=5 years</td>
<td>7</td>
</tr>
<tr>
<td><strong>Cancer Recurrence (yes)</strong></td>
<td>5</td>
</tr>
</tbody>
</table>
Draft questionnaire examined using CI and CTA

Draft items were classified into the domains identified in our previous qualitative study. Diagnosis and Treatment-related (chemotherapy, surgery and complementary therapies), relationships with family/friends, financial aspects, health services and interactions with health professionals, and coping strategies. Challenges related to diagnosis and treatments were documented. Key themes such as physical wellbeing, emotional wellbeing, relationships with family/friends, health services and interactions with health professionals, and coping strategies were identified as related to living with an OC diagnosis across the clinical journey. A Likert response scale was created for the items.

The draft questionnaire acknowledged all data from the original qualitative study and included a set of questions to collect participant demographic and cancer history information. The next four sections focused on challenges related to diagnosis and treatment and included skip questions which directed participants to appropriate sections based on the responses given, with the response scale measuring the severity of challenges. The remaining sections with items related to HRQOL, satisfaction with services and coping strategies were provided with a response scale of frequency (Table 3).

Table 3: Total number of items per questionnaire section prior to modification based on CI data

<table>
<thead>
<tr>
<th>Section</th>
<th>Items (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>10</td>
</tr>
<tr>
<td>Cancer History</td>
<td>5</td>
</tr>
<tr>
<td>Section 1: Clinical Diagnosis</td>
<td>4</td>
</tr>
<tr>
<td>Section 2: Chemotherapy</td>
<td>5</td>
</tr>
<tr>
<td>Section 3: Surgery</td>
<td>5</td>
</tr>
<tr>
<td>Section 4: Complementary Therapies</td>
<td>2</td>
</tr>
<tr>
<td>Section 5: Emotional Wellbeing</td>
<td>52</td>
</tr>
<tr>
<td>Section 6: Financial Wellbeing</td>
<td>10</td>
</tr>
<tr>
<td>Section 7: Health Services</td>
<td>15</td>
</tr>
</tbody>
</table>
Refinement of HRQOL items

A multistep analysis process was then used to classify how the items could be modified, using four broad themes. Refinement of HRQOL items is illustrated with examples below.

**Item intent and clarity.**
Responses for several items were inconsistent with the item intent, failing to interpret the researcher’s objectives. For some items, participants reported, “I do not understand what this means” or “I couldn’t get to the meaning of the question”. For example, one original item was “I felt frustrated during and/or after receiving a treatment”. A majority of the participants comprehended “frustrated” in terms of the treatment received, but the researcher’s intent was to measure “frustrated” in relation to a participant’s activities whilst undergoing treatment. With participant input, the item was modified to “I felt frustrated that I could not take part in usual activities during and/or after treatments”.

**Item wording.**
Difficulties with comprehension of the meaning of some items was identified. For instance, the statement “I feel valued because I can still contribute to the workforce” created confusion in the participant. One particular response was “I am not working, but I still feel valued. I would put not applicable for that one. But I would put strongly disagree because I feel valued because of work”. To better structure it, the item was modified to “I have felt valued because of the work that I can do (home, workforce)”.

Other items were considered vague by participants and difficulties arose in communicating the researcher’s intent of the items to the participants. For example, the item “My family/friends have reacted unexpectedly to my illness” could have been interpreted as a positive or negative experience. With participant feedback, the item was modified to “My family/friends have reacted unexpectedly (in a negative way) to my illness”.
**Item relevance and context.**
Some items had little relevance to participants’ age. These items included: “I have been embarrassed by the way my body has changed” and “I have felt less feminine because of my illness”. Moreover, several items specific to emotional wellbeing were not relevant to participants who were under surveillance and not receiving treatment. For example, when asked about “I have felt sick and unwell due to the side-effects of treatments I have experienced”, participants replied saying “that’s hard because during the chemo, I felt unwell and sick but since the chemo, I have had no problem”.

Finally, the complexities of some items made it difficult for participants to respond precisely. For example, one original item was “My family/friends are generally supportive of me at this time”. However, based on the participant’s perspective, the support received from family and friends could have been different. Thus, the item was separated into two items. In particular, one participant couldn’t comprehend the context of the item within the social domain. Initially, the statement was developed as “I have felt isolated socially because of my illness. The participant could not, however, answer in what context the word "socially" meant. The item was subsequently changed to “I have found it difficult to connect socially with people because of my illness (e.g. at work, in public)”.

**Refinement of items describing contextual factors for HRQOL**
The qualitative dataset contained additional themes of disease/treatment and financial issues, communication with health professionals and coping strategies. These themes were developed into three sets of questions that reflected contextual factors for HRQOL: patient symptoms, satisfaction with health services and strategies for self-sufficiency and resilience. These items were refined using the same multistep analysis process and examples are presented below.

**Item wording.**
Some items related to technical terms that were complex to understand. For example, concerns were raised on specific terminologies such as “cancer recurrence”, “mucositis”, “full cycle of chemotherapy”, “complementary therapies”. In response, clear definitions were constructed.
**Item relevance and context.**

Relevance of specific items was age dependent. For instance, questions regarding “sudden onset of menopause” and “inability to have children” had no impact on the wellbeing of many participants because they had undergone menopause prior to receiving their OC diagnosis. Thus, a “not applicable” response column was included to the patient symptom section. Since there were items of little relevance across the questionnaire and upon joint agreement amongst the supervisory team, a timeline was provided for every section.

The context of the item “There is a lack of financial assistance with practical support” was unclear as one participant expressed, “I haven’t had to seek that out. So, I don’t really know. I haven’t needed it but to listening other ladies I think there probably is a need for it”. However, the researcher’s intent was to know whether the participants had any challenges accessing the services or not. The item was modified as “There has been a lack of practical support offered to me”. In addition, the item “I maintained a sense of gratitude” seemed out of context to a participant. The item was modified to “I have maintained a sense of gratitude for what I am able to do/achieve”.

**Questionnaire construct**

Some participants mentioned that the response format type for HRQOL and wellbeing items could be improved as responses could have reflected upon frequency, rather than merely agreeing/disagreeing to a statement. For instance, participants responded by using expressions such as “at times” or “sometimes” and found it difficult to merely agree/disagree to the items. Thus, a frequency format of Always/Often/Sometimes/Rarely/Never was applied to sections that measured aspects of HRQOL and wellbeing.

In summary, the CI and CTA processes informed substantial item reconstruction to achieve content validity for this participant group. The questionnaire in its entirety was restructured: including 67 items which were modified, 10 items were condensed and merged into appropriate sections, 66 items were deleted, and 15 items were added. The items describing HRQOL were grouped, forming an HRQOL instrument named the OVArian cancer health related Quality of Life (OVAQOL) scale. This scale comprises items that contributed conceptually to three HRQOL domains: physical wellbeing (n=7), emotional wellbeing (n=21) and social wellbeing (n=10. The rich original qualitative dataset and the
comprehensive interview and analysis processes informed the development of accompanying sets of questions on demographic characteristics, disease and treatment status, patient satisfaction with healthcare services and patient resilience (Table 4).

Table 4: Final structure and number of items in the questionnaire with examples of OVAQOL items

<table>
<thead>
<tr>
<th>Section</th>
<th>Items (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section 1: Demographics</strong></td>
<td>14</td>
</tr>
<tr>
<td><strong>Section 2: Disease and Treatment related symptoms</strong></td>
<td>26</td>
</tr>
<tr>
<td><strong>Section 3: OVArain cancer health related Quality Of Life (OVAQOL) scale</strong></td>
<td>7</td>
</tr>
<tr>
<td><strong>Physical Wellbeing</strong></td>
<td></td>
</tr>
<tr>
<td><em>Example:</em></td>
<td></td>
</tr>
<tr>
<td>“felt sick due to treatment side-effects”</td>
<td></td>
</tr>
<tr>
<td>“bothered by the symptoms”</td>
<td></td>
</tr>
<tr>
<td>“frustrated by not being able to exercise”</td>
<td></td>
</tr>
<tr>
<td>“difficult to care for my family and/or friends”</td>
<td>21</td>
</tr>
<tr>
<td><strong>Emotional Wellbeing</strong></td>
<td></td>
</tr>
<tr>
<td><em>Example:</em></td>
<td></td>
</tr>
<tr>
<td>“afraid of cancer coming back”</td>
<td></td>
</tr>
<tr>
<td>“felt valued because of the work that I can do”</td>
<td></td>
</tr>
<tr>
<td>“felt less self-worth”</td>
<td></td>
</tr>
<tr>
<td>“worried about loss of income”</td>
<td>10</td>
</tr>
<tr>
<td><strong>Social Wellbeing</strong></td>
<td></td>
</tr>
<tr>
<td><em>Example:</em></td>
<td></td>
</tr>
<tr>
<td>“difficult to understand carer’s/partner’s feelings”</td>
<td></td>
</tr>
<tr>
<td>“family has been generally supportive”</td>
<td></td>
</tr>
<tr>
<td>“found it difficult to connect socially with people”</td>
<td></td>
</tr>
<tr>
<td>“partner needed more self-time”</td>
<td></td>
</tr>
<tr>
<td><strong>Section 4: Satisfaction with Health Services</strong></td>
<td>11</td>
</tr>
<tr>
<td><strong>Section 5: Resilience</strong></td>
<td>22</td>
</tr>
</tbody>
</table>
Discussion

Using a CI approach, the purpose of this study was to refine and validate the wording of the items extracted from the data collected during a previous qualitative study. Four broad themes of item adjustment emerged based on the feedback and suggestions provided by the participants, and following modification and evaluation, evidence for the content validity of the items was generated. Going forward, this new questionnaire has capacity to measure outcomes in women with OC and contribute to improving their health outcomes across the survivorship trajectory, and is ready for further validation.

Originally, the draft instrument consisted of 52 HRQOL items, and thereafter, has been reduced to 38 items. Since the questionnaire seeks to measure disease and treatment specific HRQOL outcomes of women diagnosed with OC, the items and its contents should reflect the purpose of measuring HRQOL. HRQOL is a multidimensional construct that measures the impact of a disease on physical, psychological and social relations aspects on a person’s life as defined by the World Health Organisation. Upon modification and evaluation, the items were examined and categorised into physical/functional, emotional and social domains consistent with this definition. The concept of HRQOL does not measure aspects such as job or income security. Thus, items pertaining to accessing information in relation to financial needs were included in the patient satisfaction section with health services, while an item that measures psychological distress in relation to loss of income was merged with HRQOL emotional domain.

Our study findings illustrate how disease/treatment related symptoms had substantial impacts on the HRQOL of our study population, consistent with previous studies. As an aftermath effect, these symptoms in turn affect the ability and capability to perform tasks either it be usual activities or professional. Emergence of physical wellbeing constituted one of the important HRQOL domain. Included statements pertained to both physical health and functioning status of patients diagnosed with OC. The statements illustrated the impacts of symptoms from the patient perspective. Items related to “fatigue” and “difficulty sleeping” measure patient health while “participation in usual activities” focuses to measure patient functional ability. Similar to our findings, other studies have also revealed that people with chronic illness struggle with daily life tasks by being dependent on others, revealing that it is important to measure physical domain of HRQOL for patients with OC.
Emotional wellbeing is a fundamental component of HRQOL instruments. Items including “depression”, “anxiety”, “fear of recurrence” were included in OVAQOL. Inclusion of such items enable evaluation of psychological distress experienced by women whether it be disease and/or treatment related by how severely it has impacted their HRQOL. In addition, it enables the researcher to identify whether such items impact other domains of HRQOL as previous research shows that psychological distress is related to poor performance status.  

Social functioning is also an essential component of HRQOL, particularly in relation to support provided by the family and friends which is emphasized in other similar qualitative studies. In turn, social relations and mental wellbeing domains are interconnected. In a 2001 study of individuals with breast cancer, Kornblith and colleagues identified that women with low levels of support either it be through family, friends or professional, had higher levels of psychological distress throughout their clinical journey. 

The initial qualitative dataset included important information describing factors related to the women’s HRQOL, including their satisfaction with health services, help-seeking throughout their clinical journey and resilience. In a recent study, it was indicated that HRQOL for those affected with systemic lupus erythematosus found a positive association between patient health care satisfaction and health status, possibly due to supports in the physical, emotional and social domains. Recent studies also show that there is a direct relationship between resilience, life satisfaction and wellbeing on those living with chronic illness and indicates the importance of measuring the impact of such variables on wellbeing and HRQOL. Thus, opportunistically and based on our findings and supporting information from various literature, relevant items associated with health services and informational challenges were collected into a module of questions describing ‘satisfaction with health care services’. Items that measured various coping strategies and resilience were collected into a ‘resilience’ module of questions to enable measurement of the self-empowerment and self-sufficiency strategies used by women during these difficult times.

Based on the development processes, the researchers believe that the content of OVAQOL truly reflected the consumer voice as was captured through the preceding qualitative study and the current CI procedures, each with patient involvement. This had not been performed to this extent in the development of existing OC HRQOL instruments suggesting limited patient involvement during the developmental stages of these PROMs. Consumer involvement in
PROM development is essential as it is only patients who can determine outcome relevance and comprehensibility of the instrument.\textsuperscript{46,47} Previous studies have indicated that lack of patient involvement affects the sensitivity, validity and response of the questionnaire tool,\textsuperscript{48,49} in which a 2017 study showed patient involvement had not increased in PROM development over time.\textsuperscript{19}

The study methodology itself is one of the main strengths of this study. Utilization of CI not only aided in the refinement of the statements in the tool, but also enabled identification of limitations which in turn assisted in the modification of the questionnaire construct that defines HRQOL. This study also had certain limitations. The onset of COVID-19 during the course of this study hindered the participant recruitment process, thereby impacting the study progress. Administering CI to a small sample size contributed to the second limitation as sampling variation could have increased with even more participant recruitment where evaluating and reviewing the contents of the items could have improved. Even though research has suggested that it is ideal to recruit between seven to 10 participants to check and confirm participant’s item comprehension, the variability in the participant number depends upon factors such as maximum sampling variation, questionnaire complexity and participant understanding of the items.\textsuperscript{50}

**Conclusion**

The current study utilized a systematic process to develop an OC specific PROM and highlights the value of CI for questionnaire item modification and content validity. Validation of the PROM in a larger sample and evaluation of its psychometric properties is an essential next research project.

**Abbreviations**

CCWA, Cancer Council Western Australia; EORTC QLQ-C30, CI, Cognitive Interviewing; CTA, Concurrent Think-Aloud; European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer Patients; EORTC QLQ-OV28, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Ovarian; FACIT FACT-G, Functional Assessment of Chronic Illness Therapy Functional Assessment of Cancer Therapy–General; FACT-O, Functional Assessment of Cancer Therapy–Ovarian; FOSI, Functional Assessment of Cancer Therapy–ovarian cancer symptom index; HRQOL, Health-Related Quality of Life; MOST, Measure of Ovarian Symptoms and Treatment
concerns; OC, Ovarian Cancer; OCA, Ovarian Cancer Australia; OVAQOL, OVarian cancer health related Quality Of Life scale; PROMs, Patient Reported Outcome Measures; UNDA, University of Notre Dame Australia.

Acknowledgements
The authors wish to thank all the patients who participated in this study. This study was supported by the Continuous Improvement in Care-Cancer Project. Ms. Sharolin Boban is a Masters’ of Science student at the University of Notre Dame Australia, Fremantle and this work forms part of her thesis.

Authors’ contributions
All authors significantly contributed to the study design and implementation, research results, data collection, analysis and evaluation of data, collaborated to its writing or critical reviews for essential intellectual material, agreed to send to the current journal, gave final approval for the version to be written, and agreed to hold all the authors transparent.

Disclosure

Funding
This study was done with the support of a Cancer Research Trust grant and is part of the Continuous Improvement in Care-Cancer Initiative, a multi-disciplinary research program, aiming to provide value-based healthcare in clinical settings in Western Australia. JD was supported by Department of Health Western Australia Merit Award.

Conflicts of interest
There are no conflicts of interest in this study.

Declarations

Consent to participate: All participants were asked to return their signed informed consent form prior to the commencement of the interview. Participants were informed the intent of the study which included agreement to the release of study results.

Consent for publication: The participant informed consent form included a statement related to the authorization for publishing study results.
Availability of data and material: Not applicable.

Code availability: The dataset was transcribed verbatim and analysed in QSR NVivo version 12.

Informed consent and patient details

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.
References


Chapter summary

This chapter has reported the analysis and results of data obtained from Phase Two.

To our knowledge, this is the first study to use Cognitive Interviewing (CI) to refine and validate items for an OC-specific tool. The application of a CI technique using the concurrent think-aloud protocol enabled a better understanding of the thought process of participants and use their feedback to develop the tool. The study also found aspects that the study participants found important and relevant were not included in the current OC-specific tools. This suggested the need to create a unique tool tailored specifically for OC patients through their meaningful participation in the development of the tool.

The themes that emerged from the data revealed the problems related to item interpretations and the overall structure of the tool. The qualitative technique not only allowed the items to be refined and moreover helped the researcher develop a method by identifying both HRQOL and contextual factors for HRQOL. It also enabled the researcher to better construct the final draft instrument by including all information collected during Phase One.

Upon study completion, it was recognised that CI could be considered as a method for enhancing the design of the questions as it played a significant role that allowed data validation to be achieved. Moreover, additional benefits were accompanied such as it gave an opportunity for a good partnership between participants and the researcher, provided the respondent a capacity to fulfill the part of an evaluator and narrator, helped to understand the value of the significance of the items and helped to examine the credibility of the questionnaire design.
Chapter Six: Discussion & Conclusion
Overview

This thesis outlines the development of a draft HRQOL PROM specifically for women with OC, through patient involvement at each phase of the tool development. The tool creation was conducted in two sequential phases, to address the gaps identified. **Phase One** employed preliminary work using community conversation, followed by semi-structured telephone interviews and focus groups. The qualitative dataset collected during Phase One paved the way to the subsequent phase, **Phase Two**, by employing CI using the CTA procedure. As a result, the two studies have been structured to answer the research questions and address the limitations in the current OC tools. The results of the studies collectively offered a detailed, theoretically driven interpretation of patient results with practical implications for the further development of OVarian cancer health related Quality of Life (OVAQOL) scale, a PROM tool that measures three core domains of HRQOL in women diagnosed with OC: physical and functional status, emotional and social.

**Key priorities of outcomes identified and described by women diagnosed with OC**

This research utilised a ‘ground-up’ approach to holistically identify various outcomes that were derived from the patients’ perspectives. Findings from the study conducted in Phase One explored a wide range of challenges faced by women living with OC and their relative concerns were heard, ranging from pre-diagnosis to post-treatment and beyond. The six themes described both HRQOL outcomes and their contextual factors.

As described in **Chapter Four**, many of the women described experiencing various symptoms including abdominal/bowel discomfort, fatigue, toilet urgency. Even though these symptoms are not disease specific nor gynaecological (Bankhead et al., 2005), OC symptom related studies indicate women experiencing gastrointestinal and urinary-related problems where the frequency, severity and persistence of these symptoms will be higher in the months prior to having a diagnosis (Bankhead et al., 2008; Ebell et al., 2016; Freij et al., 2018; Natarajan et al., 2018).

Experiencing a delay in the clinical diagnosis of the disease was another key issue identified from this study. The study data identified various factors that contribute to the delay. Primarily, in the absence of an effective screening tool or specific symptoms, the
The majority of cases of OC are diagnosed at advanced stages (III & IV) (Miranda & Ahmed, 2016) often resulting in adverse disease outcomes (Buys et al., 2011). There is an urgent need to develop new strategies for screening, and early detection as the analysed data illustrates that women with delayed diagnosis faced various challenges including emotional, informational and lack of adequate services. Further to the results displayed in chapter four, it was also identified that potentially some GPs also contributed to the diagnostic delay. The identified factors include excessive time span to make the right diagnosis, ignorance of disease symptoms, becoming unaware of the symptoms assuming it referred to urinary or perimenopausal problems. Reports of past studies support our findings that women follow complex referral paths before being correctly diagnosed. Most women are initially presented with observed and persistent symptoms in primary care. Several studies suggest that primary care professionals have a significant role in identifying the symptoms and signs of the disease and taking timely evidence-based decisions on further investigations and referrals (Bankhead et al., 2008; Funston et al., 2018; Williams et al., 2019). In order to alleviate the incidence of delayed diagnosis, recent research suggests that GPs should take detailed family histories to identify women who may be at increased OC risk, and perform abdominal-pelvic examinations, review recurring symptoms and send referrals without delay to gynaecological cancer clinics (Funston et al., 2018).

HRQOL has become a well-recognised concept in cancer care, with qualitative datasets clearly showing that physical, functional ability, emotional and social well-being in women were significantly decreased, during post-diagnosis and treatment and that it’s a challenge to manage HRQOL during the clinical journey. It was recognised that patients’ HRQOL could be improved through better patient-clinician communication as it would help patients raise their concerns without hesitation and aid in treatment symptom management (Greenhalgh et al., 2018; Street, 2013). In addition, it was also found that the inclusion of patients in informed decision-making will help maximise patient-centred care (Elshaug et al., 2017; Lavallee et al., 2016).

Further, the qualitative data indicated many challenges in traversing the disease journey especially when diagnosed with a chronic illness such as OC, consistent with the findings of a recent study (Ahmed-Lecheheb & Joly, 2016). Our research data showed that not only the long-term side effects of the treatments were impacted but contextual factors of
HRQOL such as financial issues, interaction with HPs, information and service challenges and patient coping strategies were also highly compromised. Based on the richness of the data that was collected, various concepts of patient healthcare service satisfaction and resilience were explored further that formed two important contextual factors of HRQOL.

Several challenges concerning patient satisfaction with the services provided including those provided by GPs were identified. Challenges such as lack of communication with and between HPs; receiving reliable information in relation to financial assistance, treatments, support and service programmes; inadequate services offered by HPs in relation to patient concerns being heard, the extent of support provided to patients and their active involvement in patient clinical trajectory were identified. Patient satisfaction is a vital factor that provides healthcare professionals with useful data on the quality of their treatment and helps them to assess the effectiveness of their service (Ullah et al., 2020). Studies have found that patient satisfaction with both healthcare services and the system can be measured for better patient evaluation and improvement of their HRQOL (Davidson et al., 2017; Senić & Marinković, 2013) as a recent study shows that poor patient satisfaction has an association with psychological symptoms such as anxiety and depression (Kavalnienė et al., 2018).

Despite the numerous challenges faced, patients shared their individual strategies to exact a measure of control over the management of their disease including dietary adjustments and lifestyle activities, family/friend support and having to connect with nature and their spiritual beliefs. Moreover, resilience methods such as individual self-empowerment were also identified. Having a determined mind, sense of humour, positive attitude, adaptability of illness and looking forward to the future were used across their clinical journey. Past studies suggest that self-management techniques should be used by patients living with chronic illness where social support is a significant component for patients at advanced cancer stage (Schulman - Green et al., 2012; Wen et al., 2017).

Based on the study findings, patient-clinician communication should be progressed to discuss and understand individual HRQOL outcomes of patients with OC. One of the mediums to communicate these outcomes is through the self-administration of PROM tools.
This study has found the solution by taking the initial step in developing a unique OC PROM through patient involvement that measures all domains of HRQOL. Research has also demonstrated that involving patients during each stage of PROM development can yield a PROM instrument that is valid and comprehensible to patients. Further, implementation of these measurement tools into both clinical care and research serves as a key component in delivering value-based patient-centred care (Johansen & Saunders, 2017). Measuring patient experiences such as disease and treatment related symptoms (frequency, severity and duration) and HRQOL, can aid in assessing individual treatment progress and disease recurrence.

**Identification of items describing HRQOL & contextual factors for HRQOL**

Since the Phase One outcomes captured a rich mix of challenges faced during the clinical journey, it was vital to distinguish the outcomes that accurately measured HRQOL and its contextual factors. The emergence of four broad themes with regards to item comprehensions and questionnaire construct enabled outcomes to be refined and operationalised into respective sections that define and measure HRQOL and its contextual factors, thereby achieving content validity.

Overall, the development of a HRQOL PROM should place importance on factors related to the women’s HRQOL. HRQOL is a multidimensional aspect and is defined by the World Health Organisation as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (World Health Organisation, 2014). Within the four broad themes identified, the student researcher was able to identify different aspects that describe HRQOL of women diagnosed with OC and classify them according to these three domains to develop the OVAQOL measure. In addition, recent studies indicate that HRQOL surveillance is especially relevant in advanced cancer care because it increases the clinical understanding of the patient's changing clinical needs (Basch et al., 2016; Etkind et al., 2015).

No previous studies have been conducted to investigate various contextual factors of HRQOL in patients with OC. The two studies conducted in this thesis also identified and refined contextual factors. Factors such as disease and treatment-related symptoms,
satisfaction with health services inclusive of informational and poor healthcare service challenges, patient coping strategies and resilience methods were refined, evaluated and segregated into appropriate sections with the overall questionnaire. It is equally important to measure these variables as they influence patients’ HRQOL across the OC disease spectrum. Some studies financial strains impact clinical outcomes and psychological wellbeing in cancer patients (Perrone et al., 2016; Sharp et al., 2013), confirmed in a further study conducted in 2018 (Chen et al., 2017). As patient satisfaction is a significant indicator of HRQOL (Al-Abri & Al-Balushi, 2014) and findings from a Prostate cancer study identified that patient satisfaction on healthcare service quality is an important element as patients experienced better survival outcomes (Gupta et al., 2015). Resilience is defined as a baseline trait that is identified and expressed in the face of adversity. According to a report, practicing resilience across the cancer spectrum is critical as social assistance, hope, appreciation, recognition helps to build inner strength and thereby alleviating distress and increases overall patient well-being. (Molina et al., 2014). Based on information-rich qualitative data obtained, the researcher was able to determine specific items that contributed to the creation of the respective domains.

Identification of issues related to item interpretation and questionnaire construction enabled the researcher to realise how interviewees' interpretations differed from the researcher's intentions thereby validating the scale further. One of the identified shortcomings of the existing validated OC PROMs is that have not developed a tool that integrates target populations during its developmental stages. Thus, the research candidate believes that the content of OVAQOL and contextual factors are likely to represent the consumer voice because multiple processes for consulting with patients informed the development of the OC-specific tool, OVAQOL.

Findings from Phase One & Two led to the exploration of various limitations by using the current validated OC tools. The limitations are widely discussed below and in Chapters Two and Five respectively.
Are the key outcomes identified through these processes different from existing tools and if so, how are they different?

Through a multi-stage approach, this thesis enabled a comprehensive development of an OC-specific tool that could measure various health domains and contextual factors of women diagnosed with OC. Moreover, the student asserts that the newly developed tool is distinctive from other existing OC tools.

Chapters Two and Five have addressed in-depth the numerous shortcomings regarding the methodological procedures of the current OC tools. These include minimum to no presence of patients during the stages of development. In addition, it was noted in the respective chapters why an OC-specific measure is required to be developed which adequately depicts the experiences of women diagnosed with OC. The findings obtained from Phase One and Two (see Chapters Four and Five) enabled the researcher to distinguish significant differences in the questionnaire structure and content and not just in the tool development process.

What makes the developed measure unique?

Structure: OC Questionnaire and OVAQOL.

Taking into account the existing four OC tools, this is the first developed OC questionnaire that contains HRQOL outcomes developed from the individual level. The evaluated outcomes are structured in a way that can be used by any patient despite the clinical stage they are in (Appendix 10). The purpose of aligning the set of outcomes in such a way would help clinicians to better assess various challenges and provide value-based care on an individual basis. Unlike FACT-O, EORTC QLQ C-30 and EORTC QLQ-OV28 were not developed with domain-specific item banks that measure various aspects of HRQOL. In addition, differences exist in their scale structure and an overall scoring system where QLQ-C30 score is generated by averaging responses to only two questions (global health and quality of life), while FACT-G offers a summary of all 27 items (Luckett et al., 2011). FOSI and MOST provide a symptom checklist focusing to measure disease/treatment symptoms and side effects. Without considering the items measured in the questionnaire, it might be hard for the clinicians to score and measure the patient outcomes which also seems to be time-consuming.
**Item content: OC Questionnaire and OVAQOL.**

Based on study findings in this thesis, the contents of both the OVAQOL measure and its contextual variables are distinctive in nature. There is an agreement in the literature that HRQOL should reflect more than just a symptoms rating, by integrating areas of physical, functional, emotional and social aspects that go beyond clinical interventions and reflect on the patients’ health (Darling et al., 2020; Uy et al., 2020). A 2020 study that aimed to construct an HRQOL instrument found that such instruments need to truly portray the experiences and expectations of the target population whose health and wellbeing they measure (Uy et al., 2020). With the limited invoke of OC patients throughout the creation of the four OC instruments, it must be questioned that the conceptualisation, priorities and health and wellbeing perspectives of women living with OC are accurately represented. Second, while these instruments are considered adequately reliable for population-level measurement of HRQOL, they may not calculate HRQOL with adequate accuracy to measure patients’ wellbeing over time as they traverse across the clinical journey. In addition, some items in EORTC QLQ-C30 and FACT-G are cancer general and may not be specific to OC patients.

It is believed that the outcomes defined in the OC questionnaire and OVAQOL measure include all HRQOL domains. A study that was conducted a decade ago reported that patient-clinician communication had been restricted to physical and functional HRQOL without including psychological and social wellbeing aspects (Rodriguez et al., 2010). Additional to a HRQOL scale, the OC questionnaire includes a disease/treatment symptom checklist, patient satisfaction with healthcare services and resilience. HRQOL and wellbeing are interconnected concepts. The positive facets of life such as positive feelings and satisfaction with life measure patients’ wellbeing (People., 2020).

The differences addressed in this chapter make our measure distinctive because it captures the true nature of numerous facets of living with OC as encountered by patients during the course of their disease. Moreover, these outcomes have achieved content validity, making a good evaluation of the questionnaire. Studies report that adequate content validity is important when creating a measure. A 2009 study that assessed the measuring properties of the 29 QOL tools verifies that content validity is critical and that the role of the target
population in the item development and selection is essential to achieve successful content validity because patients are experts in their very own QOL (Albers et al., 2009).

Limitations

It is estimated that more than 4000 women are living with OC in Australia and that this would equate to approximately 400 women living with OC in WA (Cancer Australia, 2019). Further, the incidence rate of OC is relatively low with only 1,510 new cases expected to be diagnosed in Australia in 2019. Based on its population size, this translates to approximately 150 new OC diagnoses per year in Western Australia. Thus, unlike other more prevalent cancer types, such as breast cancer and colorectal cancer, the studies involved in this thesis collected data using a relatively small sample size (Ong et al., 2017; Zerillo et al., 2017). The small sample may not accurately represent the population of women with OC and the results of the studies may not be generalizable. Furthermore, there could be an unveiling bias where patient experiences may contribute to higher variability. As the emphasis of this study was the importance of the participants’ diverse perspectives, demographic variables may not have been representative of the patient population.

As this study was conducted using semi-structured telephone interviews and focus groups with OC patients, the accuracy of recollecting and recalling their experiences especially at the time of diagnosis journey could be questioned. However, for most of the participants, the challenges faced since receiving a diagnosis and subsequent management of OC remain uppermost in their minds and thus the crux of their stories are unlikely to change. Verbalizing thoughts is indeed one of the tasks required in CI. Challenges were encountered in the administration of interview questions to less articulate respondents, as they were continuously urged to engage in their full capacity to take part in CI. In addition, while participants were briefed on the CTA procedure prior to the interview, the CI process itself may have impacted how participants responded to the questions. Nonetheless, the extensive literature review of OC and QOL will provide a triangulation in terms of the concepts and priority areas defined by the women.

Strengths

There are also several strengths of this thesis. The highly centralised care of OC patients in Western Australia facilitated participant recruitment, where the studies were
conducted by the guidance of a supervisory team with the previous track record which includes PROMs, qualitative, health and comprehensive outcomes researchers, and a gynaecological oncologist. clinician. The utilisation of sound qualitative approaches ensured a comprehensive exploration of the issues and provided rich and descriptive data that studies of this type should seek (Mason, 2010). The usage of CI showed certain ways of enhancing the tool through the refinement of items that will eventually allow future researchers to gather better quality data on women's OC clinical experiences and thereby improve their HRQOL. In addition, utilising a sequential approach, enabled a holistic understanding of patients’ and carers’ lived experiences and the implications relating to the research problem. Finally, the ‘ground-up’ approach of involving patients from the commencement of initial phases will ensure that priorities are clearly identified by the consumers (women with OC themselves).

**Practical Implications**

Through purposive sampling, the researcher candidate was able to capture the perspective and experience of patients across the disease continuum. Although the purpose of the study was to hear patient health outcomes and to establish a measure based on defined data, the overall vision is to enhance the overall quality of cancer care. Based on the collective data, several interventions could be designed and tested at the levels of patients, health professionals and the healthcare system.

*Chapter Four* extensively explored numerous clinical implications of our findings. One of the main issues raised was delayed diagnosis. With no specific screening tools or early detection approaches to better identify OC, patient and clinician education on OC symptom awareness should be promoted, thereby mitigating misdiagnosis. Moreover, it is of vital importance to pay attention to subgroups including those who have had a relapse and those who consider transitioning to palliative treatment with regular assessment and evaluation (Lessard et al., 2019).

At the health professional and healthcare system level, it may be helpful to scale up the early referral procedures for newly diagnosed individuals, with enhanced supervision to support women to manage their HRQOL. The healthcare system and health professionals should encourage patient advocacy techniques to improve illness self-management. Based on the richness of qualitative data obtained, patients in various phases of their disease may
obtain varying attention to clinical management. For example, recently diagnosed patients encounter problems that are distinctive from those who are undergoing treatment, those who had a recurrence, those who are considering shifting to palliative care and those who are living with OC (Bergh et al., 2011; Vogel et al., 2013). Based on our findings, newly diagnosed women should be sufficiently educated about the disease and its treatment. It should also be confirmed that women have appropriate social support and that coping methods, including having a positive attitude to the illness combined with techniques of resilience such as a determined mind and making plans to look forwards, should be practiced managing the diagnosis as the thought of dying is inevitably present in women. Empowerment and psychological strategies would be suitable for those who have had a relapse while coping strategies and daily task accomplishments can be provided to those transitioning from oncology to palliative care in order to keep a balance of their HRQOL. Those living with OC may also benefit from regular follow-up sessions. These initiatives and recommendations could lead to the high provision of quality care by focusing on clinical pathways for various patients’ groups and aid in better patient outcomes.

**Implications for future research**

The studies conducted in this thesis led to the development of an OC-specific tool through the implementation of qualitative approaches. As a continuation of the work done thus far, future studies should be undertaken to field test and evaluate its psychometric properties such as specificity, validity, reliability, and evaluation of its feasibility in clinical care and trials.

In this thesis, it was identified that there was minimal to no involvement of patients in the developmental processes of existing OC tools. Therefore, a relevant starting point for potential studies in OC could undertake research using a similar framework in the development of other cancer specific PROMs for OC and general PROMs. We also recommend studies that choose to use CI, either by spreading the administration of the questionnaire over two days or by assigning separate parts of the questionnaire to different participants.
This thesis explored and identified outcomes across the OC disease spectrum. The research candidate believes that treatment-related outcomes should be explored further. Another path for future study will then be to develop OC treatment specific PROMs to achieve a thorough understanding of OC treatments and their maintenance therapies. Likewise, MOST, which measures signs and symptoms of patients undergoing Carboplatin chemotherapy, PROMs relating to radiotherapy and immunotherapy outcomes should also be developed.

Eventually, researchers should be transparent about the chosen methodology they have taken with respect to the PROM development, taking account of such topics including the expertise, time commitment, the scope of existing information and literature.

Conclusion

The potential of PROMs to improve the care of cancer survivors is increasingly recognised because they allow accurate measurement of a range of outcomes through the patient’s lens and throughout a patient’s clinical journey. Important aspects of HRQOL and contextual factors for women with OC were identified in Phase One, such as the need for mitigation strategies to reduce diagnostic delay and enhance their HRQOL. Through Phase Two, the content validity of the items was confirmed thereby confirming the specific outcomes that contribute to accurately measuring HRQOL of women diagnosed with OC. These findings uncovered a number of far-reaching implications for the experiences of diagnosis and how women navigate the health care system whilst undergoing treatment. By involving patients with OC, this thesis newly developed an agreed specific set of outcomes that are different to existing tools both in terms of methodological design and questionnaire content using a sequential mixed methods approach to help determine what was important to patients in order to directly improve their HRQOL.

Chapter summary

While OC PROM instruments do exist, they are few in number, are beset with limitations due to lack of patient involvement during their development and may not adequately cover associated symptoms during the whole disease trajectory. This chapter
discussed and answered the research questions, and the primary and secondary research addressed the gaps identified during the comprehensive literature review.
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Appendices
Appendix 1: Ethics Approval Letter (Phase One)
1 April 2019

Associate Professor Caroline Bulsara
Institute for Health Research
The University of Notre Dame Australia
Fremantle Campus

Dear Caroline,

Reference Number: 018158F

Project title: “Patients First: Continuous Improvement in Cancer Care (CIC Cancer) project – Ovarian Focus Groups.”

Your application for an amendment to your approved research project has been reviewed by the University of Notre Dame Human Research Ethics Committee (HREC) in accordance with the National Statement on Ethical Conduct in Human Research (2007, updated 2018). I am pleased to advise that ethics approval has been granted for the proposed changes.

Other researchers identified as working on this project are:

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<thead>
<tr>
<th>Name</th>
<th>School/Centre</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharolin Boban</td>
<td>Institute for Health Research</td>
<td>PhD Student</td>
</tr>
<tr>
<td>Dr Paul Cohen</td>
<td>Institute for Health Research</td>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Ms Anne McKenzie</td>
<td>WA Health Translation Network</td>
<td>Co-Investigator</td>
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<td>Ms Briony Williams</td>
<td>WA Health Translation Network</td>
<td>Co-Investigator</td>
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<td>Ms Judith Brown</td>
<td>Ovarian Cancer WA</td>
<td>Co-Investigator</td>
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<tr>
<td>Prof Jim Codde</td>
<td>Institute for Health Research</td>
<td>Co-Investigator</td>
</tr>
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All research projects are approved subject to standard conditions of approval.

Please read the attached document for details of these conditions.

On behalf of the Human Research Ethics Committee, I wish you well with your study.

Yours sincerely,

Dr Natalie Giles
Research Ethics Officer
Research Office

Cc: A/Prof Fleur McIntyre, SRC Chair, School of Health Sciences
Appendix 2: Participant Information Sheet-Semi-structured telephone interviews
PARTICIPANT INFORMATION SHEET
Patients First: Continuous Improvement in Cancer Care (CIC Cancer) project
Ovarian Cancer

You are invited to participate in the research project described below.

What is the project about?

Although patient information is collected throughout the clinical journey when someone is diagnosed with ovarian cancer, this information is divided both before, during and after cancer diagnosis. Much of the information is not shared across cancer specialists and services and so is largely siloed, inaccessible for review and incomplete. The Continuous Improvement in Care - Cancer (CIC Cancer) program of research wants to enable health services to improve outcomes for patients through creating better information sharing mechanisms about what is important to ovarian cancer patients and their carers. There is an urgent need for linking information that helps identify gaps in care and assists in developing interventions to improve patient outcomes while minimizing long-term side-effects.

Who is undertaking the project?

This research is being conducted by Associate Professor Caroline Bulsara [Institute for Health Research, the University of Notre Dame], Professor Jim Codde [Institute for Health Research, the University of Notre Dame], Dr Paul Cohen [consultant gynecologist and obstetrician at the University of Western Australia], Ms Anne McKenzie [WA Health Translation Network Lead consumer representative], Ms Briony Williams [WA Health Translation Network consumer representative officer], Ms Judith Brown [consumer advocate with the Ovarian Cancer Australia].

What will I be asked to do?

The intended interviews are part of a wider study to engage you as a consumer who has been affected by ovarian cancer, either as a patient or a carer. You are asked to participate in an interview by telephone about your views on ways in which ovarian cancer has affected you and what you personally felt were the most important outcomes to you as a patient / carer for someone with ovarian cancer.

The interview will take about 30 – 45 minutes and will be audio-recorded using a digital recording device. The interview recording will then be transcribed and later on analysed by the researcher. If you have agreed to being contacted again, the transcript will be sent to you for agreement regarding the content of the transcript and to raise any issues or further comment regarding the transcript. This process should take no more than two weeks from the time of the interview.

Are there any risks associated with participating in this project?

We don’t anticipate any risk to you in participating in this research project. However, if you find that questions asked brings up difficult feelings, we have notified the Cancer Council of WA that they may be contacted during the project timeframe. Their confidential support and information line is 13 11 20.

What are the benefits of the research project?

As stated, the main aim of the overarching CIC Cancer study is to define a set of relevant patient reported outcomes measures (PROMs); in this instance for those who are affected by ovarian cancer. A crucial part of the development of PROMs is to seek your input as a consumer who has experienced ovarian cancer. Although you are not likely to benefit directly from this study, your self-identified key issues are central to developing a PROMS set for ovarian cancer in the future.

What if I change my mind?

Participant Information Sheet template (October 2017)
Participation in this study is completely voluntary. Even if you agree to participate, you are free to withdraw from further participation at any time without giving a reason and with no negative consequences. You are also free to ask for any information which identifies you to be withdrawn from the study.

**Will anyone else know the results of the project?**

Information gathered about you will be held in strict confidence. This confidence will only be broken if required by law; data may be subject to subpoena, freedom of information request or legal reporting obligations. The audio-recording from the interviews will be transcribed and stored on a password protected computer and the audio-recordings will be deleted. Data collected through the focus groups will be de-identified and any responses that are deemed to be potentially identifiable will be removed at the point of data analysis and will not be published as part of the results. Only the researchers conducting this study will have access to individual information. Once the study is completed, the data collected from you will be de-identified and stored securely in the School of Nursing and Midwifery locked filing cabinet at The University of Notre Dame Australia for at least a period of five years following the end of the 5-year research project (i.e. to 2027). The results of the study will be published as a journal article and conference presentation.

**Will I be able to find out the results of the project?**

Once we have analysed the information from this study we will email out the key findings summary to those participants who have elected to receive this information. You can expect to receive this feedback in one year from the start of the study.

**Who do I contact if I have questions about the project?**

If you have any questions about this project please feel free to contact Caroline Bulsara at 9433 0217 or email caroline.bulsara@nd.edu.au. We are happy to discuss with you any concerns you may have about this study.

**What if I have a concern or complaint?**

The study has been approved by the Human Research Ethics Committee at The University of Notre Dame Australia (approval number reference 018158F). If you have a concern or complaint regarding the ethical conduct of this research project and would like to speak to an independent person, please contact Notre Dame’s Research Ethics Officer at (+61 8) 9433 0943 or research@nd.edu.au. Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

**How do I sign up to participate?**

If you are happy to participate, please sign both consent forms which has been sent through with the information sheet, keep one for yourself and mail the other to me in the envelope provided / contact the researchers. Thank you for your time. This sheet is for you to keep.

Yours sincerely,

RESEARCHER NAME/S
A/Professor Caroline Bulsara
Ms Anne McKenzie
Ms Briony Williams
Ms Jude Brown
Dr Paul Cohen
Professor Jim Codde

Participant Information Sheet CIC Cancer Ovarian Focus group (November 2018)
Appendix 3: Participant Information Sheet-Focus groups
You are invited to participate in the research project described below.

**What is the project about?**

Although patient information is collected throughout the clinical journey when someone is diagnosed with ovarian cancer this information is divided both before, during and after cancer diagnosis. Much of the information is not shared across cancer specialists and services and so is largely siloed, inaccessible for review and incomplete. The Continuous Improvement in Care – Cancer (CIC Cancer) program of research wants to enable health services to improve outcomes for patients through creating better information sharing mechanisms about what is important to ovarian cancer patients and their carers. There is an urgent need for linking information that helps identify gaps in care and assists in developing interventions to improve patient outcomes while minimizing long term side-effects.

**Who is undertaking the project?**

This research is being conducted by Associate Professor Caroline Bulsara [Institute for Health Research, the University of Notre Dame], Professor Jim Codde [Institute for Health Research, the University of Notre Dame], Dr Paul Cohen [consultant gynecologist and obstetrician at the University of Western Australia], Ms Anne McKenzie [WA Health Translation Network Lead consumer representative], Ms Briony Williams [WA Health Translation Network consumer representative officer], Ms Judith Brown [consumer advocate with the Ovarian Cancer Australia].

**What will I be asked to do?**

The intended focus groups are part of a wider study to engage you as a consumer who has been affected by ovarian cancer, either as a patient or a carer. You are asked to participate in a focus group interview about your views on ways in which ovarian cancer has affected you and what you personally felt were the most important outcomes to you as a patient / carer for someone with ovarian cancer.

The focus group interview will take about 1 ½ hours (including refreshment time) and will be audio-recorded using a digital recording device. The focus group recording will then be transcribed and analysed by the researcher. If you have agreed to being contacted again, the transcript will be sent to you for agreement regarding the content of the transcript and to raise any issues or further comment regarding the transcript. This process should take no more than 1 month from the time of the focus group.

**Are there any risks associated with participating in this project?**

We don’t anticipate any risk to you in participating in this research project. However, if you find that questions asked brings up difficult feelings, we have notified the Cancer Council of WA that they may be contacted during the project timeframe. Their confidential support and information line is 13 11 20.

**What are the benefits of the research project?**

As stated, the main aim of the overarching CIC Cancer study is to define a set of relevant patient reported outcomes measures (PROMs); in this instance for those who are affected by ovarian cancer. A crucial part of the development of PROMs is to seek your input as a consumer who has experienced ovarian cancer. Although you are not likely to benefit directly from this study, your self-identified key issues are central to developing a PROMS set for ovarian cancer in the future.
What if I change my mind?

Participation in this study is completely voluntary. Even if you agree to participate, you are free to withdraw from further participation at any time without giving a reason and with no negative consequences. You are also free to ask for any information which identifies you to be withdrawn from the study.

Will anyone else know the results of the project?

Information gathered about you will be held in strict confidence. This confidence will only be broken if required by law; data may be subject to subpoena, freedom of information request or legal reporting obligations. The audio-recording from the focus groups will be transcribed and stored on a password protected computer and the audio-recordings will be deleted. Data collected through the focus groups will be de-identified and any responses that are deemed to be potentially identifiable will be removed at the point of data analysis and will not be published as part of the results. Only the researchers conducting this study will have access to individual information. Once the study is completed, the data collected from you will be de-identified and stored securely in the School of Nursing and Midwifery locked filing cabinet at The University of Notre Dame Australia for at least a period of five years following the end of the 5-year research project (i.e. to 2027). The results of the study will be published as a journal article and conference presentation.

Will I be able to find out the results of the project?

Once we have analysed the information from this study we will email out the key findings summary to those participants who have elected to receive this information. You can expect to receive this feedback in one year from the start of the study.

Who do I contact if I have questions about the project?

If you have any questions about this project please feel free to contact Caroline Bulsara at 9433 0217 or email caroline.bulsara@nd.edu.au. We are happy to discuss with you any concerns you may have about this study.

What if I have a concern or complaint?

The study has been approved by the Human Research Ethics Committee at The University of Notre Dame Australia (approval number reference 018158F). If you have a concern or complaint regarding the ethical conduct of this research project and would like to speak to an independent person, please contact Notre Dame’s Research Ethics Officer at (+61 8) 9433 0943 or research@nd.edu.au. Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

How do I sign up to participate?

If you are happy to participate, please sign both consent forms which has been sent through with the information sheet, keep one for yourself and mail the other to me in the envelope provided / contact the researchers. Thank you for your time. This sheet is for you to keep.

Yours sincerely,

Signature removed for privacy

RESEARCHER NAME/S
A/Professor Caroline Bulsara
Ms Anne McKenzie
Ms Briony Williams
Ms Jude Brown
Dr Paul Cohen
Professor Jim Codde
Appendix 4: Consent Form-Semi-structured telephone interviews
CONSENT FORM

Patients First: Continuous Improvement in Cancer Care (CIC Cancer) project
(Ovarian Cancer)

- I agree to take part in this research project.
- I have read the Information Sheet provided and been given a full explanation of the purpose of this research project and what is involved.
- I understand that I will participate in a one on one telephone interview and that the interview will be audio-recorded.
- The researcher has answered all my questions and has explained possible risks that may arise as a result of the interview and how these risks will be managed.
- I understand that I do not have to answer specific questions if do not want to and may withdraw from participating in the project at any time without prejudice.
- I understand that all information provided by me is treated as confidential and will not be released by the researcher to a third party unless required to do so by law.
- I agree that any research data gathered for the study may be published provided my name or other identifying information is not disclosed.

<table>
<thead>
<tr>
<th>Name of participant</th>
<th>Signature of participant</th>
<th>Date</th>
</tr>
</thead>
</table>

- I confirm that I have provided the Information Sheet concerning this research project to the above participant, explained what participating involves and have answered all questions asked of me.

<table>
<thead>
<tr>
<th>Signature of Researcher</th>
<th>Date</th>
</tr>
</thead>
</table>
Appendix 5: Consent Form-Focus groups
CONSENT FORM

Patients First: Continuous Improvement in Cancer Care (CIC Cancer) project (Ovarian Cancer)

• I agree to take part in this research project.
• I have read the Information Sheet provided and been given a full explanation of the purpose of this research project and what is involved.
• I understand that I will participate in a focus group and that the focus group will be audio-recorded.
• The researcher has answered all my questions and has explained possible risks that may arise as a result of the interview and how these risks will be managed.
• I understand that I do not have to answer specific questions if do not want to and may withdraw from participating in the project at any time without prejudice.
• I understand that all information provided by me is treated as confidential and will not be released by the researcher to a third party unless required to do so by law.
• I agree that any research data gathered for the study may be published provided my name or other identifying information is not disclosed.

<table>
<thead>
<tr>
<th>Name of participant</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Signature of participant</td>
<td>Date</td>
</tr>
</tbody>
</table>

• I confirm that I have provided the Information Sheet concerning this research project to the above participant, explained what participating involves and have answered all questions asked of me.

| Signature of Researcher | Date |
Appendix 6: Ethics Approval Letter (Phase Two)
25 February 2020

A/Prof Caroline Bulsara & Sharolin Boban
Institute for Health Research
The University of Notre Dame Australia
Fremantle Campus

Dear Caroline and Sharolin,

Reference Number: 2020-010F


Your response to the conditions imposed by the University of Notre Dame Human Research Ethics Committee (HREC) has been reviewed in accordance with the National Statement on Ethical Conduct in Human Research (2007, updated 2018). I am pleased to advise that ethics approval has been granted for this proposed study.

Other researchers identified as working on this project are:

<table>
<thead>
<tr>
<th>Name</th>
<th>School/Centre</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/Prof Jenny Downs</td>
<td>Telethon Kids Institute</td>
<td>Co-Supervisor</td>
</tr>
<tr>
<td>Prof Jim Codde</td>
<td>Institute for Health Research</td>
<td>Co-Supervisor</td>
</tr>
<tr>
<td>Dr Paul Cohen</td>
<td>University of Western Australia</td>
<td>Co-Supervisor</td>
</tr>
</tbody>
</table>

All research projects are approved subject to standard conditions of approval.
Please read the attached document for details of these conditions.

On behalf of the Human Research Ethics Committee, I wish you well with your study.

Yours sincerely,

Dr Natalie Giles
Research Ethics Officer
Research Office
Appendix 7: Participant Information Sheet
PARTICIPANT INFORMATION SHEET

Implementation of patient involvement in the development of a Patient-reported outcome measure for ovarian cancer.

You are invited to participate in the research project described below.

What is the project about?
We are seeking your help to develop a questionnaire which can be used by clinicians and researchers in the management and future research of ovarian cancer. We have previously talked with women with ovarian cancer to find out how ovarian cancer has affected their lives. From those interviews, we have identified items that could form a new measurement tool for women with ovarian cancer to describe what is important to them in day-to-day life. We now want to test how well the wording of the items captures real-life experiences.

Who is undertaking the project?
This research is being conducted by Sharolle Ann Boban and will form the basis for the degree Doctor of Philosophy at the University of Notre Dame Australia (UNDA). The supervision team includes Professor Caroline Bauld (Institute for Health Research, UNDA), Professor Jim Codde (Institute for Health Research, UNDA), Associate Professor Jenny Downe (Telethon Kids Institute) and Dr Paul Cohen (University of Western Australia).

What will I be asked to do?
For this research project, we are using a “Think Aloud” interviewing technique. The “Think Aloud” technique involves us asking you a range of questions and you saying whatever comes to mind by talking through your answer and how you came to it. We especially would like to hear what you mean by the answer you give and if you think any of the questions we ask are unclear or don’t make sense to you.

The interview will take about 1 hour of your time, which we will do by telephone or Skype. We will audio-record the interview using a digital recording device which will be transcribed and analysed.

If needed, we may ask you for a follow-up interview to check over the transcript of the interview and ask some further questions.

Are there any risks associated with participating in this project?
We don’t anticipate any risk to you while taking part in this research. However, if you find that any questions we ask brings up negative feelings, we can arrange for you to access support from a counselor through the Cancer Council of Western Australia (13 11 20 Information and Support Line) or through the support group coordinators at ovarian Cancer Australia (WA Branch). The support group coordinators have been working closely with the research team on this project and are aware of the project progress to date.

What are the benefits of the research project?
The “Think Aloud” interview is very helpful in “fine-tuning” the design of questionnaires. We are hoping that the questionnaire we develop will provide clinicians and researchers with the most accurate
information to the day to day issues you face having ovarian cancer and for women diagnosed with ovarian cancer in the future.

**What if I change my mind?**

Participation in this research is completely voluntary. At any stage of the interview, if you no longer have an interest in participating, you are free to withdraw without giving a reason and with no negative consequences. You are also free to ask for any information which identifies you to be withdrawn from the research.

**Will anyone else know the results of the project?**

Information gathered about you will be held in strict confidence. This confidence will only be broken if required by law. The audio-recordings from the interviews will be transcribed and stored on a password protected computer and the audio recordings will be stored in a locked cabinet. Only the researchers will have access to this information during the project.

Once the study is completed, the data collected from you de-identified and stored securely in the School of Nursing and Midwifery at UNDA for at least five years. The data may be used in future research. The results of the study will be published as a journal article, conference presentation, book chapter and thesis.

**Will I be able to find out the results of the project?**

Once we have analysed the information from this study we will email a summary of our key findings. You can expect to receive this feedback in a year’s time since the commencement of the study.

**Who do I contact if I have questions about the project?**

If you have any questions about this project, please feel free to contact Sharolin Boban at email 32009365@my.nd.edu.au. Alternatively, you can contact Assoc Prof. Caroline Bulsara at 94330217 or email caroline.bulsara@nd.edu.au. We are happy to discuss with you any concerns you may have about this study.

**What if I have a concern or complaint?**

The study has been approved by the Human Research Ethics Committee at The University of Notre Dame Australia (approval number 2020-010F). If you have a concern or complaint regarding the ethical conduct of this research project and would like to speak to an independent person, please contact Notre Dame's Research Ethics Officer at (+61 8) 9433 0943 or research@nd.edu.au. Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

**How do I sign up to participate?**

If you are happy to participate, please sign both copies of the consent form which has been sent through via e-mail along with the information sheet, keep one for yourself and either mail the other to me in the envelope provided or scan and email to me.

Thank you for your time. This sheet is for you to keep.

Yours sincerely,

Sharolin Ann Boban, Professor Caroline Bulsara, Professor Jim Codd, A/Professor Jenny Downs, Dr Paul Cohen.
Appendix 8: Consent Form
CONSENT FORM

Implementation of patient involvement in the development of a patient-reported outcome measure for ovarian cancer

- I agree to take part in this research project.
- I have read the Information Sheet provided and been given a full explanation of the purpose of this research project and what is involved.
- I understand that I will be interviewed and that the interview will be audio-recorded.
- The researcher has answered all my questions and has explained possible risks that may arise as a result of the interview and how these risks will be managed.
- I understand that I do not have to answer specific questions if do not want to and may withdraw from participating in the project at any time without prejudice.
- I understand that all information provided by me is treated as confidential and will not be released by the researcher to a third party unless required to do so by law.
- I agree that any research data gathered for the study may be published provided my name or other identifying information is not disclosed.
- I understand that research data gathered may be used for future research but my name and other identifying information will be removed.

<table>
<thead>
<tr>
<th>Name of participant</th>
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<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature of participant</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- I confirm that I have provided the Information Sheet concerning this research project to the above participant, explained what participating involves and have answered all questions asked of me.

<table>
<thead>
<tr>
<th>Signature of Researcher</th>
<th>Date</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
Appendix 9: Draft set of interview statements for Phase Two
INTRODUCTORY QUESTIONS

Demographics

Q1. What is your name? ____________________________

Q2. What is your current age (years)? ____________________________

Q3. What is your suburb/postcode? ____________________________

Q4. What is the highest level of education you have COMPLETED?

<table>
<thead>
<tr>
<th>Option</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Some primary school</td>
<td></td>
</tr>
<tr>
<td>Completed primary</td>
<td></td>
</tr>
<tr>
<td>Some high school</td>
<td></td>
</tr>
<tr>
<td>Completed high school</td>
<td></td>
</tr>
<tr>
<td>TAFE certificate</td>
<td></td>
</tr>
<tr>
<td>University undergraduate degree</td>
<td></td>
</tr>
<tr>
<td>University postgraduate degree</td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td></td>
</tr>
</tbody>
</table>

Q5. What is your MARITAL STATUS?

<table>
<thead>
<tr>
<th>Option</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Single / never married</td>
<td></td>
</tr>
<tr>
<td>Married / de facto</td>
<td></td>
</tr>
<tr>
<td>Separated / divorced</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td></td>
</tr>
</tbody>
</table>

Q6. Do you have children?  Yes   No

Q6a. If yes, please specify their gender and age

<table>
<thead>
<tr>
<th>Child</th>
<th>Gender</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other children</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Q7. Which of the following best describes your employment status at time of your diagnosis?
Q7a. Which of the following best describes your current employment status?

<table>
<thead>
<tr>
<th>Full time paid work</th>
<th>Part time paid work</th>
<th>Home duties</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Studying</th>
<th>Currently looking for work</th>
<th>Retired</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disability pension</th>
<th>Other (specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>____________________________</td>
</tr>
</tbody>
</table>

Q8. Do you have a health care card? *(please circle one)* Yes / No / Not sure
Cancer History

Q9. Were you previously diagnosed with other cancer types before Ovarian Cancer (e.g. breast, colorectal)?

(please circle one) Yes / No
If Yes, could you please specify? (Type of cancer(s) & Time when you received a diagnosis (months/years))

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Q10. Were you aware of any genetic or hereditary issues that you might have had prior to receiving Ovarian Cancer Diagnosis (e.g. BRCA gene; Breast/Colorectal/Ovarian cancer in family members, etc)?

(please circle one) Yes / No
If Yes, please provide the details.

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Q11. When did you receive your diagnosis of Ovarian Cancer (month/year)?

Q12. At what stage was the cancer when you received the diagnosis?

Q13. Have you had a cancer recurrence? If yes, have you received any treatments?
Section 1: Clinical Diagnosis

Q1.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
<th>Can’t remember</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

My ovarian cancer was diagnosed accidentally (e.g. during surgery, emergency presentation at the Emergency Department at the hospital)

Q2.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
<th>Can’t remember</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Had no obvious signs and symptoms

If the answer to Q2 is Yes, please go to Section 2, page 6.

Q3. The following questions are about the disease signs and symptoms and symptom presentation challenges you may have experienced prior to receiving a diagnosis. Please mark one answer per statement.

For each statement, please rate the overall impact of following symptoms on your well-being. Before I received my diagnosis, I.....

<table>
<thead>
<tr>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Had abdominal and bowel pain/discomfort (e.g. bloating, constipation)

Had joint pain

Had menopausal symptoms

Had pain in my vaginal area

Had the sensation of needing to go to the toilet more frequently

Experienced eye issues (eg. itchy eyes)

Felt fatigued (e.g. tiredness, lack of energy)

Gained weight

Wasn’t really aware of my symptoms as part of ovarian cancer (i.e. I thought they were due to something else, e.g. menopausal symptoms)
Q4. Please describe **other challenges** that you might be experiencing or have experienced in terms of your physical health:

<table>
<thead>
<tr>
<th></th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-</td>
<td></td>
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<td>B-</td>
<td></td>
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<tr>
<td>C-</td>
<td></td>
<td></td>
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<tr>
<td>D-</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
**Section 2: Chemotherapy**

Q1. Have you received chemotherapy in the past five years? (please circle one) Yes/No

If the answer is **No**, please go to Section 3, page 8.

Q2. How many full cycles of chemotherapy treatment have you received to date?

_______________________

Q3. When was the last cycle of chemotherapy you have completed (month/year)?

_______________________

Q4. The following questions specifically ask about the **challenges** (e.g. side effects, chemotherapy administration) you have experienced during or after receiving chemotherapy. Please mark one answer per statement.

For each statement, please rate the overall impact of following side effects on your well-being. *During my chemotherapy, I experienced*.....

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back pain (mild, moderate, severe)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bloating with Cisplatin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood clots due to collapsed veins</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bowel problems (e.g. diarrhoea, constipation, bloating)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carboplatin side effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac arrest at time of chemo administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collapsed veins</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue (tiredness, lack of sleep)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent urgency to pass urine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hair loss</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Issues receiving chemo as an out-patient (e.g. chemo at home)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Issues receiving PICC line treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint pain</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Loss of appetite</td>
<td></td>
<td></td>
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<tr>
<td>Medication related side effects (e.g PEG allergy, Phenergan)</td>
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<tr>
<td>Memory loss</td>
<td></td>
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<tr>
<td>Mouth ulcer/s</td>
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<tr>
<td>Mucositis</td>
<td></td>
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</tr>
<tr>
<td>Nausea</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Neuropathy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor balance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taste disorder with Olaparib</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tinnitus</td>
<td></td>
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</tr>
</tbody>
</table>
Q5. Please describe **other** chemotherapy related challenges you have experienced:

<table>
<thead>
<tr>
<th></th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-</td>
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<td>B-</td>
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<td>C-</td>
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<tr>
<td>D-</td>
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</tbody>
</table>
Section 3: Surgery

Q1. Have you undergone a treatment related surgery in the past five years? (please circle one) Yes/No
   If the answer is No, please go to Section 4, page.9.

Q2. How many surgeries have you received to date? _______________________

Q3. When was the last surgery you have undergone (month/year)?
   _______________________

Q4. We would like to know any concerns and/or challenges that you may have faced after undergoing surgery. Please mark one answer per statement.
   For each statement, please rate the overall impact of the following challenges on your well-being. I experienced.....

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporarily cessation of chemotherapy due to surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaesthetic issues during the surgery (e.g. fault of Anesthesiologist)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid filled stomach post-surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight loss</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sudden onset of menopause</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficulties with Stoma Bag</td>
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<tr>
<td>Inability to have children</td>
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</tbody>
</table>

Q5. Please describe other surgery related challenges you have experienced:

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-</td>
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</tbody>
</table>
Section 4: Complementary therapies

Q1. Have you received any alternative treatments? (please circle one) Yes/No

If the answer is No, please go to Section 5, page 10.

Q2. Please provide the details of any alternative cancer treatments you have received in the past five years:

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

___________________________________________________________________________
___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________
**Please complete all the following sections, from pages 10-16.**

**Section 5: Emotional Well-Being**

Now, we would like to ask you about your **well-being in terms of your feelings/emotions.** When we talk about emotional well-being we are talking about any feelings, worries or concerns that you may have had across the course of the disease. 

Please tick one answer per statement. *Since my diagnosis of ovarian cancer....*

<table>
<thead>
<tr>
<th><strong>I am frustrated by not being active or able to exercise (as I used to)</strong></th>
<th><strong>I feel powerless at not making decisions myself (e.g. both small decisions and larger decisions) about my care</strong></th>
<th><strong>I feel that I have lost my sense of who I am</strong></th>
<th><strong>I feel that there is a lack of awareness around this disease by others</strong></th>
<th><strong>I feel there is little awareness of ovarian cancer outside of my family and close friends (e.g. lack of social awareness)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I feel valued because I can still contribute to the workforce (I am in paid employment)</strong></td>
<td><strong>I find it difficult to stay strong in front of others</strong></td>
<td><strong>I find it hard to stay strong for myself</strong></td>
<td><strong>I have been embarrassed by the way my body looks (e.g. having a colostomy bag, stoma bag)</strong></td>
<td><strong>I have been unwilling to accept my diagnosis</strong></td>
</tr>
<tr>
<td><strong>I have been worried about loss of income due to my illness</strong></td>
<td><strong>I have difficulty accepting the reality of my diagnosis</strong></td>
<td><strong>I have felt less feminine because of my illness</strong></td>
<td><strong>I have felt there was a lack of treatment choices offered to me</strong></td>
<td><strong>I have felt uncertainty when looking forward because of my illness</strong></td>
</tr>
<tr>
<td><strong>I have had concerns with medications that can have severe side effects</strong></td>
<td><strong>I have had difficulty in looking forward to the future</strong></td>
<td><strong>I have had emotional issues due to sudden menopause</strong></td>
<td><strong>I have had issues with not being able to have children (due to surgery)</strong></td>
<td><strong>I have had lower self-esteem and feelings of self-worth due to my illness</strong></td>
</tr>
<tr>
<td><strong>There are some taboo topics (e.g. Euthanasia) that I have no one to talk to about</strong></td>
<td><strong>CHALLENGING EMOTIONS</strong></td>
<td><strong>I have been in shock about my diagnosis and illness</strong></td>
<td><strong>I have felt angry about my illness</strong></td>
<td><strong>I have felt frustrated about my illness</strong></td>
</tr>
<tr>
<td><strong>I have felt stressed as a parent because of my illness</strong></td>
<td><strong>I have had negative feelings and emotions (e.g. stress, anger) when participating in Ovarian Cancer support groups because of my illness</strong></td>
<td><strong>I felt frustrated during and/or after receiving a treatment (e.g. not able to take part in activities that I used to do)</strong></td>
<td><strong>I have felt sick and unwell due to the side-effects of treatments I have experienced</strong></td>
<td><strong>I have felt stressed during and/or after receiving a treatment</strong></td>
</tr>
<tr>
<td>ANXIETY</td>
<td>DEPRESSION</td>
<td>FEAR</td>
<td>ISOLATION</td>
<td>RELATIONSHIPS</td>
</tr>
<tr>
<td>---------</td>
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</tr>
<tr>
<td>I have been anxious because of my illness</td>
<td>I have been diagnosed with depression in relation to my illness</td>
<td>I have felt afraid (of illness, treatment and prognosis)</td>
<td>I felt like I was being categorised (e.g. physical appearance-hair loss) because of my illness</td>
<td>I found it difficult to understand my carer’s/partner’s feelings since my diagnosis</td>
</tr>
<tr>
<td>I have felt downhearted and sad because of my illness</td>
<td>I have felt downhearted and sad because of my illness</td>
<td>I have felt afraid of dying from my illness</td>
<td>I have felt isolated socially because of my illness</td>
<td>My family/friends are generally not supportive of me at this time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I have felt afraid that the cancer will come back again</td>
<td></td>
<td>My family/friends have reacted unexpectedly to my illness</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td>My partner and I experience a lack of intimacy since my diagnosis</td>
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</table>
**Section 6: Financial Wellbeing**

Q1. The following statements are about other *practical challenges* you may have faced during/after a particular treatment. We would like to know any financial challenges you may have faced that have impacted your well-being.

Please tick one answer per statement. *I experienced*...  

<table>
<thead>
<tr>
<th>Statement</th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial barriers due to living in a rural or remote place (e.g. travelling difficulties to receive a treatment)</td>
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<tr>
<td>Barriers to undergoing surgery due to work commitments</td>
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<tr>
<td>Difficulties with ambulance cover costs (insurance)</td>
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<tr>
<td>Difficulties with car parking whilst attending appointments at the hospital</td>
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<tr>
<td>Financial instability since my diagnosis</td>
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<tr>
<td>Lack of information regarding financial support (e.g. HBF, PBS)</td>
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<tr>
<td>Limited travel options for work or holiday (e.g. interstate, within the state) due to my treatment</td>
<td></td>
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</tr>
<tr>
<td>Out of pocket expenses due to my medical costs (e.g. surgery, insurance cover issues, PET scan test, MRI tests)</td>
<td></td>
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<tr>
<td>A need for financial support (e.g. superannuation and/or disability pension support, private health insurance)</td>
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</tbody>
</table>

Q2. Please describe *other* practical challenges (not mentioned above) that you have experienced:

<table>
<thead>
<tr>
<th>Other Challenges</th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-</td>
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</tbody>
</table>
Section 7: Health Services

The following statements focus on issues you may have faced in relation to the services provided to you once you were diagnosed with ovarian cancer. This includes any health services provided including those provided by your GP.

Please tick one answer per statement and rate the overall impact of the following challenges on your well-being.

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel there are less services provided to ovarian cancer patients compared to other higher profile cancer types (e.g. Breast, Prostate)</td>
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<tr>
<td>I have experienced poor medical decision making by the health professionals</td>
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<tr>
<td>I have had genetic testing (BRACA gene)</td>
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<tr>
<td>The health professionals I consulted about my symptoms did not consider ovarian cancer</td>
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<tr>
<td>There are inadequate support service programs (e.g. counselling)</td>
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<tr>
<td>There is a lack of financial assistance with practical support (e.g. house cleaning)</td>
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<tr>
<td>There is lack of communication between health professionals (e.g. GP and specialists)</td>
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<tr>
<td>There is lack of opportunity to participate in clinical trials for new treatments</td>
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<tr>
<td>There is lack of respite care for Ovarian Cancer patients (e.g. single parents)</td>
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</tbody>
</table>

GP

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel that my GP was biased and did not take my concerns seriously because I am a woman</td>
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<tr>
<td>I felt that my GP contributed to the delay in my diagnosis</td>
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<tr>
<td>I had to be proactive and request that my GP refer me for testing</td>
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<tr>
<td>I presented at the hospital with specific symptoms (e.g. Abdominal discomfort, Fatigue, bloating) that had not been identified by my GP</td>
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<tr>
<td>My GP is actively involved throughout my diagnosis and illness</td>
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<td></td>
<td></td>
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<tr>
<td>Overall, I feel that my GP is supportive of me and my illness</td>
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</tbody>
</table>
Section 8: Communication & Informational Challenges

Now, we would like to know of any communication challenges you may have experienced in particular with health professionals (e.g. lack of patient centered care, poor medical decision making), including whether you have had trouble getting information during active treatment.

Please tick one answer per statement and rate the impact of following challenges on your well-being. I have experienced communication challenges in....

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>An ability to meet my language needs (e.g. English not the first language)</td>
<td></td>
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<tr>
<td>Receiving accurate information about my treatment and my illness in general (e.g. hospital staff, specialists, nurses)</td>
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<tr>
<td>Accessing central and accessible ovarian cancer specific information</td>
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<tr>
<td>Shared communication &amp; information between health professionals</td>
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<tr>
<td>Shared communication &amp; information between hospital departments</td>
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<td></td>
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<tr>
<td>Shared communication &amp; information with health professionals</td>
<td></td>
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<tr>
<td>Shared communication &amp; information with the ambulance crew</td>
<td></td>
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</tr>
<tr>
<td>Health professionals’ ovarian cancer knowledge</td>
<td></td>
<td></td>
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<tr>
<td>Health system information (e.g. lack of information provided after receiving a treatment, lack of follow-up after receiving treatment)</td>
<td></td>
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<tr>
<td>Inability to ask questions of those providing treatment and services</td>
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<tr>
<td>Getting information regarding the OC Resilience Kit</td>
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<tr>
<td>Treatment information (i.e. options and side effects of each)</td>
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</tr>
<tr>
<td>Lack of willingness to listen to my concerns</td>
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</tbody>
</table>
Section 9: Seeking Help & Coping Strategies
Now, we would like to know what helped you to cope and improve your sense of wellness once you (i) were diagnosed and/or (ii) received active treatment. This includes whether or not you sought help and what your main strengths were throughout your clinical pathway. Please select one answer per statement and rate the impact of following challenges on your well-being. *I was able to cope better because .....*

| I have prior medical knowledge and training (e.g. a health professional such as a doctor or nurse) | SA | A | D | SD |
| I adjusted my diet and lifestyle activities (e.g. physical activities, yoga, reflexology) | | | | |
| I aimed to stay positive throughout | | | | |
| I benefitted from available information (medical knowledge, information provided by HPs) | | | | |
| I drew strength from my spiritual beliefs (e.g. religion, connecting with nature) | | | | |
| I managed well with the support of my family and friends | | | | |
| I relied on being treated ‘normally’ by others | | | | |
| I sought informational help (e.g. Google, research, survivor stories) | | | | |
| I took symptom relief medications (e.g. Anti-Depressants) as complementary to my treatment | | | | |
| The information I received from organisations helped me manage my illness (e.g. Psychologist referrals, Cancer Council, Support groups) | | | | |
We would like to know how **resilient you believe that are/were during your treatment.** Please mark **one answer** per statement and rate the impact of each statement on your well-being. *In regards to managing my illness.....*

<table>
<thead>
<tr>
<th>Statement</th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have had a determined mind</td>
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<tr>
<td>I benefitted from having medical knowledge (professional &amp; training)</td>
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<td></td>
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<tr>
<td>I drew strength from family and friends</td>
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<tr>
<td>I found time for myself</td>
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<tr>
<td>I gained adaptability to my illness</td>
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<tr>
<td>I had a positive attitude to the illness</td>
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<tr>
<td>I had a sense of humour</td>
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<td></td>
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<tr>
<td>I kept calm</td>
<td></td>
<td></td>
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<tr>
<td>I looked forward to the future</td>
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<tr>
<td>I maintained a positive attitude in relation to my illness</td>
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<tr>
<td>I maintained a sense of gratitude</td>
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<tr>
<td>I maintained a sense of humour</td>
<td></td>
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<tr>
<td>I made plans to look forward</td>
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<tr>
<td>I refused to give up on myself</td>
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<tr>
<td>I took relief medication as an alternative (e.g. anti-depressants)</td>
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</tbody>
</table>
Appendix 10: Ovarian cancer questionnaire & OVArian cancer health related

Quality of Life (OVAQOL) scale
1.0 Information about you

Q1. What is your name? ____________________________

Q2. What is your current age (years)? ____________________________

Q3. What is the highest level of education you have COMPLETED?

[Radio buttons for education levels]

Q4. What is your MARITAL STATUS?

[Radio buttons for marital status]

Q5. Do you have children?  Yes  No

Q5a. If yes, please specify their gender and age

<table>
<thead>
<tr>
<th>Child</th>
<th>Gender</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child 2</td>
<td></td>
<td></td>
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<td>Child 3</td>
<td></td>
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<tr>
<td>Child 4</td>
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<td>Child 5</td>
<td></td>
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<tr>
<td>Child 6</td>
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</tr>
</tbody>
</table>
Q6. Which of the following best describes your employment status when you received the diagnosis?

- Full time paid work
- Part time paid work
- Self-employed
- Home Duties
- Studying
- Currently looking for work
- Retired
- Disability pension
- Other (specify)

Q7. Which of the following best describes your current employment status?

- Full time paid work
- Part time paid work
- Self-employed
- Home Duties
- Studying
- Currently looking for work
- Retired
- Disability pension
- Other (specify)

Q7a. If retired, did you retire early because of your diagnosis? (please circle one) Yes/No

Q8. Do you currently have a health care card? (please circle one) Yes / No / Not sure

Q9. When did you receive your diagnosis of Ovarian Cancer (month/year)? ___________

Q10. Have you had a cancer recurrence (has your cancer returned or have you had a relapse of your cancer)? (please circle one) Yes/No

Q10a. If yes, what treatments have your received? _______________________

Q10b. If yes, what are your current treatments? _________________________
## 2.0 Symptom Checklist

The following questions are about the symptoms you may have experienced. Please mark one answer per statement (i.e. Severe / Moderate / Mild / None / Not applicable).

For each statement, please rate the overall impact of following symptoms.

<table>
<thead>
<tr>
<th>During the past 4 weeks, I experienced...</th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain/discomfort</td>
<td></td>
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<tr>
<td>Back pain</td>
<td></td>
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<tr>
<td>Bloating</td>
<td></td>
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<tr>
<td>Blood clots due to collapsed veins</td>
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<td></td>
</tr>
<tr>
<td>Collapsed veins</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhoea</td>
<td></td>
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<tr>
<td>Difficulties with the Stoma Bag</td>
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<tr>
<td>Fatigue (e.g. tiredness, lack of energy)</td>
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<tr>
<td>Frequent urgency to pass urine</td>
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<tr>
<td>Hair loss</td>
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<tr>
<td>Joint pain</td>
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<tr>
<td>Loss of appetite</td>
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<td>Memory loss</td>
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<td>Menopausal hot flushes/sweats</td>
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<td>Mouth ulcers</td>
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<td>Mucositis (Inflammation and ulceration of the digestive tract, e.g., the gums or throat or bowel)</td>
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<td>Nausea</td>
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<td>Neuropathy</td>
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<td>Pain</td>
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<td>Poor balance</td>
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<td>Regret about my inability to have children</td>
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<td>Taste disorder</td>
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<td>Tinnitus (Ringing or noises in your ear or head)</td>
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<tr>
<td>Weight gain</td>
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<tr>
<td>Weight loss</td>
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</table>
The following questions are about the treatments you may have received.

Q1. Have you ever received chemotherapy? (please circle one) Yes/No
   If No, please go to Q5.

Q2. How many prior courses of chemotherapy have you had? ________________

Q3. When was the last course of chemotherapy that you completed (month/year)?
   _______________________

Q4. Are you currently on maintenance chemotherapy? (e.g. Olaparib or Avastin)
   _______________________

Q5. Have you ever had surgery for Ovarian Cancer? (please circle one). Yes/No
   If yes, how many surgeries have you received? ______________________
   If No, please go to Section 3, page 5.

Q6. When did you last have surgery for your Ovarian Cancer (month/year)?
   _______________________

Health Related Quality of Life

Section 3: OVArian cancer health related Quality of Life (OVAQOL) scale

These questions ask about your physical, emotional and social wellbeing in relation to your ovarian cancer. This is called health-related quality of life.

**Physical domain**

Please tick one answer per statement.

<table>
<thead>
<tr>
<th>During the past 4 weeks...</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
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<tbody>
<tr>
<td>I am bothered by my symptoms (e.g. pain, altered appetite)</td>
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<td>I am frustrated by not being able to exercise (as I used to)</td>
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<tr>
<td>I am generally lacking energy to do what I wanted to do</td>
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<td>I am having difficulties sleeping well</td>
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<td>I have felt frustrated that I could not take part in usual activities because of my treatments.</td>
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<tr>
<td>I have felt sick and unwell as side-effects of my treatments</td>
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<tr>
<td>I have found it difficult to care for my family and/or friends because of my illness</td>
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</tbody>
</table>
### Emotional domain
Please tick one answer per statement.

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<tr>
<th>During the past 4 weeks...</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
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</thead>
<tbody>
<tr>
<td>I feel stressed for people around me that I care for</td>
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<tr>
<td>I have been depressed in relation to my illness</td>
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<td>I have been embarrassed by the way my body has changed</td>
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<tr>
<td>I have been feeling anxious</td>
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<td>I have been unwilling to accept my diagnosis</td>
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<td>I have been worried about loss of income due to my illness</td>
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<td>I have felt afraid (of my illness, treatment and/or prognosis)</td>
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<td>I have felt afraid of dying from my illness</td>
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<tr>
<td>I have felt afraid that the cancer will come back again</td>
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<td>I have felt angry about my illness</td>
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<td>I have felt downhearted and sad because of my illness</td>
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<tr>
<td>I have felt frustrated about my illness</td>
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<tr>
<td>I have felt frustrated as there is uncertainty of what is going to happen in the future</td>
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<tr>
<td>I have felt less feminine because of my illness</td>
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<tr>
<td>I have felt less self-worth due to my illness</td>
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<tr>
<td>I have felt powerless by not making decisions myself (e.g. both small decisions and larger decisions) about my care</td>
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<tr>
<td>I have felt stressed about my treatments</td>
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<tr>
<td>I have felt that I have lost my sense of who I am</td>
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<tr>
<td>I have felt valued because of the work that I can do (home, workforce)</td>
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<tr>
<td>I have found it difficult to stay strong in front of others</td>
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<tr>
<td>I have found it hard to stay strong for myself</td>
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</table>
**Social domain**

Please tick one answer per statement.

<table>
<thead>
<tr>
<th><strong>During the past 4 weeks...</strong></th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
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</thead>
<tbody>
<tr>
<td>I found it difficult to understand my carer’s/partner’s feelings since my diagnosis</td>
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<tr>
<td>I have felt that my carer/partner actually think/feel differently from how they are acting in front of me</td>
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<tr>
<td>I have found it difficult to connect socially with people because of my illness (e.g. at work, in public)</td>
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<tr>
<td>My carer/partner has been able to support my practical needs (e.g. driving to appointments)</td>
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<tr>
<td>My family has been generally supportive of me at this time</td>
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<tr>
<td>My friends have been generally supportive of me at this time</td>
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<tr>
<td>My family/friends have reacted unexpectedly (in a negative way) to my illness</td>
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<td>My partner and I have experienced a lack of intimacy since my diagnosis</td>
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<tr>
<td>My partner has needed more self-time since my diagnosis</td>
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<tr>
<td>People that I was close to have withdrawn from me since my diagnosis</td>
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</table>
### Section 4: Satisfaction with health care services

The following statements focus on your satisfaction in relation to the services provided to you in relation to ovarian cancer. This includes any health services provided including those provided by your GP.

Please tick one answer per statement and rate the overall impact of the following challenges on your well-being.

<table>
<thead>
<tr>
<th>During the past 4 weeks...</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
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<tbody>
<tr>
<td>Health professionals have not been willing to listen to my concerns</td>
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<tr>
<td>Health professionals have not shared communication &amp; information between each other (e.g. between hospital departments or with GPs)</td>
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<tr>
<td>I have experienced difficulties in accessing information and support regarding my financial needs (e.g. information in relation to the pharmaceutical benefit scheme or income support)</td>
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<tr>
<td>I have felt that health professionals were not really taking my needs into consideration</td>
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<tr>
<td>I have found it difficult to ask questions and receive answers from those who are providing treatment and services to me</td>
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<tr>
<td>I have not received accurate information about my treatment (i.e. options and side effects of each) and my illness (e.g. from hospital staff, specialists, nurses)</td>
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<tr>
<td>There has been a lack of information about the supports and service programs that I could access (e.g. counselling)</td>
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<tr>
<td>There has been a lack of information and opportunity to participate in clinical trials for new treatments</td>
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<tr>
<td>There has been a lack of practical support offered to me (e.g. house cleaning, home maintenance)</td>
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<tr>
<td><strong>GP</strong></td>
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<tr>
<td>I feel that my GP has been supportive of me and my illness</td>
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<tr>
<td>My GP has been actively involved throughout my diagnosis and illness</td>
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</table>
**Section 5: Self-Sufficiency & Resilience**

Now, we would like to know how resilient you believe that you are feeling in relation to your illness.

Please mark one answer for each statement.

<table>
<thead>
<tr>
<th>With regard to managing my illness and during the past 4 weeks.......</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
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<tr>
<td>I have adjusted my diet and lifestyle activities (e.g. physical activities, yoga, reflexology)</td>
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<td>I have benefitted from having medical knowledge (professional &amp; training)</td>
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<td>I have drawn strength by connecting with the nature</td>
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<td>I have drawn strengths from family</td>
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<td>I have drawn strengths from friends</td>
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<tr>
<td>I have drawn strengths from my spiritual beliefs (e.g. religion)</td>
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<td>I have found time for myself</td>
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<td>I have gained adaptability to my illness</td>
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<tr>
<td>I have had a positive attitude to managing my clinical journey</td>
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<td>I have had a sense of humour</td>
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<td>I have had a strong sense of determination</td>
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<td>I have kept calm</td>
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<td>I have looked forward to the future</td>
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<td>I have made plans to look forward</td>
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<tr>
<td>I have maintained a positive attitude in relation to my illness</td>
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<tr>
<td>I have maintained a sense of gratitude for what I am able to do/achieve</td>
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<tr>
<td>I have maintained a sense of gratitude to family/friends</td>
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<tr>
<td>I have maintained a sense of humour</td>
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<tr>
<td>I have managed well with the support of my family</td>
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<tr>
<td>I have managed well with the support of my friends</td>
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<td>I have refused to give up on myself</td>
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<td>I have relied on being treated ‘normally’ by others</td>
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Appendix 11: Co-author statement
Co-author Statement

To Whom It May Concern

I, Sharolin Ann Boban, contributed to the thesis titled “Implementation of patient involvement in the development of a health-related quality of life patient-reported outcome measure for ovarian cancer” with two following manuscripts submitted to Patient Related Outcome Measures:

1. “Women diagnosed with ovarian cancer: Patient and carer experiences and perspectives”

Work was submitted to Patient Related Outcome Measures on 18 July 2020 was accepted for publication on 15 December 2020.

2. “Employing cognitive interviewing to evaluate, improve and validate items for measuring the health-related quality of life of women diagnosed with ovarian cancer”

Submission of work to Patient Related Outcome Measures on 24 November 2020, whereby the first peer reviewer allocated.

Signature removed for privacy

I, as a Co-Author, endorse that this level of contribution by the candidate indicated above is accurate.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature removed for privacy</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caroline Bulsara</td>
<td></td>
<td>29/12/20</td>
</tr>
<tr>
<td>Jenny Downs</td>
<td></td>
<td>29.12.20</td>
</tr>
<tr>
<td>Jim Codde</td>
<td></td>
<td>19/01/21</td>
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<tr>
<td>Paul Andrew Cohen</td>
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<td>01.01.21</td>
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</tbody>
</table>