The Association Between Health Literacy and Patient Satisfaction with Consultation: An Observation

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Submitted in partial fulfilment of the requirements for the degree of

Doctor of Nursing

School of Nursing & Midwifery

College of Science, Health and Engineering La Trobe University Victoria, Australia Submitted 23rd November 2020

i

Keywords

Satisfaction

Health literacy

Patient centred care

Consultation

Consultation length

Women

Adult

Observational

Survey

Abstract

Background: Poor health literacy is a common barrier to effective communication in health care. People with low health literacy may have poorer health outcomes than those with higher health literacy. Previous studies have been inconsistent in reporting outcomes regarding health literacy and levels of patient satisfaction with clinical consultation.

A scoping review of the literature was undertaken in April 2018 and updated in October 2019. MEDLINE and EMBASE database searches were performed and 2,753 publications were identified after removal of duplicates. Following examination of the title, abstract or full publication a total of 14 papers were critically appraised using the Joanna Briggs Institute Critical Appraisal instrument. Three themes were identified - patient satisfaction, patient centred care and health literacy. Health literacy and satisfaction levels varied, with many authors linking lower subjective satisfaction with lower health literacy. Authors agreed that an individualised approach to health care, supported by appropriately presented information that was tailored to the health literacy needs of the individual was found to be essential for positive patient clinician exchange.

Objectives: There were three study objectives. This study aimed to determine the association between patient satisfaction and health literacy, length of clinical consultation. and subjective patient knowledge.

Design: Cross-sectional observational study.

Setting: The study was conducted in two specialist obstetric and gynaecology hospital settings. Female participants were recruited from the Departments of Urogynaecology, Physiotherapy, Well Women's and Pre-Admission Clinics at Mercy Hospital for Women and the Urogynaecology Clinic at Werribee Mercy Hospital in Melbourne, Australia. Method: Satisfaction with clinical consultation was measured immediately following consultation. Consultation length was measured in minutes. Subjective knowledge was assessed pre consultation, immediately post consultation and at one month. Health literacy was assessed before the consultation. Presenting symptoms were noted. Validated measures were used and included the Short Assessment of Patient Satisfaction (SAPS), the Rapid Estimate of Adult Literacy in Medicine – Revised (REALM - R) and the Australian Pelvic Floor Questionnaire. Subjective knowledge was estimated using Likert scales. Women's satisfaction was assessed following consultations with various clinicians including a nurse, physiotherapist or doctor.

Results: Two hundred and twenty-two participants were recruited to the study between September and December 2018. Two hundred and eight participants completed all study measures by February 2019. Data were analysed using SPSS (Version 26). Stepwise multivariate regression was used to test the association between patient satisfaction with consultation and health literacy, the association between patient satisfaction with consultation and consultation length and the association between patient satisfaction and subjective knowledge. Satisfaction scores were high for all participating clinics and for all clinicians (mean satisfaction score 24.6 / 28). There was no association found between patient satisfaction and health literacy (p = .61) and additionally, there was no association found between patient satisfaction and consultation length (p = .34). There was an association found between patient satisfaction and subjective knowledge post consultation (Measure 2, p = <.01 and Measure 3, p = <.01).

Conclusion: There was no association between health literacy and patient satisfaction with clinical consultation in this group of women. Furthermore, there was no association between length of clinical consultation and patient satisfaction. There was no association between length of consultation and patient satisfaction. Higher subjective knowledge scores were associated with higher satisfaction with consultation. Women with urge urinary incontinence were less satisfied. Contribution to knowledge: This study adds weight to the body of knowledge that suggests that patient satisfaction with consultation is not necessarily associated with health literacy or duration of consultation. A successful patient centred care approach is more likely to result in higher patient satisfaction, regardless of health literacy levels. The quality of the consultation, not the duration of the consultation is the key factor.

Table of Contents

Keyw	ords	. ii		
Abstract iii				
Table of Contents				
List of	List of Figuresx			
List of Tables xi				
List of Abbreviationsxii				
Statement of Original Authorshipxiii				
Ackno	owledgements	xiv		
Chap	ter 1: Introduction	. 1		
1.1	Introduction	. 1		
1.2	Background	. 1		
1.3	Objective			
	1.3.1 Study objectives	11		
	1.3.2 Research questions	11		
	1.3.3 Study hypotheses	12		
		1 2		
	1.3.4 Chapter summary	12		
Work	1.3.4 Chapter summary			
		15		
	x Package One – A Scoping Review	15 16		
Chap	c Package One – A Scoping Review ter 2: Scoping Review of the Literature	15 16 16		
Chap 2.1	x Package One – A Scoping Review ter 2: Scoping Review of the Literature Scoping review abstract	15 16 18		
Chap 2.1 2.2	ter 2: Scoping Review of the Literature	15 16 18 18		
Chap 2.1 2.2 2.3	A Package One – A Scoping Review ter 2: Scoping Review of the Literature Scoping review abstract Introduction Scoping Review question	15 16 18 18 18		
Chap 2.1 2.2 2.3 2.4	A Package One – A Scoping Review ter 2: Scoping Review of the Literature Scoping review abstract Introduction Scoping Review question Inclusion criteria	15 16 18 18 18 18		
Chap 2.1 2.2 2.3 2.4	A Package One – A Scoping Review ter 2: Scoping Review of the Literature Scoping review abstract Introduction Scoping Review question Inclusion criteria Methodology	15 16 18 18 18 18 18		
Chap 2.1 2.2 2.3 2.4	x Package One – A Scoping Review	15 16 18 18 18 18 19 19		
Chap 2.1 2.2 2.3 2.4 2.5	x Package One – A Scoping Review	 15 16 18 18 18 19 19 20 		
Chap 2.1 2.2 2.3 2.4 2.5	x Package One – A Scoping Review	15 16 18 18 18 18 19 19 20 20		
Chap 2.1 2.2 2.3 2.4 2.5 2.6	x Package One – A Scoping Review	15 16 18 18 18 18 19 20 20 20 24		
Chap 2.1 2.2 2.3 2.4 2.5 2.6	A Package One – A Scoping Review	 15 16 18 18 19 20 20 20 24 24 		
Chap 2.1 2.2 2.3 2.4 2.5 2.6	A Package One – A Scoping Review	 15 16 18 18 18 19 20 20 24 24 31 		

2.8	Quality Appraisal Results	37
2.9	Conclusions and Recommendations from the Scoping Review	39
2.10	Limitations of the Scoping Review	40
2.11	Summary of the Scoping Review	41
Worl	x Package Two – A Cross Sectional Survey	42
Chap	ter 3: METHODS	43
3.1	Study Design	43
3.2	Setting	43
3.3	Participants	
	3.3.1 Patients who were eligible for study inclusion3.3.2 Patients who were ineligible for study inclusion	
	3.3.3 Selection of the study participants	
	3.3.4 Research governance and ethical committee monitoring	
	3.3.5 Ethical considerations in the study	
	3.3.6 Potential data issues	59
3.4	Variables	
	3.4.1 Dependent variable – patient satisfaction with consultation.	
	3.4.2 Independent variable - Health literacy3.4.3 Assessment of presenting symptoms	
	3.4.4 Subjective knowledge and treatment estimation	
	3.4.5 Other independent variables	
3.5	Data Sources and Measurement	70
3.6	Bias	70
	3.6.1 Selection bias	70
	3.6.2 Social desirability bias	
	3.6.3 Presentation bias	71
3.7	Study Size	72
3.8	Quantitative Variables	72
3.9	Statistical Methods	72
3.10	Chapter summary	73
Chap	ter 4: RESULTS	74
4.1	Participants	74
	4.1.1 Flow of study participants	
4.2	Descriptive Data - primary analysis 4.2.1 Data checking	
4.3	Outcome Data	

4.4	Main Results	87
	4.4.1 Patient satisfaction scores	87
	4.4.2 Consultation length	87
	4.4.3 Subjective knowledge scores	88
	4.4.4 Health literacy measurement	
	4.4.5 Participant country of birth	
	4.4.6 Participant first language	
	4.4.7 Multiple regression	89
4.5	Results Summary	93
4.6	Other Analyses	93
Chap	ter 5: DISCUSSION	95
5.1	Key Results	95
5.2	Interpretation	96
	5.2.1 Patient satisfaction	96
	5.2.2 Satisfaction relating to clinician communication	
	5.2.3 Patient centred care	
	5.2.4 Patient satisfaction from an organisational perspective	
	5.2.5 Health literacy and older age	
	5.2.6 Health literacy testing processes	
	5.2.7 Measurement of health literacy	
	5.2.8 Subjective knowledge	
	5.2.9 Clinician type	
	5.2.10Do clinicians overestimate their patients' health literacy?	
	5.2.11Clinic type 5.2.12Length of consultation	
	5.2.12 Length of consultation	
	5.2.14Australian Pelvic Floor Questionnaire	
	5.2.14Australian refine rioor Questionnaire	
5.3	Study Strengths	
	5.3.1 Study design to minimise bias	
	5.3.2 Recruitment timeframe	-
	5.3.3 High completion rates in the study	
	5.3.4 Participants were representative of Melbourne women's hospitals	
	5.3.5 Study completion rates	
	5.3.6 Study measures that were used	118
5.4	Study Limitations	118
	5.4.1 Subjective knowledge estimation using a Likert score	119
	5.4.2 Making participation available to women who use interpreters	
	5.4.3 Minimum reading time of thirty minutes and consent to participate	
	5.4.4 Not all collected data were used in the analysis	121
	5.4.5 Possible limitations of the Short Assessment of Patient Satisfaction (SAPS) questionnaire	122
	questionnul e management a service a	***

5.4.6 Only one reviewer completed the scoping review of the literature	123
 5.5 Recommendations for Further Research into this Topic 5.5.1 Further study follow-up could have been undertaken 5.5.2 Clinic waiting times in relation to satisfaction scores 	124
Chapter 6: OTHER INFORMATION	127
6.1 Funding	127
Chapter 7: CONCLUSION	129
Appendices	132
Appendix 1 – Scoping Review – Publications retained for analysis	133
Appendix 2 - Scoping review - Quality appraisal	
Appendix 3 – Data log	
Appendix 4 - Data collection sheet	
Appendix 5 - Ethics approvals	
Appendix 6 - Short Assessment of Patient Satisfaction questionnaire	
Appendix 7 – Australian Pelvic Floor Questionnaire	151
Appendix 8 - Permissions	156
Appendix 9 - Country of birth	
Appendix 10 – First language	
Bibliography	164

List of Figures

Figure 1 - Literature search flow diagram	
Figure 2 - Study Flow Diagram49	
Of the 277 women who were randomly approached and invited to participate, 222 (80%) women agreed to take part and their written consent was obtained. One hundred and twenty (43%) women were attending one of the Urogynaecology Clinics, 39 (14%) the Physiotherapy Clinic, 46 (17%) the Wel Women's Clinic and 17 (6%) the Pre Admission Clinic (Figure 3 – Flow of stuc participants). Figure 3 - Flow of study participants	y

х

List of Tables

Table 1 - Women who declined participation, or were ineligible to	o participate77
Table 2 - Demographic characteristics of study participants	80
Table 3 - Clinical characteristics of study participants	
Table 4 - Simple linear regression	
Table 5 - Multiple regression	
Table 6 - Mean, Standard Deviation (SD), and Correlations for Sho Patient Satisfaction total and Predictor Variables	

List of Abbreviations

Serial Description Abbreviation 1 Short Assessment of Patient Satisfaction SAPS 2 Rapid Estimate of Adult Literacy in Medicine - Revised REALM - R 3 Excerpta Medica dataBASE EMBASE 4 Joanna Briggs Institute JBI 5 Hormone replacement therapy HRT 6 Brief Health Literacy Screen BHLS 7 Urinary Distress Inventory UDI-6 8 Incontinence Impact Questionnaire llQ-7 9 La Trobe University Human Ethics Committee UHEC Human Research and Ethics Committee HREC 10 11 Research Data Capture REDCap

Statement of Original Authorship

I declare that the attached manuscript is entirely my own work. No-one else's work has been used in this thesis without appropriate acknowledgement. Except where referenced, this thesis contains no material that has been previously published anywhere else. This thesis has not been previously submitted for the award of any degree in any other tertiary institution.

All work in this thesis was undertaken by myself, under the guidance of my supervisors Professor Susan McDonald and Professor Richard Gray. The development of the ideas for this research project were jointly conceived by myself and Professor McDonald and Professor Gray. Under the guidance of my supervisors I was responsible for all aspects of the project.

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Signature:

Date:

23rd November, 2020

Acknowledgements

I am honoured to have completed this research project on the ancestral lands of the Wurundjeri people of the Kulin nation. I acknowledge the First Australians as the traditional Custodians of this continent whose cultures are among the oldest living cultures in human history. I pay respect to the Elders of the community - past, present and emerging, and extend my recognition and respect to their descendants.

This doctoral project would not have been possible without the contribution of the women who agreed to take part, generously giving their time to the conduct of this research study. I sincerely thank them all.

I respectfully acknowledge the support and expertise of my supervisors, Professor Susan McDonald and Professor Richard Gray. I have appreciated their wise council, skill, patience, humour and ongoing encouragement.

I would like to acknowledge my colleagues at Mercy Health for their support and encouragement of my research endeavours. This work would not have been possible without their permission to study and evaluate their consultations with patients.

I would also like to acknowledge the support of everyone at the Judith Lumley Centre, School of Nursing and Midwifery, La Trobe University. This nurturing environment provided me with education, support, guidance and friendship.

This research was supported by an Australian Government Research Training Program Scholarship.

And finally, to my entire family, thank you for your support and belief in me throughout my candidature. I thank you for of your encouragement and your unending love. You have kept me going and I couldn't have done it without you.

Chapter 1: Introduction

1.1 INTRODUCTION

The US Institute of Medicine (2004) (as cited in Nielsen-Bohlman, 2004 p.20) defines health literacy as "The degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" (Nielsen-Bohlman & Institute of Medicine, 2004). Adequate health literacy ability is required to successfully navigate the modern health care system as patients are increasingly expected to be responsible for self care, and to be more involved in health care decision making processes (AIHW, 2016b; Brabers, Rademakers, Groenewegan, van Dijk, & de Jong, 2017). Improved health literacy has been linked to improved health outcomes by several authors (Adams et al., 2013; AIHW, 2016a; L. A. Ferguson & Pawlak, 2011; Shannon, 2017). The association between length of clinical consultation and patient satisfaction has not been tested in women attending for consultation with various clinicians (doctors, nurses and physiotherapists) for management of obstetric or gynaecological conditions. Furthermore, little is known about subjective knowledge and its link to satisfaction with clinical consultation. This thesis will examine the association between patient satisfaction with clinical consultation and health literacy, the association between length of consultation and satisfaction with consultation, as well as the association between subjective knowledge and patient satisfaction with consultation in women attending various clinics at two metropolitan hospitals.

1.2 BACKGROUND

Age, gender, education, ethnicity, language, socio-economic status and health literacy are all social determinants of health. Low health literacy has been linked to poor socioeconomic circumstances by several authors (L. A. Ferguson & Pawlak, 2011; Marmot & Wilkinson, 2006; Nutbeam, 2008; Wilkinson, 2002). The World Health Organisation notes that literacy has a central role in health outcomes, regardless of a country's affluence, and suggests that social determinants of health such as health literacy are mostly responsible for health inequities (*Together for Health: A Strategic Approach for the EU 2008–2013*, 2007). Health literacy is an important predictor of health outcomes (AIHW 2016, 2016; Shannon, 2017). Maintenance or improvements in health status can be influenced by levels of health literacy (Heijmans, Waverijn, Rademakers, & van der Vaart, 2015).

Low health literacy is known to be more prevalent in the elderly (those aged over 65 years), those who have low educational achievement or low income, those whose second language is English and those who suffer with chronic disease (2016; Barrow, 2012; Mullen, 2013; S. K. Smith, Nutbeam, & McCaffery, 2013). Low health literacy and poor health outcomes such as increased hospitalisations, increased medication errors, higher rates of morbidity and mortality as a result of chronic disease, lower utilisation of preventative health services and less effective health understanding and disease management have been linked by several authors (Adams et al., 2013; Anger et al., 2012; B. Ferguson, Lowman, & DeWalt, 2011; Heijmans et al., 2015; Jones et al., 2016; Mullen, 2013; S. K. Smith et al., 2013; Van den Brouke, 2014; Yim, Shumate, Barnett, & Leitman, 2018).

Organisational awareness of the health literacy strengths and limitations of service users is important, with organisations now required to respond to accommodate their patients or clients with low literacy. Health literacy responsiveness aims to provide equitable access to health care for all service users (Allott, Sofra, O'Donnell, Hearne, & Naccarella, 2018). The use of appropriate patient information and education materials, as suggested by Smith (2013), designed with a low health literacy emphasis, can improve patients' ability to more easily understand health conditions, be more aware of treatment options, understand potential benefits or harms of treatments, and more readily engage in decision making processes (S. K. Smith et al., 2013). Successful uptake by patients of health information materials can be an important element in an effective health care partnership, regardless of any health literacy limitations.

Identification of people who have low health literacy may enable alternative strategic approaches to communicating important clinical information and concepts during a consultation between patient and clinician to take place more readily. Health information and educational materials are known to be an important aspect of health literacy and aim to aid in the effective delivery of health care. Provision of high quality health information materials can positively affect health behaviour and increase patient satisfaction and decision making ability. Health information materials are available in many formats and these may include print or electronic formats. In more recent times media based materials and other information available on-line are now readily available to our patients (Sophie Hill, 2009).

What is health literacy?

According to Berkman (2011, p.2) health literacy is "is associated with health-related knowledge and comprehension, hospitalization rates, global health measures, and some chronic diseases" (Berkman et al., 2011). Health literacy includes the ability to read, understand and interpret written text (print literacy), understand measurements and numbers (numeracy) and be able to speak and understand the spoken word (oral literacy) (Chinn, 2011). Health literacy can be divided into three distinct interconnected domains according to Nutbeam (Nutbeam, 2000). Nutbeam suggests that these domains include functional literacy. Functional literacy comprises reading, writing and literacy, as well as a basic understanding of health, anatomy and physiology, and knowledge and understanding of health conditions. Nutbeam's second concept is interactive literacy (or communicative literacy) and relates to the ability to obtain information, derive meaning from the information that has been obtained, be able to communicate adequately and to be able to rationalise and apply newly obtained information to health issues. Nutbeam's final domain is

3

critical literacy, referring to analytical and social skills necessary to process information and act on health knowledge to the benefit of the individual (Nutbeam, 2000).

The acquisition of these skills may allow for greater control over social, economic and environmental determinants of health and can be linked to health care outcomes (Ishikawa & Yano, 2008; Nutbeam, 2000). This theoretical approach is supported by Suri (2016) who divides health literacy into five domains including the ability to find, appraise and understand health information and the ability to manage health and eHealth literacy. Suri further distinguishes between health care information and health lifestyle information (such as information regarding health promotion or prevention, management of chronic disease, illness or health care and treatments) and suggests that different approaches to information gathering may be used by individuals to improve health understanding (such as the internet and the utilisation of more traditional information sources such as handouts or brochures) (Suri, Majid, Chang, & Foo, 2016). This information gathering process may require the adoption of practices that includes finding or locating, validating, adequately understanding and acting upon available health information. Basic skills necessary for this process to be successful include reading, writing, listening, negotiating, assessment and critical evaluation (Lytton, 2013).

Fundamental health literacy skills are required to meaningfully interact with the health care system in diverse areas such as health information understanding, costs of health care delivery, health care treatments or health related instructions (both oral and written). According to Lytton (20130, increased involvement and community participation in health care activities may improve current health or serve to prevent or minimise future ill-health (Lytton, 2013). Ishikawa (2009) suggests that people with low levels of health literacy are less likely to seek out health information from traditional or electronic sources themselves, instead relying more on their doctor or other health professionals to provide oral information to them regarding ongoing health matters (Ishikawa & Yano, 2008). Low health literacy, with identified social determinants of health such as older age, low income, low education, chronic illness and ethnicity, is a strong predictor of poor health outcomes according to several authors (Barrow, 2012; Berkman et al., 2011; Heijmans et al., 2015; Lytton, 2013; MacLeod et al., 2017; Mullen, 2013; Roett & Wessel, 2012). Overestimation of health literacy by health professionals, or lack of knowledge of patient health literacy levels is common in health care and this overestimation by clinicians can negatively impact levels of patient satisfaction (L. A. Ferguson & Pawlak, 2011; K. Goggins, Wallston, Mion, Cawthon, & Kripalani, 2016; Macabasco-O'Connell & Fry-Bowers, 2011; Roh et al., 2016).

Many validated assessment measures can be used to objectively or subjectively measure both health literacy and patient satisfaction. They are widely available for use in health care, across all health care settings. Systematic uptake of such measures, according to Schoenfelder (2014) has been limited to date (Schoenfelder, Schaal, Klewer, & Kugler, 2014). Clinicians have a duty to take health literacy into account as low health literacy and decreased patient satisfaction have been linked (MacLeod et al., 2017; Roh et al., 2016).

What is patient satisfaction?

In 1982 Linder-Pelz rationalised that patient satisfaction or dissatisfaction was a necessary outcome of any encounter in health care (Linder-Pelz, 1982). A more recent paper by Ng (2019) has suggested that the definition of patient satisfaction has previously been poorly stated. This author suggests that satisfaction constitutes numerous elements including patient expectation, attitude and competence of the clinician, service accessibility and service efficacy. The consequent advantages of satisfied patients includes greater compliance with treatment regimes, improved health outcomes, improved clinician loyalty and increased referrals (Ng & Luk, 2019).

Can patient satisfaction be determined individually or across organisations?

An increased emphasis on individual patient satisfaction is an important issue in modern health care partnerships. Patient satisfaction can be determined from an individual's perspective and it can also be assessed from an organisational standpoint. Formalised assessment of patient satisfaction (both from the individual's perspective and of the organisation as a whole) can be used as a key quality indicator for an organisation to evaluate care from the patient's own, individual perspective. To this end, patient and clinician communication and resultant levels of satisfaction can be linked (Ellis, 1999; Walker, 2006). Patient satisfaction is an important consideration in assessment of overall quality of health care service delivery. Health care organisations can evaluate patient satisfaction subjectively in diverse areas such as patient experiences, needs, expectations and care provision. Assessable areas can include waiting times for an appointment, clinic accessibility, clinician communication, costs of care, treatment outcomes and satisfaction related to a particular clinic or clinician (Batterham, Hawkins, Collins, & Buchbinder, 2016).

Clinician communication, education skills, clinician patient relationships and staff professionalism can all be assessed from the patients' individual perspective. Patient satisfaction assessment may allow health administrators to adapt their organisations' practices to meet their patients' uniquely identified needs. Subjective satisfaction measurement can provide organisations with insight into the need for, or the application of quality improvement strategies, with a direct patient focus. Identification of people with low health literacy may enable organisations to develop and implement alternative strategic approaches to communicating important clinical information and concepts. Identification of people with low health literacy may also result in improved patient satisfaction levels. Involvement of patients, their families or their carers in the delivery of health care may be a method for hospitals to improve their quality practices in relation to patient satisfaction. Health literacy training for all medical and administrative health care staff, not just physicians, is recommended, in an effort to improve communication and patient health outcomes across organisations (Stempniak, 2014).

What are the benefits of a patient centred care approach?

A patient centred care approach seeks to improve individualised care and was first described in 1988 (as cited in Richards, 2015, pp 319-322) (Richards & Goldin, 2015). A patient centred care approach to clinical consultations has generally been shown to result in patients who are more satisfied with health care outcomes (Altin & Stock, 2016; Delaney, 2018; Gluyas, 2015). A patient centred care style promotes an equal partnership between the clinician and the patient and promotes a universal precautions approach to communication, aimed at improved communication between patient and clinician alike. The minimal use of medical jargon during the consultation process may also improve information exchange. Ferguson (2011) proposes that the responsibility for good communication in a consultation is primarily the responsibility of the clinician (L. A. Ferguson & Pawlak, 2011). A patient centred care approach aims to correct the power imbalance that was held by doctors and other health professionals in the past, and their patients. Without the use of a patient centred care approach, Tingle (2014) suggests that this power imbalance can lead to patients seeming to understand discussed issues when they do not, and may result in decreased levels of patient satisfaction, decision making ability and empowerment (Tingle, 2014).

Patient centred care strategies aim to increase holistic care by encompassing both physiological and biosocial care, and encourage acceptance of a person's individuality in personal approaches, experiences, preferences, beliefs and values. Patient centred care has been associated with increased patient satisfaction with care (Gluyas, 2015). Satisfaction and an increased level of shared decision making has been shown to improve when patients are active participants in their own health care (O'Donnell & Hunskaar, 2007). This contemporary approach may result in increased and successful shared decision making regarding health care management options, as well as increased satisfaction with the outcomes of care episodes (Delaney, 2018). A modern, egalitarian relationship between clinician and patient is one where the patient leads the discussion and the consultation integrates and acknowledges the value of both patient centred and clinician centred approaches, resulting

7

in improved communication and heightened levels of patient satisfaction (Ong, de Haes, Hoos, & Lammes, 1995).

Communication approaches used by health professionals may enhance or impede transfer of information between the patient and clinician, or the clinician and patient, depending on the approach used by clinicians during consultations. Low health literacy levels of the patient, or poor clinician communication skills, may impede the transfer of information between patient and clinician. Increased knowledge transfer between both parties may allow the patient to make better, more informed decisions regarding treatment or health management. Uptake of information by patients is vital for effective health partnerships, regardless of literacy limitations. Provision of appropriate health information to patients of all abilities is a vital element of health literacy in a patient centred care approach (S Hill & Sofra, 2017).

Is there an association between length of clinical consultation and patient satisfaction?

There have been several publications that have examined consultation duration in relation to patient satisfaction (Barratt & Thomas, 2018; Cape, 2002; Elmore et al., 2016; Lemon & Smith, 2014). There were no studies which examined various clinician types such as doctors, nurses or allied health practitioners such as physiotherapists. Most of these published studies were based in primary practice settings.

There was one author (Cape, 2002) who studied consultation length in medical consultations in general practice and concluded that if patients estimated that the consultation had taken longer they were more likely to be satisfied (Cape, 2002). Barratt (2018), examined nurse practitioner consultations and investigated the association between consultation interaction styles, consultation length and patient satisfaction. This author found that longer consultations did not necessarily result in greater levels of patient satisfaction (Barratt & Thomas, 2018). Lemon (2014) conducted a systematic review which involved consultations with doctors only and described encounters involving patients and general practitioners. This author concluded that consultation duration does not necessarily

affect satisfaction. Rather, Lemon concluded that there are other variables that may determine whether patients are satisfied with the clinical consultation (Lemon & Smith, 2014). Elmore (2016) also studied the association beiween satisfaction and length of consultation with doctors in a primary care setting and concluded that there was no association between the length of a consultation and resulting satisfaction levels of patients (Elmore et al., 2016). One author (Barber, 2016) conducted a study in a gynaecology oncology hospital setting and also concluded that time spent with the doctor was not associated with patient satisfaction levels (Barber, Bensen, Snavely, Gehrig, & Doll, 2016). Though study settings and clinicians who were evaluated varied, these authors have all concluded that quality of consultation, not consultation duration is the important factor in maximising levels of patient satisfaction.

Does health literacy deteriorate as people age?

Low health literacy has been associated with older age, with those over 65 years particularly at risk of low health literacy (Carollo, 2015; Findley, 2015; MacLeod et al., 2017; Mullen, 2013; K. H. Smith, 2014; Sripad et al., 2017). Baker (2000) asserts that reading ability may deteriorate as a person ages, due to deficits in interactions between the ability to see, concentrate, recognise, remember and process information. Older people may have an increased prevalence of cognitive impairment, chronic disease, less effective vision and hearing, and other physiological changes of aging such as decreased dexterity (Baker, Gazmararian, Sudano, & Patterson, 2000). These related conditions or limitations may influence reading and comprehension ability. People aged over 65 years may have more difficulty following treatment directions or medication instructions. To help them, or prevent them from discontinuing medication or treatments, they may need to have instructions developed that are tailored to their individual needs, their level of knowledge and their level of cognition (Mullen, 2013).

As older people are the main health care users due to the prevalence of chronic disease, these matters require acknowledgement and consideration by health care

9

organisations. According to Mullen (2013) clinicians, patients and carers must collaborate to improve health outcomes for older people (Mullen, 2013). Health care procedures and processes may need to be considered, developed and implemented to improve access and enhance communication for older people. MacLeod (2017) suggests that older people who have low health literacy may struggle to manage multiple conditions in an increasingly complex medical world, and that low health literacy is a more accurate indicator of health status than other measures such as age, education or income (MacLeod et al., 2017). According to Smith (2014) clinicians should consider the health literacy ability of their older patients, as well as their ability to successfully navigate health care on-line formats that are increasingly used in the provision of health care education (K. H. Smith, 2014). The ability of clinicians to adequately assess an older person's health literacy may be problematic due to issues such as vision or hearing loss, cognitive decline, patient lack of communication ability or patient anxiety or embarrassment regarding low health literacy (Findley, 2015).

Improvements in health literacy can lead to enhanced clinical partnerships and may result in improved patient engagement, decision making ability and satisfaction with health care processes, according to McCormack (2017). McCormack describes this improvement as positive and bidirectional, with improved health literacy providing multiple benefits for all, including patients, clinicians and the broader health care organisation. McCormack links individual health literacy with broadly based health literacy, which encompass both organisations and policy makers. This perspective includes concepts such as accessibility of health education materials, methods used to communicate with people with low health literacy, and ways in which health care organisations embrace their patients who have varied literacy attainment and abilities (McCormack, Thomas, Lewis, & Rudd, 2017).

In a study based at three hospital sites, Hayran (2018) found that organisations who had higher levels of organisational health literacy were associated with higher levels of patient satisfaction (Hayran & Ozer, 2018). Barrow (2012, p.21) also states that "effective patient-provider interactions are fundamental to achieving successful clinical outcomes" (Barrow, 2012). This author, along with Aboumatar (2013) and Glick (2019), have suggested that clinicians need to consider taking universal health literacy precautions (by providing more simplified written and verbal information) in relation to health literacy so that communication is as effective as possible (Aboumatar, Carson, Beach, Roter, & Cooper, 2013; Glick, Brach, Hsiang, & Dreyer, 2019). People who have the health literacy capacity can then build on the basic, simple, clear health literacy information which has been provided, allowing them to become more knowledgeable regarding their condition or treatment if they choose or are able to. People with low health literacy may find that the appropriate, simple, basic information provided by the clinician gives them enough of the information that they require to confidently make decisions regarding their treatment or care. Improved functional health literacy can allow patients to more effectively engage with health care systems and improve health care outcomes (Lytton, 2013; Nouri & Rudd, 2015).

1.3 OBJECTIVE

1.3.1 Study objectives

The aim of this research project was to test the association between health literacy and patient satisfaction with clinician consultations in women. The association between patient satisfaction with clinical consultation and consultation length was also assessed. Subjective patient knowledge about the woman's consition or treatment, in relation to satisfaction with consultation was also assessed.

1.3.2 Research questions

1. What is the association between patient satisfaction with clinical consultation and health literacy?

2. What is the association between patient satisfaction with clinical consultation and length of consultation?

3. What is the association between patient satisfaction with clinical consultation and subjective knowledge?

1.3.3 Study hypotheses

Study hypothesis 1: Women with low health literacy (defined as a score of 6 / 8 or less on Rapid Estimate of Adult Literacy in Medicine - Revised (REALM – R) literacy testing) are less satisfied with clinician consultations than those with average or above health literacy scores (defined as a score of 7 / 8 or more on REALM - R literacy testing).

Study hypothesis 2: Women who have a short consultation time of 15 minutes or less are less satisfied than women who have a longer consultation time of 16 minutes or more.

Study hypothesis 3: Women who have higher levels of subjective knowledge of their condition or treatment are more satisfied with the clinical consultation than women who have lower levels of subjective knowledge of their condition or treatment.

1.3.4 Chapter summary

Health literacy is an important social determinant of health and people with low health literacy are known to have poorer health outcomes than those with higher levels of health literacy. Adequate health literacy may be advantageous when trying to successfully navigate a complex health care system, as patients are increasingly expected to be responsible for self care, and to be more involved in collaborative health care decision making processes. Previous publications have shown mixed results regarding the association between differing levels of health literacy and satisfaction with consultation, with a patient centred care approach being shown to improve levels of patient satisfaction with consultation. Estimates of satisfaction can be measured individually or across organisations and are an important quality measure in the provision of health care service delivery.

This research project is presented as a program of work in two parts:

Work package 1 – Scoping review of the literature.

Work package 2 – A cross sectional survey.

Chapter 2: Scoping Review of the Literature

2.1 SCOPING REVIEW ABSTRACT

Objective: To identify and synthesise publications examining the association between patient satisfaction with clinical consultation and health literacy, to test the association between patient satisfaction and consultation duration, and further, to test the association between patient satisfaction and subjective knowledge.

Method: A systematic approach was used in this scoping review and included the proposal of a research question, database searches to identify published papers, the identification of studies that met the search criteria, the quality appraisal and analysis of selected studies, and the description of summarised results.

Databases searched included Excerpta Medica dataBASE (EMBASE) and MEDLINE. Papers that were experimental or observational in nature, and published in English, were included in the scoping review. Explicit mention of education level or any measure of satisfaction with clinical patient exchange was included. The sample related to any clinician, and subjects were 18 years or older. No date limits were set.

Results: Database searches took place in April 2018 and were updated in October 2019. Combined database searches identified 3,592 publications. Duplicate publications were deleted and 2,753 papers remained and were screened. Fourteen papers were identified and included in the scoping review. Four distinct themes were identified - patient satisfaction, patient centred care, health literacy and consultation duration. Health literacy and associated satisfaction levels varied. High satisfaction levels were reported by many study participants. Authors agreed that an individualised approach to health care, supported by appropriately presented information that was tailored to the health literacy needs of the individual, was found to be essential for positive patient clinician exchange.

Conclusion: Quality appraisal of selected papers revealed a broad range of results. There was no consistency of results in regard to health literacy and satisfaction with clinical consultation. Studies did not consistently report an association between increased satisfaction and higher levels of health literacy. An individualised and patient centred care approach to health service delivery was associated with higher patient satisfaction levels.

2.2 INTRODUCTION

A scoping review was chosen for the review and a literature search was initially conducted in April 2018. A further search was conducted in October 2019 to identify and update the existing results, aimed at locating any new research that had been published since the initial searches were conducted. Results of the two searches have been combined.

Reporting of the findings of this scoping review have followed the checklist described in the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA guidelines) (Mohler et al., 2015).

2.3 SCOPING REVIEW QUESTION

What is the association between health literacy level and patient response to clinical consultation?

2.4 INCLUSION CRITERIA

Sample characteristics:

- Adults aged 18 years or older
- Attending any clinician

Study characteristics:

- Explicit mention of health literacy level
- Any measure of satisfaction with clinical consultation
- Experimental or observational (survey, cohort or case control) design
- In English

2.5 METHODOLOGY

A scoping review was undertaken and aimed to locate and examine any publications which met the search criteria. According to Arksey (2005, p.1047), a scoping study, in

comparison to a systematic literature review, "tends to address broader topics where many different study designs might be applicable" (Arksey & O'Malley, 2005). Scoping reviews, according to Cooper (2019), aim to assemble research from a wide variety of research sources (Cooper et al., 2019). To identify key components of the search question, the mnemonic SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) as developed by Cooke (2012) was used (Cooke, Smith, & Booth, 2012).

- S Clinician and patient consultation
- PI Relationship between satisfaction and health literacy
- D Systematic review of the literature
- E Meta-synthetic
- R Quantitative methodology

2.5.1 Data sources

Excerpta Medica dataBASE (EMBASE) and MEDLINE databases were searched for eligible literature. I considered that these two databases would contain adequate depth of content of published literature. The search strategy was adapted for each of the two databases that were searched.

2.5.2 Search strategy

Keywords were conjoined with relevant subject headings in a highly sensitive syntax. The following search strategy was used (key words are italicised, and Boolean operators are capitalised) -

1. 'health literacy' OR 'low health literacy' OR 'literacy test' OR communication OR 'communication method' OR 'education status' OR knowledge OR 'patient knowledge' OR 'health knowledge' OR understanding OR 'disease understanding' OR 'health information' OR 'health education' OR 'patient education' OR comprehension OR 'self-management' OR 'selfcare' 2. satisfaction OR happiness OR approval OR 'patient satisfaction' OR 'patient happiness' OR contentment OR 'patient appreciation' OR 'patient clinician satisfaction' OR 'patient contentment' OR 'patient clinician relationship' OR 'patient acceptance of health care' OR displeasure OR dissatisfaction OR discontent OR unhappiness OR frustration OR 'patient centred care'

3. 'nurs* consultation' OR consult* OR 'professional relations' OR consultation OR 'medical interviews' OR interview* OR 'chemotherapy nursing' OR clinician OR nurs* OR physiotherapist OR 'physical therapist' OR 'women's health physiotherapist' OR doctor OR appointment OR 'professional patient relation*' OR medic* OR doctor* OR clinician* OR 'consultation time' OR 'waiting time' OR appointment

2.6 RESULTS

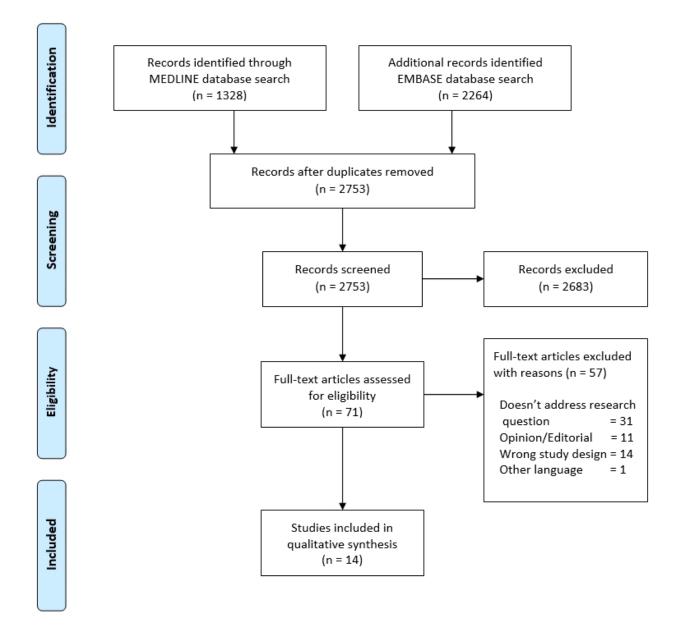
2.6.1 Study selection

The flow of results of the scoping review searches are shown (Figure 1 - Literature search flow diagram). Searches were conducted using MEDLINE and EMBASE research databases. An EndNote database was used to list the details of the 2,753 identified research papers (author, title, year of publication). No date limits were set. Results were initially screened by title or abstract and papers were rejected if the topic was shown to be inappropriate. Seventy-one of the 2,753 papers were initially set aside for further examination and scrutiny. Further investigation involved reading of each of the papers' title and abstract to assess the relevance of each paper in relation to the stated literature search criteria. Potentially useful studies were identified and set aside for further examination of the full text publication. Following examination, fourteen papers were selected and included in the scoping review.

In regard to conflict of interest, six authors reported no conflict of interest in the conduct of their research studies (Altin & Stock, 2016; Arora et al., 2010; Barber et al., 2016;

Hallock, Rios, & Handa, 2017; Hendriksen, Van Delft, Bremer, & Mertens, 2011; Radu, Radu, Condurache, & Lorin Purcarea, 2018). Five authors declared that their studies were funded by a variety of agencies (Anger et al., 2012; Beattie, Dowda, Turner, Michener, & Nelson, 2005; Bungard, Barry, Jones, & Brocklebank, 2013; Kandelaki, Marrone, Lundborg, Schmidt, & Bjorkman, 2016; Mallinger, Griggs, & Shields, 2005). Three authors made no reference at all to any conflict of interest issues (Cape, 2002; Kenton, Pham, Mueller, & Brubaker, 2007; Torres & Marks, 2009). One study (Beattie, 2005) declared that the research was funded by an agency called MedRisk and was given further study approval by the MedRisk Inc. Institutional Review Board (Beattie et al., 2005). Mallinger (2005) mentioned that the study was supported by an agency, though no detail of the type of support was provided. Another publication by Hendriksen (2011) made an acknowledgment regarding a researcher and recognised her contribution related to data sampling (Hendriksen et al., 2011). No other authors made any acknowledgements regarding conflict of interest.

Figure 1 - Literature search flow diagram



Quality appraisal

All publications considered for the scoping review were evaluated using the quality appraisal instrument from the Joanna Briggs Institute (JBI) (The Joanna Briggs Institute, 2017). All papers that were identified as meeting the search criteria were included in the appraisal, regardless of the quality of each of the publications. Use of the JBI critical appraisal instrument provided further, detailed insight into each publication, allowing for an examination and consideration of the contents of each of the selected papers. Furthermore, the Critical Appraisal Skills Program Cohort Study Checklist was also used to consider the quality and content of the selected papers (2018).

Fourteen publications were included in the scoping review, following the quality appraisal process. Ten of the papers were cross-sectional studies, one was a prospective postal survey and three were observational studies. Ten of the studies were performed in hospital clinics (urogynaecology/urology (1), physical therapy (1), pelvic surgery clinic (2), gynaecology/oncology (4), obstetrics/gynaecology (1) and a menopause clinic (1)). Two of the publications were national surveys and one was a postal survey. One study was conducted in a general practice setting. Seven of the studies were conducted in the United States of America, and one publication each was conducted in Germany, Netherlands, Australia, Canada, England, Romania and Sweden.

Following a comprehensive search using the strategies described, identified publications were assembled and organised, in an effort to present what is known about the topic of patient satisfaction, health literacy, length of consultation and clinician consultation. Papers were organised according to the recognised main topic. Identified topics were considered and relationships between topics or concepts described, in order to demonstrate a thorough understanding of the existing published literature. When the literature was scrutinised, four emerging topics became apparent and are further discussed –

- Satisfaction
- Patient centred care

- Health literacy
- Length of consultation

The four distinct themes were identified as analytical themes rather than search topics. The four identified themes became apparent after the quality appraisal process and the detailed analysis of the selected papers.

2.7 DISCUSSION

2.7.1 Satisfaction

The scoping review question was - What is the association between health literacy level and patient response to clinical consultation?

The aim of this scoping review was to identify and appraise published literature that addressed the review question. Most authors failed to provide a definition of either satisfaction or patient satisfaction. Only one author (Beattie, 2005, p1047) described patient satisfaction with care as "...a construct reflecting the overall experience of an individual receiving examination and treatment in a given environment during a specific time period" (Beattie et al., 2005). Publications examined in the scoping review were based in various care settings, including community health, general practice, hospital inpatient and hospital outpatient units.

How did the study authors measure satisfaction?

Methods used to assess patient satisfaction levels varied. Formal satisfaction measures were used across a number of areas (primary, secondary and tertiary care settings) to subjectively indicate a patient's overall rating of a treatment, treatment outcome, treatment facility or the provision of particular health care service. In selected publications, areas of service provision, where patients were asked to record their satisfaction, were diverse. Study participants were asked to assess areas that included delivery of care by the clinician, interpersonal manner of the clinician, overall medical care, disease specific aspects of care, whether a patient was listened to, whether a clinician explained issues in a way that was understandable, satisfaction with time spent with clinicians, satisfaction with information provision, satisfaction with costs of care or treatment and courtesy and respect by clinicians and other professional health care staff.

Communication was a further area of measurement and included personal communication and information conveyance, and interpretation of outcomes regarding an individual's expectations. Non-clinical elements subjectively assessed by authors included satisfaction with financial aspects of care, clinic accessibility, ease of access to the health care facility itself, length of consultation and logistics of hospital care including admission processes and waiting procedures.

Which satisfaction measures were used in the 14 identified papers?

Authors used a variety of validated and non-validated measures to record their patients' satisfaction levels. Eleven of the authors used a variety of validated questionnaires. Bungard (2013) and Radu (2018) used non-validated measures to assess satisfaction (Bungard et al., 2013; Radu et al., 2018). Though Cape (2002) described a 50 question measure of satisfaction that was used, this author did not state which questionnaire was used, or provide any description of its content (Cape, 2002).

Authors selected a satisfaction measure that was either condition specific or generalised in nature. The satisfaction assessment measures used in the studies were usually aligned with the clinical nature of the patients involved in the selected studies. For instance, authors that were involved in a urology or urogynaecology setting employed measures relevant to that specific specialty, such as the Pelvic Floor Distress Inventory (PFDI-20) (Anger et al., 2012), or the Urinary Distress Inventory (UDI-6) (Kenton et al., 2007). Other condition specific measures included the Satisfaction with Decision Scale – Pelvic Floor Disorder (SDS-PFD) and the Informed Consent Questionnaire (ICQ-20). This adapted questionnaire combined 15 yes/no questions and five free text questions. A pre operative study performed by Hallock (2017) was conducted in person, on-line or by telephone. This study used a validated measure of decisional satisfaction, but used a non-validated measure of knowledge, though the measure used was based on a previously validated questionnaire (Hallock et al., 2017).

In a Romanian study, Radu (2018) used a series of selef developed, five-point Likert scales as the sole method of assessing satisfaction in an obstetrics/gynecology clinic, though many adequate satisfaction questionnaires are available to assess satisfaction in this distinct patient group (Radu et al., 2018). Though the paper was published in an English language journal, this paper's figures were presented and labelled in a language other than English, making it difficult to assess or comprehend the results displayed in the graphs. Radu (2018) also provided no details on the methods used for patient selection, or detailed any recruitment strategies used in the study, only reporting that questionnaires had been completed by 150 clinic attendees.

A questionnaire specific to oncology inpatient treatment or care was used by Arora (2009). Arora used a validated questionnaire (The European Organisation for Research and Treatment (EROTC) (IN-PATSAT-32). Unlike other authors who used the originally designed questionnaire, Arora's group supplemented this validated questionnaire with a further 16 additional questions covering aspects of service provision and patient care. This paper based these additional questions on feedback received from patients, although which patients provided this information and their connection to the study were not described, reported or detailed. Analysis of the results of this study were performed with and also without these additional study questions (Arora et al., 2010).

A study by Bungard (2013) was conducted involving patients undergoing outpatient anticoagulant therapy. The study used a survey measure designed specifically for patients receiving anticoagulant therapy but confusingly it had not been validated in this population group. Bungard compared study results with other publications and reported favourable results. These comparisons seem questionable as no common, previously validated measure was used in this study (Bungard et al., 2013).

In a breast cancer treatment setting Mallinger (2005) examined satisfaction with information provided to a group of breast cancer patients and employed two distinct satisfaction measures. The first was patient focused and comprised of a hybrid questionnaire developed after focus groups identified areas of patient information need. This questionnaire did not appear to have been validated, although some later, non-specific review of the new questionnaire was undertaken by a group of patients. The second measure used by Mallinger was clinician focused and had previously been validated. This questionnaire used a four question subscale of the Primary Care Assessment Survey (PCAS) to assess physician knowledge of the patient following consultation. Study participants were surveyed on their perceptions of the physicians' knowledge of their personal, medical and social details. Mental health was also assessed using five questions of the mental health component subscale of the Medical Outcomes Study (MOS) of the SF-36 questionnaire. This questionnaire had been previously validated (Mallinger et al., 2005). Patient recruitment techniques in Mallinger's study involved clinicians themselves inviting potential participants to take part, after deciding which patients seemed interested in participation. No systematic selection process was described in the study's methods section. Therefore, there was a moderate risk of selection bias in this study, as no formal system was in place in regard to patient selection and recruitment (Mallinger et al., 2005).

General (as opposed to condition specific) satisfaction questionnaires were used by some authors. Two authors used general patient satisfaction questionnaires such as the Patient Satisfaction Questionnaire (PSQ) (Barber et al., 2016) or the MedRisk Instrument for Measuring Satisfaction (MRPS) (Beattie et al., 2005). These validated measures can be used, and are applicable to any clinical setting. Specific satisfaction measures that were used in the studies were not always detailed by the study authors. For example, Bungard (2013) stated that a 25 question measure was employed in an anticoagulant clinical setting but did not specify which specific measure it was (Bungard et al., 2013). Cape (2002) also stated that a 50 questionnaire measure of satisfaction had been used but provided no detail of the measure that was employed (Cape, 2002).

When were satisfaction levels measured?

Satisfaction levels were measured after a consultation or treatment episode in 11 of the 14 studies scrutinised. Two studies surveyed study participants prior to scheduled surgery. Most researchers sought satisfaction estimates after completion of a clinical appointment or a treatment episode (Barber et al., 2016; Beattie et al., 2005; Bungard et al., 2013; Hendriksen et al., 2011; Kandelaki et al., 2016; Mallinger et al., 2005). Inpatient satisfaction assessments were generally completed at the time of a patient's discharge. One study was conducted while patients were in hospital receiving treatment (Arora et al., 2010). Two studies which examined surgical consent and patient preparedness for surgery were conducted in the pre operative period (Hallock et al., 2017; Kenton et al., 2007). Radu (2018) failed to describe when any of the satisfaction assessments were undertaken (Radu et al., 2018).

How was knowledge about and satisfaction with consultation measured?

Most authors used Likert scales to measure each patient's level of subjective knowledge. There were many methods reported which were used to assess subjective knowledge. None of the authors appeared to use Likert scales that were validated for the specific conditions being surveyed.

Study authors frequently employed Likert scales to record subjective measures of patient satisfaction. Responses were generally listed as a range and respondents were asked to choose the response which best suited the question asked. Likert scales were most often presented as a five point scale. Five point scales included highly dissatisfied, dissatisfied, neutral, satisfied and highly satisfied. Another five point range gave participants a choice of responses which included poor, fair, good, very good or excellent. Another used total disagreement, disagreement, neither disagreement nor agreement, I agree and I fully agree. Some additional Likert scales used responses which ranged from three to 10 measures. Some four point scales were presented with responses such as poor, fair, good or very good, and another used responses always to never. Alternative four point responses were listed as strongly agree, agree, uncertain or disagree. In Hallock's study (2017) a six point scale was utilised but this author did not provide detail of the individual responses available to the research participants to choose from (Hallock et al., 2017).

Another author (Hendriksen, 2011) assessed aspects of care including information provision, communication, admission procedures, aftercare and patient autonomy. This paper used a Likert scale which included 10 responses which ranged from very poor to excellent, though each available individual response was not specified or discussed in the methods or results sections of this paper. This author did not identify the specific study measure that was used and admitted that the use of a written questionnaire, available only in Dutch may have shown presentation bias as it excluded those whose language was other than Dutch, or those with low health literacy (Hendriksen et al., 2011). A satisfaction questionnaire with 50 questions was used by Cape (2002) but the name of the questionnaire was not stated in the publication (Cape, 2002).

Generally domains in the questionnaires that the authors used included aspects of care such as interpersonal and communication skills, respect, information provision and clinic accessibility (Arora et al., 2010; Barber et al., 2016; Beattie et al., 2005; Bungard et al., 2013; Hallock et al., 2017; Kandelaki et al., 2016; Kenton et al., 2007). Two measures were used by Mallinger (2005) to assess satisfaction, with both questionnaires using a six point Likert scale. Kenton's paper (2007) surveyed patients regarding preparedness for urogynaecology surgery. This paper's results section lacked sufficient detail, with the reporting of the statistical analysis seeming abbreviated (Kenton et al., 2007).

Another method used to estimate patient satisfaction levels was the use of open ended, free text questions. When open ended questions were used by the researchers, the text was later analysed for content. This method was used to identify themes relating to questions asked about aspects of clinical service delivery, often as an adjunct to a more formal, objective research measure. One author used open ended questions to measure satisfaction (Hallock et al., 2017). Hallock (2017) incorporated open ended questions in her study on satisfaction with informed consent for surgery. No detail or information was provided by Hallock in the methods or results section of this paper regarding the specific questions asked or the analysis of the five free text questions which the participants had been asked to complete.

Two studies in the scoping review reported on the association between satisfaction and the duration of the clinical consultation. In a gynaecology/oncology clinic Barber (2016) referred to time spent with the doctor and reported no association between time spent with the doctor and resulting satisfaction levels (Barber et al., 2016). This publication was part of a larger prospective study. In a general practice based setting Cape (2002) also examined length of consultation and patient satisfaction. This author determined that patient satisfaction was greater when patients estimated that the length of the clinical consultation was longer, even when this was not the case (Cape, 2002).

Was there an association shown between satisfaction and health literacy?

Several authors did discuss patient satisfaction and its relationship to a person's health literacy, though satisfaction was not usually the main identified theme in these publications. Altin's (2016) paper combined topics including shared decision making and patient satisfaction in relation to health literacy (Altin & Stock, 2016). Anger (2012) discussed satisfaction and health literacy and found that higher health literacy did not necessarily relate to better disease understanding and may lead to increased levels of dissatisfaction due to increased patient expectations in those with higher levels of health literacy (Anger et al., 2012). Disease understanding and patient treatment in regard to hormone replacement therapy (HRT), and its relationship to health literacy was discussed by Torres (2009). Torres (2009) reported a positive relationship between higher health literacy and existing knowledge of hormone replacement therapy, finding that those women who had higher levels of health literacy also had increased knowledge and understanding of HRT. This paper defined the conceptual model that was the basis of the research and provided a broad definition of and fundamental elements pertaining to shared decision making. Study materials were presented in English and Spanish, allowing participants speaking these languages to be included in the research study (Torres & Marks, 2009).

In a study examining pre operative satisfaction with a previous consultation regarding informed consent, Hallock (2017) discussed shared decision making and satisfaction in relation to pre operative surgical consent. Hallock found that higher levels of patient satisfaction were associated with increased knowledge levels regarding details of the proposed surgical intervention. This study's results showed that patients who had higher levels of knowledge of informed consent (including issues pertaining to the aims, risks and benefits of the upcoming surgery) also had higher levels of satisfaction (Hallock et al., 2017).

In a Romanian study, Radu (2018) asked participants to assess the gynaecology services provided, as well as the participants' response to the consulting clinician. Curiously, this author asked the study's participants to assess whether the organisation was a good employer and also asked about the organisation's financial viability (Radu et al., 2018). These two questions seem to be peculiar when the aim of the study was to assess satisfaction based on demographic details of the study participants (Radu et al., 2018). This publication was poorly written and lacked background with only five references used in the paper (all in the introduction section). Results of this study were also poorly presented and there was no discussion of the study's findings. Though this paper was published in an English language journal the table descriptions were not presented in English. This paper was published in an established peer reviewed journal.

2.7.2 Patient centred care

Patient centred care was identified by authors as an important element in a successful clinical consultation. The World Health Organisation states that a person centred care approach is not disease focused but rather emphasises the health needs of all people, including individuals, families, the community and the broader society (World Health Organization, 2020). Similar terms used to describe this concept include patient centred medicine, person centred medicine or client centred counselling, but all encourage an

holistic approach to care, focusing on the whole, individual's person's preferences, values or needs (Kandelaki et al., 2016; Mallinger et al., 2005).

Three authors identified in the scoping review specifically discussed patient centred care or communication (Altin & Stock, 2016; Kandelaki et al., 2016; Mallinger et al., 2005). Patient centred care or communication was described by Mallinger (2005). This author separated the concept of patient centred care from physician centred or disease orientated communication and reports that this type of approach recognises the patient as a whole person, both physiological and social, and involves the individual patient in each consultation. According to Mallinger (2005), patient centred care is associated with improved patient satisfaction and health outcomes (Mallinger et al., 2005).

Patient centred care was linked to satisfaction by Kandelaki (2015) and this author also provided a definition of the concept. Like Mallinger (2005), this author contrasted patient centred care with disease centred medicine where holistic and individualised care, with the whole person as the focus, was the norm. Kandelaki (2016), in a large study with 232,518 participants, used a postal survey to assess randomised patients in primary, emergency, inpatient and outpatient health care settings. This study allowed for participants who spoke Swedish as well as several other languages and it was completed either by post or on-line. Kandelaki found that a positive measure of satisfaction was generally associated with increased patient centredness (Kandelaki et al., 2016). Kandelaki (2016), Altin (2016) and Mallinger (2005) all agree that improved patient outcomes are the aim of a patient centred care approach.

One paper combined health literacy, patient centred care, patient satisfaction, health service delivery and shared decision making. Altin (2016) examined the association between these four distinct issues. A definition of patient centred care was provided and like Mallinger and Kandelaki, this author stressed the importance of individualised and personalised patient care. Altin suggested that organisations should change from disease centred care to close physician patient relationships, respecting individual values and preferences. Results of this study showed that higher health literacy and a greater emphasis on patient centred care was generally related to greater patient satisfaction with the treatment or care that participants had received (Altin & Stock, 2016).

According to Altin & Stock (2016), patient centred care can be improved by the use of plain, simple language (including any interpreter assisted communication) during all consultations, which can result in improved two way communication between both clinician and patient, resulting in greater levels of patient satisfaction. Altin & Stock (2016) found that the use of a patient centred care approach and the encouragement of a shared decision making style of communication improved patient satisfaction, in this case in a primary care setting. Altin & Stock (2016) suggested that by adopting a patient centred care approach the whole person (physiological as well as social) would become the focus of the clinical encounter, not merely the condition or disease with which the patient had presented. This style of consultation allows patients to obtain information that is important to them, received in an individually appropriate and suitable manner, allowing for increased and improved communication (Altin & Stock, 2016).

Three authors who focused on patient centred care agreed that an individualised approach to patient treatment or care is required, and these three studies all aimed to involve the patient in decision making regarding their care or treatment (Altin & Stock, 2016; Kandelaki et al., 2016; Mallinger et al., 2005). Altin & Stock (2016), Kandelaki (2016) and Mallinger (2005) all agreed that a patient centred care approach aimed at improving two way communication between clinician and patient should be individualised and based according to each patient's capabilities, needs, beliefs, preferences and wishes. An individualised approach to any consultation employing patient centred care principles enables patients to put forward their own ideas and opinions in an equal and respectful partnership with clinicians.

2.7.3 Health literacy

Health literacy was the main theme identified in three studies in this scoping review (Altin & Stock, 2016; Anger et al., 2012; Torres & Marks, 2009). A health literacy definition was provided by two authors (Anger et al., 2012; Torres & Marks, 2009). Altin & Stock (2016) failed to provide a definition of health literacy. Altin & Stock (2016), Anger (2012) and Torres & Marks (2009) have all agreed that low health literacy and patient health outcomes can be linked. They established that communication, health system navigation, management of disease and decision making processes could all be influenced by health literacy levels. These three authors agreed that low health literacy could have a detrimental effect on health outcomes, and that health communication could be more challenging for any person with low levels of health literacy. Altin & Stock (2016), Anger (2012) and Torres & Marks (2009) agreed that participation in health care decision making could also be problematic if health literacy is low, when a patient centred care style of consultation is not actively employed by clinicians (Altin & Stock, 2016; Anger et al., 2012; Torres & Marks, 2009).

A pilot study by Anger (2012) in a urology/urogynaecology context, failed to use a formalised patient selection process, with physicians identifying potential participants from clinics, based solely on their symptom status (Anger et al., 2012). This method of participant selection could introduce selection bias to Anger's pilot study, because the study researchers may have selected patients for inclusion in the study without using an apparent predetermined patient selection method. Demographic details showed that study participants were highly educated and were mostly of white race. This may also demonstrate that selection bias may have occurred if a predetermined selection method has not been implemented. Also, during consultations with study participants, both in person and at telephone follow-up, no formal verbal script was instituted. This may imply that an imprecise method was used to assess participant knowledge in this study (Anger et al., 2012).

Measures of health literacy

Formal, validated health literacy assessments were conducted by three of the authors in this scoping review (Altin & Stock, 2016; Anger et al., 2012; Torres & Marks, 2009). Anger (2012) and Torres & Marks (2009) employed the Test of Functional Health Literacy in Adults (TOFHLA) health literacy screening test. Anger also added audiotaping to record patient and clinician exchange, which was later analysed for content. One author (Altin & Stock, 2016) used only a part of the Brief Health Literacy Screen (BHLS). This study was a telephone based survey. A validated, one item screening question was used, using a five point Likert scale based on the original BHLS. This subjective Brief Health Literacy Screen question asked study participants "how often do you have problems learning about your medical conditions because of difficulty understanding written information?" A criticism of this paper could be that participant responses were subjective, and definitive health literacy testing procedures were not conducted objectively. Although this screening question had previously been validated, a more objective measure of health literacy could have produced more accurate health literacy scores in this group of participants (Altin & Stock, 2016).

In the study examining health literacy and hormone replacement therapy (HRT), Torres & Marks (2009) used the 36 item short Test of Functional Health Literacy (sTOFHLA) health literacy test to assess health literacy. In this study Torres (2009) then went on to categorise health literacy scores into three groups which included inadequate, marginal and adequate. Torres determined that women with higher levels of health literacy also had higher levels of knowledge of hormone replacement therapy, and this higher knowledge was associated with greater decision making ability in regard to HRT management (Torres & Marks, 2009).

The Test of Functional Health Literacy (TOFHLA), short Test of Functional Health Literacy (sTOFHLA) and the BHLS health literacy screening tests are all validated health literacy test instruments. The rationale for selection of each measure used for formal measurement of health literacy was not discussed by any of the authors for whom health literacy was the main identified theme. Results of Anger's cross sectional pilot study concluded that even women with high health literacy scores had poor recall of their diagnosis or treatment options that were discussed during the consultation with the clinician (in this study a urologist or a urogynaecologist).

In her study Anger (2012) acknowledged that her patients' presenting conditions (pelvic organ prolapse and/or urinary incontinence) were complex subjects for patients to grasp. Anger (2012) concluded that a high TOFHLA score did not necessarily align with increased levels of disease knowledge or understanding. Anger stated that a lack of disease or condition specific understanding may limit a patient's ability to make effective treatment decisions and may ultimately cause long term dissatisfaction, regardless of the level of a patient's health literacy. Anger concluded that more work is needed to develop measures aimed at improving understanding of complex issues related to patient diseases and treatments (Anger et al., 2012).

In contrast to Anger's (2012) paper, Altin & Stock (2016) concluded that higher levels of health literacy and patient satisfaction were linked. Altin (2016) reported that study participants who self reported their health as excellent or good were more likely to be satisfied than those who self reported their health as fair or poor (Altin & Stock, 2016). Torres & Marks' (2009) results concluded that higher health literacy was associated with greater self efficacy and resultant positive behaviour change, improved decision making abilities and overall improved health outcomes (Torres & Marks, 2009).

In a national, cross-sectional postal survey in Sweden with 232,518 subjects, Kandelaki (2015) examined patient centred care and in the process reported on participant education levels. In contrast to papers by Anger (2012) and Altin & Stock (2016), Kandelaki (2016) found that people with low health literacy were more satisfied with previous treatment or care than those who had higher levels of health literacy (Kandelaki et al., 2016). Torres & Marks (2009) discussed information seeking in relation to health literacy and found that increased levels of knowledge about hormone replacement therapy and health literacy were positively linked, with women with higher health literacy having better knowledge and understanding

of HRT treatment. Torres also linked higher health literacy with increased self efficacy in relation to HRT treatment (Torres & Marks, 2009).

What actions could authors have taken to minimise bias?

Across the 14 papers that were appraised, a major source of potential bias was the processes reported in relation to patient identification, selection and study recruitment processes. Four authors failed to adequately demonstrate that they had used a formal, planned process to identify and recruit participants to their studies and this was a major source of potential bias in these publications (Anger et al., 2012; Cape, 2002; Mallinger et al., 2005; Radu et al., 2018). Anger (2012), Mallinger (2005), Cape (2002) and Radu's (2018) publications could have been improved if planned, structured and unbiased methods had been described and used to identify and recruit study participants.

2.7.4 Length of consutation

Two papers were identified which considered length of clinical consultation in relation to patient satisfaction (Barber et al., 2016; Cape, 2002). Barber (2016) assessed length of consultation in relation to patients' perception of consultation duration, in a mental health setting. No association was found. Cape (2002) used a general health questionnaire, along with a 50 item satisfaction questionnaire. No relationship was found between consultation length and patient satisfaction. Cape (2002) found that if patients believed the consultation length to be longer than it actually was, the study participants reported higher levels of satisfaction. A limitation of this study is that it was restricted to patients who were psychologically distressed and may have required a longer consultation time. The author recommends that the results may not be generalisable to the whole population (Cape, 2002).

2.8 QUALITY APPRAISAL RESULTS

All of the 14 identified papers were listed and their details are presented (Appendix 1 -Scoping Review, Publications Retained for Analysis). All of the papers that were identified in the inclusion and exclusion process as meeting the search criteria were included in the appraisal and subsequent discussion, regardless of the quality of each of the publications. Poor quality papers that were identified in the scoping review's search processes were not excluded from the quality appraisal process. All of the fourteen papers identified were included in the quality appraisal and subsequent review processes.

Following creation of the list of selected papers, a quality appraisal was undertaken utilising the Joanna Briggs Institute Quality Appraisal instrument (2015). Results of the appraisal of the studies were diverse (Appendix 2 – Scoping Review - Quality Appraisal). Publication dates of the selected texts ranged from 2005 to 2018. Most authors clearly stated the aims of their studies. Altin (2016) failed to state any study aims (Altin & Stock, 2016).

Thirteen authors id state the research inclusion criteria for their studies, with Radu (2018) failing to provide these study details. Participant numbers in the analysed papers ranged from a minimum patient cohort of 36 patients in a pilot study (Anger et al., 2012) to a maximum number of 232,518 in a national survey (Kandelaki et al., 2016). Thirteen of the authors clearly described the study setting or the study population. Radu (2018) failed to describe the study setting adequately (Radu et al., 2018). Research outcomes were measured and described using an acceptable and valid approach by most of the authors. Most authors described the outcome measures that were used. Most authors used validated questionnaires to measure study outcomes. All of the authors used systematic statistical methods to analyse their study results. Strategies used to deal with confounding factors were stated by only five of the 14 authors. Study populations varied. Interventions and study results were diverse. Ten papers were cross sectional studies, one was a prospective postal survey and three were observational studies.

Thirteen authors provided an appropriate discussion section that linked their research to existing, published results and current opinion. Radu's paper (2018) failed to provide an adequate discussion that put the research into any context. Only five references were quoted in this paper, all of which were in the introduction section. Radu (2018) failed to provide any link between existing publications and the findings of the research study. This author's discussion section merely restated the study's results and did not relate these results to existing published research or current opinion (Radu et al., 2018).

2.9 CONCLUSIONS AND RECOMMENDATIONS FROM THE SCOPING REVIEW

This scoping review asked the research question – What is the association between health literacy level and patient response to clinical consultation?

Following identification and analysis of 14 papers, satisfaction was identified as the main theme in all analysed publications. A patient centred care approach to clinical consultation was consistently associated with higher levels of patient satisfaction. Patient satisfaction levels were a major measure of success or failure in a patient centred care approach to health care delivery. Longer length of clinical consultation was not associated with increased levels of patient satisfaction. Publications which primarily focussed on health literacy also encompassed assessment of satisfaction with various aspects of health care.

The majority of authors measured satisfaction with health service delivery. Timing of assessments were diverse. Two publications concerned pre operative satisfaction assessment. Thirteen studies were conducted following a treatment or care episode. Studies took place in various inpatient, outpatient, primary care settings, secondary health settings and tertiary hospital settings. Validated measures were generally used by researchers to assess aspects of satisfaction, with selected measures incorporating either condition specific or generalised satisfaction measures.

Fourteen papers were included in the scoping review analysis. In the studies appraised, high satisfaction levels were consistently found across the various study sites. Health literacy and patient satisfaction levels varied, with most authors linking low health literacy with lower subjective patient satisfaction levels. Many authors agreed that an individualised approach to health care, supported by appropriately presented information that was tailored to the

literacy needs of each individual, was found to be essential for positive patient clinician exchange. A successful, individualised and patient centred care approach to health service delivery was associated with higher levels of patient satisfaction. There were important elements of bias, mostly focused on patient selection strategies and study recruitment processes.

All of the fourteen publications that have been assessed in this scoping review have encompassed elements of satisfaction in a variety of health settings including primary, secondary and teriary care. None of the publications examined in the scoping review identified the link between patient satisfaction, health literacy and length of clinical consultation. My study assessed subjective levels of satisfaction, health literacy levels of participants, length of clinical consultation and patient subjective knowledge with several types of clinicians in various obstetric and gynaecological clinical settings at two hospital sites.

A gap in knowledge was identified regarding the relationship between patient satisfaction and health literacy, length of clinical consultation and subjective knowledge in women attending for obstetric or gynaecological care when they consult with a variety of clinicians including a doctor, nurse or physiotherapist. This study aimed to provide new evidence into the relationship between patient satisfaction and health literacy, consultation duration and subjective knowledge in adult women attending a variety of obstetric and gynaecology clinics at two hospitals. There have been 10 papers published that examine satisfaction with aspects of care, three papers which examine satisfaction and health literacy and one paper which examines satisfaction in relation to length of clinical consultation. As these studies have a high risk of bias further investigation of these identified issues is justified.

2.10 LIMITATIONS OF THE SCOPING REVIEW

This scoping review has two important limitations. Only one reviewer was involved in the scoping review paper identification and selection process, meaning that selection bias could have been a concern. A second reviewer could have strengthened the results of this review. Secondly, specific mention of consultation duration in the scoping review search strategy may have identified further publications of interest.

2.11 SUMMARY OF THE SCOPING REVIEW

The scoping review identified and appraised 14 publications which related to the review question – What is the association between health literacy and patient satisfaction with clinical consultation?

Papers were appraised using the Joanna Briggs Quality Appraisal instrument. Patient satisfaction was clearly identified as the main theme in all of the publications included in the scoping review. Following appraisal of the included studies, high satisfaction levels were consistently found, with most authors linking low health literacy with lower subjective satisfaction levels. A successful, individualised and patient centred care approach to health service delivery was consistently associated with higher levels of patient satisfaction.

There were potential elements of bias in some of the studies, which mostly focused on patient selection strategies and recruitment processes that the authors undertook to identify and recruit patients to their studies. The selection and recruitment strategies that authors used were often not adequately described.

None of the publications examined in the scoping review examined elements of patient satisfaction relating specifically to health literacy, length of clinical consultation and subjective knowledge. My study assessed women's level of satisfaction, health literacy levels, length of clinical consultation and patient subjective knowledge, with several types of clinicians in various obstetric and gynaecological clinical settings at two hospital sites. This study hopes to provide new insight into the relationship between these three important concepts in adult women attending for outpatient care at a variety of clinics in two hospitals.

Work Package Two – A Cross Sectional Survey

Chapter 3: METHODS

3.1 STUDY DESIGN

In this chapter the following research questions will be addressed -

- What is the association between patient satisfaction with clinical consultation and health literacy?
- What is the association between patient satisfaction with clinical consultation and length of clinical consultation?
- What is the association between satisfaction with clinical consultation and subjective knowledge?

The most appropriate design for this study was a cross sectional observational study. The hierarchy of evidence was acknowledged and noted, however, a randomised controlled trial was not possible as there was no intervention tested in this study. A cohort study was not performed. An observational study was the best available methodology. A longitudinal study design may have been more robust (Ball & Regan, 2019).

An observational study is a non-experimental study which allows for true to life observation of study subjects' behaviour in the natural environment (in this instance two hospital outpatient settings), without manipulation or intervention, utilising predetermined and validated study measures. According to Cresswell (2003) a cross sectional observational study uses surveys, observations, tests and statistical procedures (Cresswell, 2003; de Vaus, 2001). This is the type of research that I chose to undertake.

3.1.1 Setting

The study research settings were specialist outpatient clinics including Urogynaecology Clinic, Well Women's Clinic, Physiotherapy Clinic and Pre Admission Clinic located at the Mercy Hospital for Women and the Urogynaecology Clinic at Werribee Mercy Hospital in Melbourne, Australia. Both of these hospitals are standard hospitals in an advanced economy, in a typical metropolitan setting. Study recruitment commenced in September 2018 and was concluded in December 2018. One month follow-up telephone calls were completed in February 2019. Data collection and data entry were continuous and on-going.

As this was an observational study, there was no specific intervention planned. The study consisted of three measures carried out before (Measure 1) and immediately after (Measure 2) the patient's scheduled appointment with any clinician (a doctor, nurse or physiotherapist) in the Urogynaecology Clinic, Well Women's Clinic, Physiotherapy Clinic or Pre Admission Clinic at either of the two hospitals involved. There was one follow-up telephone call (Measure 3) which took place one month following the initial consultation. All interviews, health literacy test, study questionnaires and study documentation were completed in a private location within the hospital setting during the course of the three interviews.

Details of the study recruitment settings

The main site for the conduct of this study was the Mercy Hospital for Women. The Mercy Hospital for Women is a 247 bed public hospital and specialist referral centre with medical, nursing, midwifery and allied health staff expertise, located in the north eastern suburbs of Melbourne, Australia. It provides complex obstetric, neonatal, specialist and sub specialist obstetric, gynaecological and neonatal care to women and babies. The hospital provides services to women and babies who primarily live in the north and eastern suburbs of Melbourne. It also acts as a tertiary referral centre for specialist obstetric, gynaecological and neonatal management across all areas of south eastern Australia. A level three neonatal intensive care unit provides services to newborn babies, including a neonatal intensive care unit. The hospital is a university teaching hospital, in partnership with La Trobe University, University of Melbourne and the Australian Catholic University. Doctors, nurses, midwives, physiotherapists and other health professionals train in various department such as Obstetrics and Gynaecology, Physiotherapy, Anaesthetics, Midwifery, Social Work, Operating Room, Radiology and Neonatology.

The second study site is the Werribee Mercy Hospital. This hospital is a general hospital located in the western suburbs of Melbourne, Australia. It is situated in a rapidly developing suburban area. It currently has 300 beds, is a teaching hospital and it is associated with the University of Notre Dame. This hospital has specialty departments including Medicine and Surgery, Obstetrics and Gynaecology, Mental Health, Renal Dialysis, Aged Care, Palliative Care and Accident and Emergency Medicine. It also has a Urogynaecology sub-specialty clinic.

I aimed to measure satisfaction with various clinicians (doctors, nurses and physiotherapists) in several clinical settings at two hospitals and surveyed patients attending Urogynaecology, Well Women's, Physiotherapy or Pre Admission Clinics. Both of these hospitals are average hospitals in an advanced economy, in a typical metropolitan setting.

3.2 PARTICIPANTS

Study participants were all adult women attending the Urogynaecology Clinic, Well Women's Clinic, Physiotherapy Clinic or Pre Admission Clinic for consultation with any clinician (doctor, nurse or physiotherapist). All of the women involved in this research study identified themselves as female.

All women who were approached were given written information regarding the purpose and processes of the study and if they agreed to participate they were required to provide written consent.

3.2.1 Patients who were eligible for study inclusion

Patients eligible for inclusion in the study were -

• English speaking adult women (aged 18 years and over).

 Women attending any Urogynaecology Clinic, Well Women's Clinic, Physiotherapy Clinic or Pre Admission Clinic for consultation with any clinician (doctor, nurse or physiotherapist).

3.2.2 Patients who were ineligible for study inclusion

Women who were seen with an interpreter

The interpreter could have been a family member, a friend or a professional interpreter provided by the hospital. Recruitment to the study was limited to English speaking women. All study materials, patient information documents, consent forms and study questionnaires were prepared in English only. The Rapid Estimate of Adult Literacy in Medicine Revised (REALM - R) health literacy test was available in several languages other than English, but not all of the languages that patients speak and read at each of the participating hospitals. Women who used any type of interpreter were excluded as the patient information and consent documents, health literacy test and study questionnaires were not available in all languages. At present there are women from approximately 171 language groups who access care at each of the hospitals involved in the study. Translation of all study materials into 171 languages other than English was not possible due to staff and time limitations, translation costs and questionnaire validation issues.

Women who had severe visual impairment

Women with severe visual impairment would not have been able to complete the Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) health literacy test. This visual test requires women to be able to see and then read aloud the test words displayed on an electronic tablet screen. The literacy test results are an important study outcome measure.

Women who had severe cognitive impairment

This included women who were severely developmentally impaired, had severe dementia or other conditions which resulted in them being unable to complete all of the

necessary questionnaires and the health literacy test. These women were excluded from my study. Women who were severely cognitively impaired, based on my clinical judgment, may not have been able to complete or complete adequately, the study questionnaires, the health literacy test or other study requirements which form the formal study outcome measures. Women with severe cognitive impairment may not have been able to understand the aims of the study and the requirements of participation. Women with significant cognitive impairment may not have been competent to sign the study consent form.

Women who were unwilling or unable to provide written consent

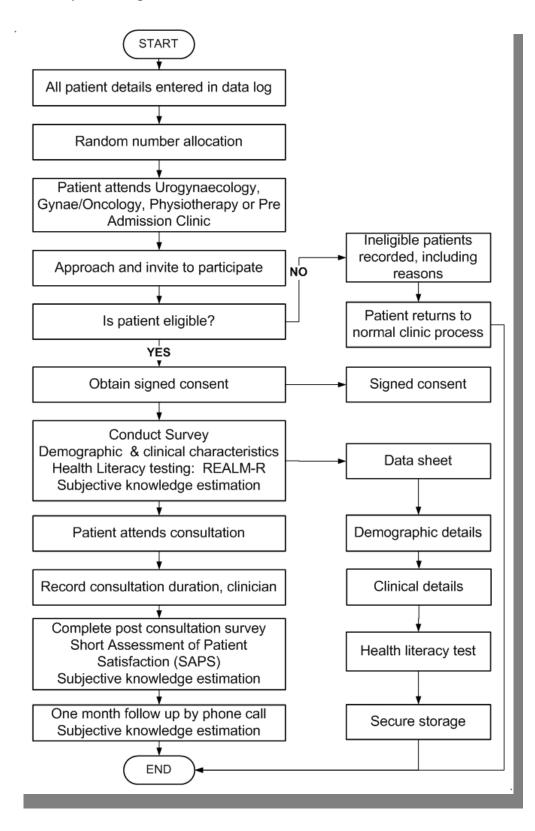
The Human Research Ethics Committees at both Mercy Hospital for Women and Werribee Mercy Hospital (HREC) and La Trobe University Human Ethics Committee (UHEC) require that all of the study participants provide written consent to participate, in the form of a signed study consent form. Women who refused to sign the study consent form were excluded from the study.

3.2.3 Selection of the study participants

A random sampling method was adopted during each of the clinic sessions when I was available to recruit women to the study. Before commencement of the particular clinic session, all patient details of those women who were scheduled to attend that particular clinic were entered onto an Excel spreadsheet (Microsoft, 2013), utilising the hospital's electronic appointment booking system which provided patient details for each of the clinics. The details entered onto the spreadsheet included the woman's scheduled appointment time, the particular clinic that she was booked to attend and each patient's hospital record number. No patient's name or other personal identifying details were entered onto this list. Patients who were booked to be seen with a hospital interpreter were noted. These women were ineligible for inclusion in the study and were therefore not approached and invited to participate. Their details were included on the spreadsheet but they were not approached or invited to participate due to their ineligibility. For each of the clinic's booked time slots the Excel spreadsheet was used to mix the scheduled appointment times and present patients allocated to each distinct timeslot in a different and random order. Random number generation was used and each patient was allocated a unique random number (Random.org). Working from the top (the lowest random number, then the second lowest number, then the third lowest number, then the fourth lowest number for that appointment time slot) of the newly organised random and numbered list down, potential participants who were in attendance at each clinic session were then personally approached in turn and invited to take part in the study. A record was kept of who was approached and whether they agrred to participate, or declined participation in the study. If a women declined to participate she was asked to state a reason for doingf so and this was noted on the spreadsheet. This system of patient selection and approach was continued until time ran out for recruiting new participants to the study in that time slot or during that particular clinic session. If more than one woman was allocated to the same time slot the woman with the lowest random number was approached first.

Use of this random number generation method meant that all patients who initially appeared to meet the inclusion criteria for the study and were booked to attend a clinic on any recruitment day had an equal chance of being approached and invited to participate in the research study. The anticipated flow of patients through the research process is presented in a study flow diagram (Figure 2 - Study Flow Diagram).

Figure 2 - Study Flow Diagram



How was the study introduced to potential participants?

Following discussion between the study authors, a decision was made to not send a written invitation letter and the Patient Information and Consent package by mail to potential participants, as is the normal process when a new research study is introduced to potential participants at the two participating hospitals. This decision acknowledged that some women could possibly have low health literacy and so should not be asked to sign a consent form which they may not have been able to read or fully comprehend. A written invitation letter sent to potential participants prior to the consultation was therefore withheld as it could have caused possible confusion, anxiety or distress to some women.

Instead, on the day of the scheduled consultation, all eligible women who appeared to meet the inclusion criteria may have been invited in person to participate in the study, depending on time available for me to perform this task. Each woman that I approached in person was given the Patient Information and Consent document to read (or have read to them) on the day of their scheduled consultation. A data log was constructed using an electronic tablet, where a record was kept of all women's details who were booked to attend the selected clinics. An example of a section of the data log is shown (Appendix 3 - Data Log). In this data log a record was kept of whether women were personally approached and invited to participate, whether they met the eligibility criteria, whether they were invited to participate, whether they agreed or declined participation, the reason for non participation and whether they completed all required elements of the study process on the day of their clinical consultation.

Participation in the study was voluntary

The voluntary nature of each woman's participation in this study was emphasised as part of the recruitment process. If the woman chose to participate in the study, she was asked to sign a study consent form. A person not connected to the study was asked to witness the consent form. The consent form was a formal legal document developed by each of the two participating hospitals. A photocopy of the completed consent form was given to each participant to keep. At this point the woman's details (name, clinic she was booked to attend, type of clinician she was scheduled to be seen by, and date of study recruitment) were entered into the data log so that a unique study identification number could be generated. From that point of time onwards this was the only identifying number that was connected to that study participant. No other identifying factors were noted, ensuring ongoing privacy and confidentiality.

Women were informed that their involvement or non involvement in the study would not influence any ongoing care at both of the hospitals. The women were assured that ongoing care would not be affected if they declined involvement, or withdrew their consent at any time during the conduct of the study. Though this information was contained within the Patient Information and Consent document it was also repeated verbally so that any perceived coercion was avoided. The women knew that they could decline involvement if they wished to, or curtail involvement at any time, without giving a reason and without any negative impact on their future care at either of the participating hospitals.

How long will the study take to complete?

The number of hospital clinic patients attending any Urogynaecology Clinic, Well Women's Clinic, Physiotherapy Clinic or Pre Admission Clinic varied from day to day. It was estimated that a maximum of two to three patients could be recruited at each of the clinic sessions (morning or afternoon session). All completed study documentation and tests results were processed following the completion of each clinic session. All study details were entered into a secure study database called research data capture (REDCap) (Harris, 2018). Prior to the study's commencement it was estimated that the recruitment phase of the study would see a minimum of 12 to 16 patients recruited each week. It was estimated that all study requirements would be completed in approximately 16 to 20 weeks.

Was there any risk of harm to the participants?

During the development of the study methods I considered whether there would be any risks of harm to any of the study participants. During the development phase I did not anticipate that there would be a substantial risk of harm in the conduct of this study. I thought that it was possible that I may inadvertently cause some of the participants some anxiety or distress by conducting health literacy testing or by asking sensitive questions about the women's presenting symptoms, potentially causing them some embarrassment.

Prior to the study's commencement the only foreseeable burden placed upon the participants was the time required to complete the pre and post consultation measures, which was estimated to take 15 to 20 minutes for the first interview and two to five minutes for the post consultation interview. The post consultation telephone call one month after the consultation visit was estimated to take less than five minutes to complete as it required the answering of only one question about knowledge gained from the previous consultation. The pre consultation interview took place when the woman was waiting to be called for her scheduled appointment with the doctor, nurse or physiotherapist.

All participants were reassured that waiting times for their appointment would be lengthened only briefly if they took part in the study. The post consultation questionnaires were anticipated to only take two to five minutes to complete. In relation to the health literacy test, care was taken with language that was used so that no offence was conveyed in relation to the health literacy test or the health literacy test results. Words and descriptions were used that sensitively and respectfully showed potential participants that the study aimed to involve women with all levels of reading ability. Conveyance of this information to women was important as it aimed to show them that all women were eligible for participation and that the study was inclusive of everyone.

Women were encouraged to give frank and honest answers to all of the study measures and questionnaires. Participants were reassured that any negative comments that they made about the clinician they were seen by, or other feedback they provided would not impact on any future care at either of the hospitals involved. Participants were reminded that responses would remain confidential and that the clinician that they have seen for the consultation would not have access to the results of the completed post consultation satisfaction questionnaire (Short Assessment of Patient Satisfaction (SAPS)) at any time, now or in the future.

Timing and collection of study measures

All patient details were collected by the study researcher (CJM). The initial study measures were completed and the planned points of contact were conducted over the course of one scheduled outpatient visit (before and immediately following consultation with the clinician). A third contact consisted of a follow-up telephone call made one month after the initial consultation.

The number of clinic patients attending any Urogynaecology Clinic, Well Women's Clinic, Physiotherapy Clinic or Pre Admission Clinic varied from day to day. It was estimated that a maximum of two to three patients could be recruited per clinic session (morning or afternoon session). All study documentation and tests results were processed following the completion of each clinic session (all study details were entered into a secure study database – REDCap).

Consultation duration

The duration of each of the clinical consultations was timed in whole minutes by me and recorded on the paper data collection sheet that was specifically developed for this study (Appendix 4 - Data collection sheet). The type of clinician involved in each consultation was noted (doctor, nurse or physiotherapist), though the personal identity of each of the clinicians was not recorded on the data collection sheet. If permission was granted by the study participant, a telephone number was recorded on the data collection sheet to enable a follow-up telephone call to each woman one month following consultation to again ask a subjective knowledge estimate (Subjective knowledge - Measure three).

When were the study measures completed?

The pre consultation questionnaire, health literacy test and pre consultation estimation of subjective knowledge were completed at the initial pre consultation contact, along with details of background demographic and clinical data which were recorded on the data collection sheet.

Immediately following the clinical consultation the women were asked to complete the Short Assessment of Patient Satisfaction questionnaire (SAPS) and the second estimation of subjective knowledge using a Likert scale (Subjective knowledge - Measure two). I also noted and recorded on the data collection sheet the consultation length at this time (in whole minutes). Verbal permission was sought to contact the women by telephone one month after the initial consultation to ask about subjective knowledge at one month following consultation and a telephone number recorded for that purpose (Subjective knowledge – Measure 3) (Figure 3 – Study flow diagram).

Electronic case record form (REDCap)

All of the women were personally questioned in the various hospital clinics. Background demographic and clinical data were collected and entered on to the data collection sheet before the clinical consultation took place. A Research Data Capture (REDCap) database was developed for the purpose of this study. Data from the data collection sheet were entered into the REDCap database at a later time, following completion of each clinical session. Collection of questionnaires, demographic details and health literacy test results on the specifically designed data collection sheet allowed for later systematic checking of veracity of data entry to ensure accuracy of data input. It was planned that a percentage (10%) of data records would be routinely checked at a later date to test for precision of data entry in the REDCap file. A list was kept of files that were checked in this manner.

Strengths and limitations of using electronic collection data methods

The use of paper records (data collection sheet, consent forms and study questionnaires) at the time of patient recruitment and follow-up made it administratively simple to collect details and administer the study questionnaires in any suitably private hospital location. The use of paper records removed potential confusion if women were asked to use potentially unfamiliar or unexpected electronic devices or formats to complete the study requirements. The health literacy test was undertaken using an electronic tablet. It could also have been administered on paper.

The use of electronic devices to collect demographic patient data and questionnaire responses was considered, so that patient responses could be directly recorded on a hand held electronic device or laptop computer. However, the use of an electronic device such as a laptop computer or electronic tablet may have had the potential to cause distress to any participants who are unfamiliar with technology such as computers or other electronic devices. Paper surveys were therefore chosen as a more suitable data collection method.

The choice of a paper record for each study participant also provided me with the option of checking my data entry accuracy at a later time. Using the paper record I was able to check the data collected against entries in the REDCap database and correct data entry errors where necessary. If I had used an electronic data collection method I would not have been able to check the accuracy of the data entered into REDCap.

Data capture and data management procedures

A secure, web based data file called Research Electronic Data Capture (REDCap) was used to record and assemble all collected patient data (Harris, 2018). The REDCap program was provided to me by La Trobe University's Office of Research Infrastructure. This database is a secure web application for building and managing online surveys and databases. It can be used to collect virtually any type of data but it is specifically geared to support data capture for research studies. There was support for this database within La Trobe University Department of Information and Communication Technology. The software is hosted at La Trobe University and the data remains securely stored on La Trobe University's servers. The REDCap data collection system was chosen because of its data security, accessibility, system flexibility, suitability and for its ease of use (Harris, 2018). This secure system allowed only authorised users to enter or extract any of the study data. All data were personally de-identified, with each of the participants allocated a unique study identification number, as I have previously described. Data entry into REDCap of demographic details, clinical details, health literacy test results and questionnaire responses was completed following data collection in the hospital clinics. All identifying paper records (questionnaires, Rapid Estimate of Adult Literacy in Medicine – Revised (REALM-R) health literacy test results, study consent form and the completed data collection sheet) were completed and have been securely stored in folders in a locked cabinet, in the locked Urogynaecology Department office. Access to the password protected REDCap database remains restricted to authorised users only.

Unique study identifiers

Participants were allocated a unique study identification number to ensure ongoing privacy and confidentiality. A master sheet was used to allocate the identification numbers and record each participant's identity. This file has been kept on a password protected computer at the Mercy Hospital for Women. Following completion of the research project, all files will be de-identified. All collected data will be securely disposed of after seven years from the date of publication of the study's research findings. Data on paper (questionnaires, consent forms, health literacy test results and data collection sheets) will be securely shredded. Research data collected in electronic format will be destroyed by reformatting or rewriting.

3.2.4 Research governance and ethical committee monitoring

Ethical approval was sought and obtained from Mercy Hospital for Women, Werribee Mercy Hospital and La Trobe University Research Ethics Committees (Appendix 5 - Ethical approvals). Regular reporting mechanisms continue to be in place within La Trobe University, the Mercy Hospital for Women and Werribee Mercy Hospital. At each of these institutions Research Ethics Committees meet regularly to monitor the conduct and progress of all research projects. All required reports to the Ethics Committees at each institution have been submitted in a timely manner when requested by La Trobe University Human Ethics Committee (UHEC) and Mercy Health's Human Research and Ethics Committee (HREC). No research reports are currently outstanding.

3.2.5 Ethical considerations in the study

This research project was approved by the Human Research and Ethics Committee at Mercy Hospital for Women and Werribee Mercy Hospital, overseen by a single Human Research Ethics Committee (HREC) and by La Trobe University's Human Ethics Committee (UHEC) (Appendix 5 - Ethics approvals) -

Mercy Health HREC approval – reference number 2018-041
 Date of approval - 20th August, 2018
 Approval to extend the study to include a second hospital site (Werribee Mercy) was also received.
 Date of approval of second site - 1st October 2018
 La Trobe University UHEC approval obtained, reference MercyHospitalforWomen2018-041
 Date of approval - 7th September, 2018.

Ethical considerations

Participation by women in this research study was entirely voluntary. By approaching women in person an opportunity was available to reinforce that participation was voluntary. By providing a cooling off period of at least 30 minutes between when the woman was initially approached to consider participating in the study and when she was asked to provide written consent to the study, any questions or queries she had about the study or her role in the study was able to be resolved. This minimised the risk of social desirability bias. By

allowing for a period of reflection on the decision to participate or not, any appearance of coercion was mitigated.

Women were assured that non participation would not affect their care or treatment at either of the hospitals at the time of the study, or at any time in the future, at any service offered by either hospital involved. Those women who chose to participate were assured that personally identifiable information would not be available to any other agency within the hospitals or outside, at that time or at any time in the future. Participants were reassured that all of their responses to the Short Assessment of Patient Satisfaction (SAPS) questionnaire would not be shared with the clinician involved in the consultation, at that time or at any time in the future. Participants were further assured that agreement to participate would not significantly lengthen or alter their waiting time for consultation in any of the participating clinics on the day of consultation.

Women were also assured that they were able to withdraw consent to participate in the study at any stage during the study process. The women were reminded that withdrawal for any reason would not have a negative impact on any future treatment offered at the two participating hospitals. They were assured that a reason for withdrawal from the study need not be stated. All collected data had identifying details obfuscated to ensure ongoing privacy of collected information.

By completing this study the aim was to improve women's experiences in the future, during a variety of outpatient consultations at two participating hospitals in Melbourne, Australia. Assessment of patient satisfaction in relation to health literacy could allow for the development of more appropriate information and hospital processes for women attending for appointments, management or treatment in the future.

The research was undertaken with approval from La Trobe University's Human Ethics Committee (UHEC) and the Mercy Health's Human Research and Ethics Committee (HREC). Both of the hospitals involved in the study have policies and processes in place to ensure adherence to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia (NHMRC, 2007).

Ethical approvals were obtained prior to commencement of patient recruitment. Study recruitment did not commence until approvals were obtained. Copies of the ethics approvals are included (Appendix 5 - Ethics approvals). Study findings will be reported in a peer reviewed journal and also presented at local hospital research meetings, national or international meetings. No individually identifiable participant information will be presented in any written publication or verbal presentation, at any time now or in the future. Participants will be provided with a copy of a summary of the results of the study if requested.

3.2.6 Potential data issues

When planning this research study, I did identify one potential issue. Potential participants in this study were not sent a written invitation to take part in the study, as is the usual method of approach for potential research participants, as it would have been counterintuitive to send women a large, written document when the purpose of the study was to assess each patient's health literacy. If this approach had been used, it may have deterred women who believed that they may have low health literacy from participating in the study, when in fact the study aimed to include all women with all levels of health literacy. Instead, I made a direct and personal approach to each woman on the day of consultation and if they were found to be eligible to take part they were verbally invited to do so. Discussion on the day of consultation was proposed as a more appropriate and non discriminatory method to ensure that a broad representation of participants with all levels of health literacy health literacy had the opportunity to take part in the study.

3.3 VARIABLES

3.3.1 Dependent variable – patient satisfaction with consultation.

The Short Assessment of Patient Satisfaction questionnaire (SAPS)

Patient satisfaction with clinical consultation was determined by use of the Short Assessment of Patient Satisfaction questionnaire (SAPS) (Hawthorne, Sansoni, Hayes, Marosszeky, & Sansoni, 2014). This validated questionnaire is not condition specific, and it can be used in any clinical situation by any clinician (Appendix 6 - Short Assessment of Patient Satisfaction questionnaire (SAPS)). Permission to use the Short Assessment of Patient Satisfaction questionnaire (SAPS) was obtained from the study authors (Appendix 8 – Permissions).

The Short Assessment of Patient Satisfaction (SAPS) questionnaire has previously been validated by Hawthorne in a urogynaecology context (2014). Hawthorne suggests that the use of a condition specific questionnaire may not be valid when used in a different setting. Hawthorne proposed that a generic satisfaction measure was more versatile than a condition specific measure, though he mentions that there may be limitations when such a measure is used in populations with particular diseases or other conditions (Hawthorne et al., 2014). Hawthorne suggests that other measures may be biased, too long to use, condition specific or lack robustness in relation to their psychometric properties.

Each of the seven questions in the questionnaire has five possible responses. The psychometric properties of The Short Assessment of Patient Satisfaction (SAPS) questionnaire covers seven patient satisfaction domains including 1) satisfaction with the effects of treatment, 2) satisfaction with the explanation about the results of treatment or care provision, 3) satisfaction with care with examination by the clinician, 4) satisfaction with participation in care and decision making processes, 5) satisfaction with the level of respect shown by the clinician, 6) satisfaction with the time spent with the clinician and 7) satisfaction with overall care received.

During development of the The Short Assessment of Patient Satisfaction (SAPS) questionnaire, Hawthorne (2014) found that it correlated well with existing comparable satisfaction measures such as the Consultation Satisfaction Questionnaire (ConsultSQ), the Client Satisfaction Questionnaire (CSQ-18), the Genito-Urinary Treatment Satisfaction Scale (GUTSS) and the Patient Satisfaction Index (PSI) (Hawthorne et al., 2014).

During this questionnaire's development the Short Assessment of Patient Satisfaction (SAPS) measure was found to be reliable and to outperform other, existing but longer satisfaction measurement instruments. The Short Assessment of Patient Satisfaction measure was validated in a urogynaecology population during its development in Australia but its application is not confined specifically to a urogynaecology setting. It can be applied to any clinical consultation in any field, and pertains to any clinician (Hawthorne et al., 2014). This patient satisfaction questionnaire is a short and easy to use instrument. It is a generic questionnaire, applicable to any clinician, in any clinical environment and is not condition specific.

Following a literature search only two publications were found that have previously published papers that used The Short Assessment of Patient Satisfaction (SAPS) questionnaire. Goyal (2018) categorised respondents into two group which were 1) satisfied or highly satisfied and 2) dissatisfied or highly dissatisfied (Goyal et al., 2018) depending on the total questionnaire score (Goyal et al., 2018; Vaughan et al., 2019).

During the development of the study methods, consideration was given regarding utilisation of other available, validated satisfaction questionnaires. The Smith-Falvo Patient-Doctor Interaction Scale assesses various aspects of consultation, using 19 questions with multiple choice answers. This questionnaire was discarded as the questions which patients were asked to respond to only related to consultations conducted by doctors or physicians, and did not include consultations with other health professionals such as nurses or physiotherapists (Lehmann, Fontaine, Bourque, & Cote, 1988).

The Short Assessment of Patient Satisfaction questionnaire (SAPS) was chosen over other available measures because it covers seven specific areas of satisfaction, it is applicable in any clinical consultation, with any clinician, and for its ease and speed of use. This study is being conducted in various clinical settings, involving different clinicians within two hospitals. A generic questionnaire, applicable to any consultation was most appropriate and I decided that the SAPS questionnaire would be the most suitable measure for the purpose of this study.

Study participants were asked to complete the SAPS satisfaction questionnaire immediately following the consultation with the clinician (doctor, nurse or physiotherapist). If health literacy had been determined to be low the questionnaire could have been administered verbally by a family member, friend, professional carer or a staff member. A copy of the Short Assessment of Patient Satisfaction questionnaire is shown below (Appendix 6 - Short Assessment of Patient Satisfaction questionnaire). I estimated that this seven item questionnaire would take two to five minutes to complete, either independently or with assistance.

3.3.2 Independent variable - Health literacy

Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R)

I predicted that women with low health literacy (defined as a score of 6 / 8 or less on Rapid Estimate of Adult Literacy in Medicine - Revised (REALM – R) literacy testing) would be less satisfied with clinician consultations than those with average or above health literacy scores (defined as a score of 7 / 8 or more on Rapid Estimate of Adult Literacy in Medicine -Revised REALM - R literacy testing). Permission to use the REALM – R health literacy test was obtained from the original study authors (Appendix 8 – Permissions).

To measure participant health literacy the Rapid Estimate of Adult Literacy in Medicine – Revised (REALM - R) was chosen (Pat F. Bass, Wilson, & Griffith, 2003). I estimated that this health literacy assessment would take approximately two minutes to complete before the clinical consultation, including a brief explanation of the testing process.

The Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) literacy assessment test was used to measure and quantify health literacy. Other measures which were considered included the previously published Rapid Estimate of Adult Literacy in

Medicine (REALM), the Test of Functional Health Literacy in Adults (TOFHLA), the Brief Health Literacy Screen (BHLS), the Wide Range Achievement Test - Revised (WRAT - R) and the Newest Vital Sign (NVS).

These other available literacy screening tests would also have been suitable for my study but would have taken longer to administer than the The Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) literacy test. The original Rapid Estimate of Adult Literacy in Medicine (REALM) literacy test is a 66 word test which is estimated to take five to six minutes to complete. The Wide Range Achievement Test - Revised (WRAT-R) literacy test contains 57 words and is estimated to take three to five minutes to complete. The Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) was developed by Bass (2003) as a more rapid screening test that could be used to assess how well patients are able to read commonly used words in a medical context. According to Bass this test compares well with the other available health literacy assessment measures, as well as the original REALM health literacy test (Pat F. Bass, Wilson, & Griffith, 2003).

The Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) health literacy screening test was selected over the other available literacy screening measures due to its ease of use, and the short time (less than two minutes, including patient explanation) that it takes to complete the health literacy assessment in any clinical setting. The REALM - R health literacy test has been previously validated, and is a rapid screening test. The test (containing eleven words, of which eight are scored words) correlates well with the originally developed 66 word Rapid Estimate of Adult Literacy in Medicine health literacy test (Pat F. Bass et al., 2003).

During the conduct of the study, the REALM – R health literacy test was uploaded onto an electronic tablet for accuracy and ease of use in an outpatient clinical setting. I administered the health literacy test to all of the 222 study participants. It was structured so that the 11 test words were presented in a size 18 font (as per author instructions). The included screening words automatically changed on the screen every five seconds once the test commenced, following author guidelines for the use of this health literacy test (Pat F. Bass et al., 2003). Correct reading of each word scored one point (maximum score eight).

Correct or incorrect ability to read each test word was recorded on the data collection sheet, along with the total score achieved at the completion of the test. The test contains 11 words which the patient was asked to read out loud. Eight of the 11 words were scored. Participants were shown each of the listed words, in order, for five seconds only before the next word appeared on the screen. Participants were asked to read out loud each word as it appeared. Each word changed automatically on the screen every five seconds until the test concluded. The test included the following 11 words –

- Words one to three fat, flu, pill (these three words were not scored).
- Words four 11 osteoporosis, allergic, jaundice, fatigue, directed, colitis, anemia and constipation (all of these eight words were scored. Reading of one word correctly scored one point).

The words fat, flu and pill were not scored in the test, but were included to allay any potential patient anxiety related to the test and to instil participant confidence with the REALM - R word exercise testing process, as per Bass (2003). The remaining eight words (words four – 11) were scored. A score of one was given for correct reading of each word in the time allowed (5 seconds), regardless of pronunciation. If a woman scored six or less out of a possible score of eight she was considered to have low health literacy (Pat F. Bass et al., 2003).

On the REALM – R literacy test the word anaemia is spelt in the American form (anemia). As researchers, my supervisors and I discussed the spelling of the word anemia or anaemia and we acknowledged that the listed spelling was American and not Australian. Following discussion a decision was made to leave the spelling as it was originally presented by the test's author (Pat F. Bass et al., 2003). Other authors in publications on health literacy testing that I have read have not mentioned this spelling variation from American to Australian versions of anemia or anaemia. In administering the health literacy test a cautious and sensitive approach was used when the purpose and method of the testing procedure was explained, so as not to inadvertently cause offence, embarrassment, anxiety, shame or distress to any woman involved in the study. An explanation was given to each woman that this type of literacy assessment (or word exercise) aimed to improve patient information processes and care, improve women's experiences at the hospital and tailor any written and verbal information to the appropriate level for all women who were attending hospital clinics. An explanation was given that the purpose of this study was to help all patients better understand any health information that is provided, and that the aim was to improve health outcomes for all women in the longer term. A private location within the clinic was always located in which to perform the health literacy test.

3.3.3 Assessment of presenting symptoms

Australian Pelvic Floor Questionnaire

Symptoms and symptom bother was assessed using The Australian Pelvic Floor Questionnaire (Baessler, O'Neill, Maher, & Battistutta, 2010) (Appendix 7, Australian Pelvic Floor Questionnaire). I used this measure to make a determination that the study sample was representative of women attending each of the hospital gynaecological clinics for treatment or care. The population studied was not different from other published studies in this research context.

I estimated that this 42 item questionnaire would take up to 15 minutes to complete, either independently or with assistance. Permission to use the questionnaire in this study was obtained from the original study author (Appendix 8 – Permissions).

The Australian Pelvic Floor Questionnaire was designed by its authors to evaluate the symptoms, severity and bother of pelvic floor dysfunction in women of all ages. It can be clinician administered or self administered. Questions are arranged according to the physiology of the pelvic floor. The questionnaire assesses symptom bother and condition specific quality of life. It contains 42 questions and utilises a four point scoring system. The Australian Pelvic Floor Questionnaire was used so that I could make a determination that the study sample was representative. Use of the Australian Pelvic Floor Questionnaire to assess symptoms and symptom bother allowed me to determine this.

Questionnaire domains developed include four groups of questions specifically related to a woman's bladder, bowel, pelvic organ prolapse and sexual function. Subjective estimates of quality of life and degree of symptom bother are included in each of the four sections of the questionnaire. This questionnaire was originally developed and validated for use as an interviewer administered questionnaire in 2009 (Baessler, O'Neil, Maher, & Battistutta, 2009). It was further validated as a self administered questionnaire in 2010 (Baessler et al., 2010). Most of the women in my study completed the questionnaire themselves. Some of the women preferred me to read the questions to them and to record their responses. During development, this questionnaire was compared to other published measures that were relevant, validated instruments. The bladder section was compared with the short version of the Urogenital Distress Inventory (UDI6). The pelvic organ prolapse section was related to International Continence Society definitions and was compared to an established and validated female sexuality questionnaire called the McCoy Female Sexuality Questionnaire. The bowel section of the questionnaire was compared with established bowel questionnaires (Baessler et al., 2009).

Baessler's Australian Pelvic Floor Questionnaire (2009) was selected for use as it gathers extensive, specific, subjective information on patient symptoms and bother relating to aspects of pelvic floor dysfunction, in one single measure. This questionnaire was designed for a urogynaecology population. It was validated in an Australian population. In development of the study methods other measures were considered, including the Urogenital Distress Inventory (UDI-6) questionnaire and the Incontinence Impact Questionnaire (IIQ-7). The UDI6 and IIQ7 questionnaires also assess pelvic floor symptoms and symptom bother and these two questionnaires are often used in tandem.

The Australian Pelvic Floor Questionnaire was deemed superior to these alternative measurement as it covers both symptoms and bothersomeness in a single, more detailed questionnaire. Also, the UDI-6 and IIQ-7 quality of life questionnaires were designed to be used once a woman has a urodynamic diagnosis of urinary incontinence, which women involved in this study may or may not have had (Baessler et al., 2009). A copy of the Australian Pelvic Floor Questionnaire is shown below (Appendix 7 – Australian Pelvic Floor Questionnaire).

3.3.4 Subjective knowledge and treatment estimation

In order to measure knowledge gained during the consultation a single question was asked at each of the three planned time points (Measure 1, 2 and 3). This question measured subjectively baseline knowledge and then any knowledge gained from the clinical consultation over time (one month). I estimated that this estimation of knowledge would take approximately two to five minutes to complete, including explanation, before and after the consultation, and by telephone one month post consultation. Measurement of knowledge gained from the consultation was an objective of the study. I felt that this was important information and may relate to levels of patient satisfaction with consultation. The transfer of information from clinician to patient and patient to clinician is an important element of a patient centred care approach to a consultation, where clinicians approach patients in a respectful and personal way, with communication bidirectional in nature. Information transferred in an understandable and sensitive manner may go some way to improving patient knowledge, aid in patient decision making processes and improve patient satisfaction.

Question asked at each time point – How much knowledge do you have about your condition or treatment?

An author developed Likert scale was used to measure subjective knowledge before the consultation (Measure 1), and any knowledge gained during and after the consultation (immediately after the consultation and at one month - Measure 2 and Measure 3). Participants were asked to estimate their level of knowledge regarding the particular clinical consultation immediately prior to the clinical consultation (Subjective knowledge – Measure 1) and again immediately afterwards (Subjective knowledge – Measure 2).

Women were asked to note on a scale marked from one to ten what they estimate their current knowledge level to be. On the Likert scale one represented no knowledge and 10 represented maximum knowledge. This measure was again used at a follow-up telephone call one month after the initial consultation (Subjective knowledge – Measure 3).

3.3.5 Other independent variables

Other independent variables were assessed. They are presented below -

- Age how old in years was the woman at the time of study recruitment?
- Educational background how many years did the woman attend school?

- What was the highest level of schooling attained (primary school, high school, a trade qualification, diploma, degree, higher degree)?
- Parity how many babies had the woman had?
- Body mass index (BMI). BMI is a measure of weight (in kilograms) in relation to a woman's height (in centimeters). How tall was the woman (centimeters), how much did she weigh (kilograms)? This information was self reported by each of the participants.
- Length of consultation how many minutes did the consultation take? The length of the consultation was measured by me in whole minutes.
- Relationship status was the woman single (not married or living with a partner), married, living with a partner, divorced or widowed?
- Work status did the woman work in a full time, part time or volunteer capacity? Was she a homemaker, or was she seeking work?
- Country of birth in which country was the woman born?
- Subjective knowledge about the woman's condition or treatment
- First language what was the woman's primary preferred spoken language?
- Accompanied at consultation was the woman accompanied at the consultation? Was the accompanying person a family member, a friend or a professional carer?
- Sexually active was the woman ciurently sexually active?

All of these details were noted on the data collection sheet and then entered into a REDCap database after the completion of the clinic session (Appendix 4 – Data Collection Sheet).

3.4 DATA SOURCES AND MEASUREMENT

Data analysis was conducted using SPSS (Version 26.0) (IBM, 2019). Outcome data are presented in table, graph and written form. In this study I have analysed the primary study data. My data analysis was externally checked by a statistician from the Department of Mathematics and Statistics at La Trobe University, Melbourne, Australia. Written permissions to use the included questionnaires were obtained from each of the original study authors (Appendix 8 - Permissions).

Prior to the consultation, demographic and clinical data were collected and recorded on the Data Collection Sheet. Pre consultation measures included the Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) health literacy test, the Australian Pelvic Floor Questionnaire and subjective knowledge scores (Subjective knowledge – Measure 1).

The Short Assessment of Patient Satisfaction (SAPS) questionnaire was given to participants to complete immediately after the completion of the clinical consultation. Subjective knowledge scores post consultation were completed immediately following the consultation (Subjective knowledge – Measure 2). A third estimate of subjective knowledge was recorded when participants were contacted by telephone one month following consultation (Subjective knowledge – Measure 3).

3.5 BIAS

The following procedures were adopted to minimise bias.

3.5.1 Selection bias

Selection bias could have been a feature, as the study was limited to women only. All women attending a particular clinic may not have been able to be invited to participate in the study due to time constraints. To minimise selection bias a systematic approach was used, using a random sampling method, to ensure that every woman attending a participating hospital clinic had the same chance of being invited to participate in the study.

3.5.2 Social desirability bias

Social desirability bias could also have been a factor in this study. In order to avoid social desirability bias all women who participated in the study had the purpose of the study explained to them, both verbally and in written form. The value of truthful and honest responses was stressed to each woman regarding consultation with their clinician. Participants were asked to give true and accurate responses to all of the study questionnaires. Women were reminded that answers to the surveys should reflect their own experience and be reassured that any responses would remain at all times confidential. Potential participants were reassured that the clinician she had consulted with would not see her responses to the consultation, now or at a later date. There was a danger that women who were approached in person and asked to take part would feel obliged to participate. By allowing sufficient time (a minimum reading time of 30 minutes) for potential study participants to read the Patient Information and Consent document, ask any relevant questions about the risks or benefits of participation, reflect on the provided information and consider participation, this type of bias was minimised. Women were verbally reminded that their participation was voluntary. Social desirability bias was therefore minimised as much as possible.

3.5.3 Presentation bias

In Malone (2014, p280) Hernán suggests that presentation bias may occur when participants in a study are limited to those who volunteer to take part, rather than those who are randomly selected to participate as part of a systematic approach to recruitment (Malone, Nicholl, & Tracey, 2014). Presentation bias could have been an issue in this study, however, it was not expected to be problematic as only women who were in attendance for their scheduled appointment on any given day were personally approached and invited to participate in the study. Only women who were formally approached and invited to take part were recruited to the study. Presentation bias was therefore minimised.

3.6 STUDY SIZE

The sample size was determined using Epidemiological Calculators (Sergeant, 2018). A sample size of 202 women was initially calculated and a further 20 subjects (10%) were added to the initial number to account for women who may have withdrawn from the study at any time or were lost to study follow-up. The sample size calculated was therefore 222 participants.

The sample size was based on the following assumptions - The mean satisfaction score in the high health literacy group was 47.54 (SD = 10.11); and the satisfaction score in the low health literacy group was 46.10 (SD = 10.11). An alpha of .05, power of 90% and a ratio of high to low health literacy was 1:1.

3.7 QUANTITATIVE VARIABLES

Variables were continuously entered into the specifically designed REDCap database. Quantitative variables were entered into REDCap as whole numbers. Country of birth were coded as Australia or other. First language was coded as English or other.

3.8 STATISTICAL METHODS

Results were analysed using SPSS (version 26.0) following data export from the REDCap database. Simple linear regression and multiple regression analyses were performed. Descriptive statistics and frequencies were computed to summarise the collected data. Multivariate regression was used to test the association between health literacy and satisfaction with consultation. Also, the association between satisfaction with consultation and length of consultation was tested. The association between satisfaction with consultation text and numerical format using REDCap. Checks were routinely undertaken on at least 10% of the entered data records to check for data entry accuracy. Collected data were analysed using SPSS.

How were missing data handled?

Missing data were minimal. There were a small number of women who were lost to follow-up at one month. One woman withdrew from the study after the initial consultation so was not contacted for follow up. Despite this the original sample size estimation of 202 was exceeded. All data records, including the woman who withdrew her consent, were included in the statistical analysis.

3.9 CHAPTER SUMMARY

In this observational study I aimed to recruit 222 women, in an effort to assess the association between health literacy and patient satisfaction, patient satisfaction in relation to length of clinical consultation and patient satisfaction in relation to subjective knowledge in several clinics involving various clinicians including nurses, physiotherapists and doctors.

All women who were approached were given written information regarding the purpose and processes of the study and if they agreed to participate they were required to provide written consent. Ethical approval was sought and obtained from the Mercy Hospital for Women, Werribee Mercy Hospital and La Trobe University Research Ethics Committees. Validated instruments were used to assess satisfaction with consultation, subjective knowledge, presenting symptoms and health literacy levels. Consultation duration was measured. Likert scores were used to measure subjective patient knowledge. Procedures were adopted to minimise selection bias, social desirability bias and presentation bias. A random sampling method was employed to prevent and ensure there was no selection bias. All of the collected data were entered into a REDCap database. On completion of recruitment, data were exported to SPSS for analysis. Collected data has been securely stored and has ongoing restricted access.

Chapter 4: RESULTS

The reporting of my study's results strictly adheres to the American Psychological Association reporting guidelines (APA) (American Psychological Association, 2013). In this chapter I will show demographic and clinical characteristics of the study participants, as well as show the results of linear and multiple regression analyses.

My primary hypothesis is that women with low health literacy are less satisfied with clinical consultation than women with high health literacy.

My secondary hypothesis is that women who have a shorter consultation are less satisfied with clinical consultation than women who have a longer consultation.

My third hypothesis is that women who have higher subjective knowledge levels also have higher levels of satisfaction.

4.1 PARTICIPANTS

To test the association between patient satisfaction with clinical consultation and health literacy, clinical consultation and consultation length and subjective knowledge and satisfaction, 222 study participants were recruited from the various participating hospital clinics. Participants attended the hospital for clinical consultation and were assessed before and immediately following their time with the clinician (doctor, nurse or physiotherapist). Recruitment to the study took place from September 2018 and was concluded in December 2018. A follow-up telephone call was made one month later to finalise data collection. All follow-up telephone calls were completed in February 2019.

Participating women had on average a mean age of 54 years and they had on average had two babies. On average the study participants had attended school for 14 years and

were found to have high levels of health literacy following formal health literacy testing. Study participants attended all of the targeted clinics and consulted with doctors, nurses and physiotherapists.

4.1.1 Flow of study participants

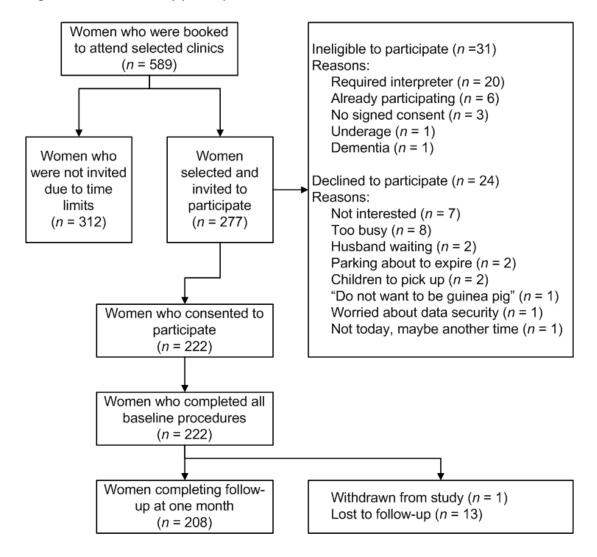
Recruitment to the study was conducted over a 13 week period between September 2018 and December 2018, and all study measures were completed in February 2019.

A total of 589 women were booked to attend the selected clinics on the days when I was available to recruit subjects to the study. Of these 589 women, 392 (67%) had an appointment scheduled in one of the Urogynaecology Clinics (Pessary Clinic, Urodynamics Clinic, Outpatients Clinic or Perineal Clinic), 98 (17%) in the Physiotherapy Clinic, 76 (13%) in the Well Women's Clinic and 23 (4%) in the Pre Admission Clinic. Two hundred and seventy-seven of the 589 women were randomly selected from the prepared clinic lists and personally approached and offered inclusion in the study, according to the random selection method previously described in the methods section of this thesis.

Three hundred and twelve (53%) of the original 589 women who were booked to attend clinics could have been approached had more time been available for study recruitment procedures. The 312 women were not able to be invited due to time constraints within the clinic structure (each morning or afternoon clinic session operated for a period of a maximum of four hours). Of the 312 women who were not able to be invited to take part in the study, 240 (77%) were booked to attend one of the Urogynaecology Clinics, 51 (16%) to attend the Physiotherapy Clinic, 28 (9%) to attend the Well Women's Clinic, and 1 (.3%) woman was booked to attend the Pre Admission Clinic.

Of the 277 women who were randomly approached and invited to participate, 222 (80%) women agreed to take part and their written consent was obtained. One hundred and twenty (43%) women were attending one of the Urogynaecology Clinics, 39 (14%) the Physiotherapy Clinic, 46 (17%) the Well Women's Clinic and 17 (6%) the Pre Admission Clinic (Figure 3 – Flow of study participants).

Figure 3 - Flow of study participants



Thirty one of the 277 women (11%) were ineligible to participate. A further 24 women (9%), when approached and invited to take part, declined to participate in the study (Table 1, Women who declined or were ineligible to participate).

Of the 55 women who were ineligible or declined participation, proportionately more women booked to attend the Well Women's Clinic declined to participate (12%), and more women booked to attend the Pre Admission Clinic were ineligible to participate in the study (23%). There was no systematic reason apparent for declining participation in the study. Reasons for declining or being ineligible are shown in Figure 3 (Figure 3 - Flow of study participants).

Clinic	Urogynaecology Clinic	Physiotherapy Clinic	Well Women's Clinic	Pre-Admission Clinic
Declined to participate (<i>n</i> =24)	14	4	6	0
Ineligible to participate (<i>n</i> =31)	16	5	5	5

Table 1 - Women who	declined participation	. or were ineligible to	participate
	accinica participation		participate

Initial consultation visit

All study participants were recruited from the nominated participating clinics which included Urogynaecology Clinics (Pessary Clinic, Urodynamics Clinic, Urogynaecology Outpatients' Clinic or Perineal Clinic), Physiotherapy Clinic, Well Women's Clinic or Pre Admission Clinic, as described in the study methods. Two hundred and twenty two women agreed to participate in the study with 120 (54%) attending one of the Urogynaecology Clinics, 39 (18%) attending Physiotherapy Clinic, 46 (21%) attending Well Women's Clinic and 17 (8%) attending Pre Admission Clinic.

Two hundred and twenty two women (100%) completed all aspects of the study at the initial consultation visit (demographic and clinical details, study questionnaires, Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) health literacy test and subjective knowledge scores (Measure 1 and Measure 2)).

One month study follow-up

A subjective knowledge question was asked – How much knowledge do you have about your condition or treatment?

One month following the initial consultation I was able to contact 208 (94%) women to ask the final follow-up question regarding subjective knowledge. At this follow-up telephone call I was able to complete the final study measure (Subjective knowledge – Measure three). Fourteen (6%) records had missing data at this time point. Unsuccessful attempts to contact 13 women by telephone at one month were made on several occasions, in an effort to collect and finalise the study measures. One woman had withdrawn her consent so was not contacted for follow-up at one month. The details of study participants is shown in Figure 3 (Figure 3 – Flow of study participants).

4.2 DESCRIPTIVE DATA - PRIMARY ANALYSIS

What were the demographic characteristics of the study participants?

Demographic characteristics are shown in Table 2 (Table 2 - Demographic characteristics of study participants).

All demographic details of participants were collected at the time of recruitment and clinical consultation. These details were noted on the paper data collection sheet. Participants had an average age of 54 years and had on average had two babies. They had attended school on average for 14 years. Eighteen (8%) of the 222 participants had attended primary school only. Sixteen women (7%) had a higher degree. Almost two thirds of the women were married (54%) or were living with a partner (10%). Half of the women were in paid work (50%) or peformed volunteer work (6%). Health literacy test scores were high with a mean REALM – R score of 6.95/8. One quarter of the study's participants failed the REALM – R health literacy test (Table 2 - Demographic characteristics of participants).

Variable	n = 222, n (%)
Age (in years, mean), (SD), 95% Cl	54.15 (17), 51.86, 6.44
Parity (number of babies), mean (SD), 95%Cl	2.14 (2.00), 1.92, 2.36
Formal schooling years, mean (SD), 95%Cl	13.68 (4.00), 13.11, 14.25
Highest qualification	
Primary school	18 (8%)
High school	82 (37%)
Trade qualification	5 (2%)
Diploma	41 (19%)
Degree	60 (27%)
Higher degree	16 (7%)
Relationship status	
Single	33 (15%)
Married	120 (54%)
Living with partner	21 (10%)
Divorced	27 (12%)
Widow	21 (10%)
Work status	
Full-time	50 (23%)
Part-time	60 (27%)
Volunteer	14 (6%)
Homemaker	96 (43%)
Seeking work	2 (0.9%)
REALM – R* score , mean (SD), 95%Cl	6.95 (1.88), 6.71, 7.20

Table 2 - Demographic characteristics of study participants

*REALM –R is the Rapid Estimate of Adult Literacy in Medicine - Revised

What were the clinical characteristics of the study participants?

Satisfaction with consultation scores were high with a mean score of 24.6/28. The mean consultation duration was 26.5 minutes. More than half (54%) of the women attended one of the participating Urogynaecology Clinics. Participants consulted with all of the clinicians involved with more women being seen by a doctor (45%), than a nurse (37%) or a physiotherapist (18%).

When asked, women generally felt knowledgeable about their condition or treatment with subjective knowledge scores high prior to the clinical consultation (8/10). These scores increased immediately after the consultation (9/10) and were maintained above the pre consultation score at one month (8.4/10).

Women self reported various presenting symptoms, with urge urinary incontinence (37%) and stress urinary incontinence (35%) most commonly reported. Other presenting symptoms were reported by the study's participants. Seventy two of the 222 (32%) women presented to the four participating clinics for various clinical reasons classified as other. Of these 72 women, 46 women (64%) presented to the Well Women's Clinic for cervical screening and 17 (24%) women presented to the Perineal Clinic for assessment and management of a pre existing obstetric anal sphincter injury. Further conditions such as recurrent urinary tract infection, menorrhagia, uterine polyp, voiding difficulty, interstitial cystitis, constipation, vesico vaginal fistula and faecal incontinence were also reported by women and categorised as other presenting symptoms. More than half (51%) of the participants reported that they were not sexually active. Participants had a mean body mass index of 28. Thirty-seven (17%) women were accompanied during the clinical consultation.

Clinical characteristics of the study participants are shown in Table 3 (Table 3 - Clinical characteristics of study participants).

Variable	n = 222, n (%)
	Mean
	Standard deviation (SD)
	95% Confidence Interval
Short Assessment of Patient Satisfaction total, mean (SD), 95%Cl	24.64 (3.9), 24.13, 25.16
Clinic	
Urogynaecology	120 (54%)
Physiotherapy	39 (18%)
Well Women's	46 (21%)
Pre-Admission	17 (8%)
Clinician	
Doctor	99 (45%)
Nurse	83 (37%)
Physiotherapist	40 (18%)
Presenting symptom	
Stress incontinence	77 (35%)
Urge incontinence	85 (38%)
Mixed incontinence	48 (22%)
Prolapse	35 (16%)
Pain	14 (6%)
Other	72 (32%)
Body Mass Index , mean (SD), 95%Cl	28 (6.00), 27.40, 29.0
Accompanied at consultation?	37 (17%)
Consultation duration (minutes), mean (SD), 95%Cl	26.50 (10.96), 25.05, 27.94
Australian Pelvic Floor Questionnaire score	
Bladder score , mean (SD)	12.01 (9.12)
Bowel score, mean (SD)	6.32 (5.01)
Prolapse score, mean (SD)	1.86 (3.48)
Sexual function score, mean (SD)	4.00 (2.95)
Subjective knowledge	
Pre Consultation score, mean (SD)	7.95 (2.18)
Post Consultation (immediate) score, mean (SD)	8.98 (1.13)
Post Consultation (one month) score, mean (SD)	8.38 (1.60)
Sexually active	109 (49%)

Table 3 - Clinical characteristics of study participants

4.2.1 Data checking

Collected data were first recorded on the paper data collection sheet and then entered into a REDCap database at a later time. On completion of the data entry processes for the 222 study participants, data were exported to an Excel spreadsheet, then downloaded to SPSS for analysis.

As described in the study methods, initially a randomly selected 10% of the 222 data records (20 records) were checked for accuracy of manual data entry. Every tenth study record (records number 1, 11, 21, 31, 41, 51, 61, 71, 81, 91, 101, 111, 121, 131, 141, 151, 161, 171, 181, 191, 201, 211 and 221) was selected for data entry accuracy checking. Following this method of checking, some minor data entry errors were discovered and rectified. Due to the discovery of some errors, all 222 sets of patient data entered into REDCap were checked against the paper data sheet for accuracy and minor corrections remedied when discovered. Outliers were not removed from the data sample.

4.3 OUTCOME DATA

Report numbers of outcome events or summary measures

There were three occasions when data were collected.

The first measures were collected at the initial study recruitment when demographic and clinical data were obtained for all study participants. Questionnaires included Australian Pelvic Floor Questionnaire and estimation of subjective knowledge (Measure one). Health literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R).

The second time point occurred immediately following the consultation. Measures included the recording of the consultation's duration, the Short Assessment of Patient Satisfaction questionnaire (SAPS) and measurement of subjective knowledge (Measure two).

The third time point was at a follow-up telephone call. It was made at one month to further record subjective knowledge (Measure 3).

Simple linear regression

Simple linear regression was used to determine the association between patient satisfaction with clinical consultation and each of the study variables. Regression aimed to investigate patient satisfaction (Short Assessment of Patient Satisfaction - SAPS) scores in relation to the independent variables. Following simple linear regression analysis a significant association was found between satisfaction with consultation (SAPS score) and the following variables - Clinic Type, Presenting Symptom - Urge Incontinence, Presenting Symptom - Other, Subjective knowledge score (Measure – 2) and Subjective knowledge score (Measure – 3).

There was no association found between satisfaction with consultation (SAPS score) and health literacy score, length of consultation, age, BMI, highest educational qualification, formal schooling years or clinician type. These results are shown in Table 4 (Table 4 - Simple linear regression).

Simple linear regression model summary (satisfaction and health literacy)

A simple linear regression analysis was undertaken to evaluate the association between patient satisfaction with clinical consultation (SAPS score) and REALM - R health literacy scores. There was no linear relationship found between health literacy and patient satisfaction with consultation (p = .61).

Model summary –

(F(1,220) =.202, p = <.61, with an R² value of .001). The adjusted R² value was -.003. This indicates that the strength of the relationship is small, with <1% of the variance in Short Assessment of Patient Satisfaction (SAPS) scores explained by health literacy scores. Health literacy score is not a significant predictor of patient satisfaction (p = .61). The adjusted R² = .003, which indicates a poor fit.

Simple linear regression model summary (satisfaction and consultation duration)

A further simple linear regression analysis was undertaken to evaluate the association between patient satisfaction with clinical consultation (Short Assessment of Patient Satisfaction - SAPS) and length of clinical consultation. There was no linear relationship found between patient satisfaction with consultation and consultation length (p = .34).

Model summary

(F(1,22) = .904, p = <.34, with an R² value of .004). The adjusted R² value was .000. This indicates that the strength of the relationship is small, with <1% of the variance in Short Assessment of Patient Satisfaction (SAPS) scores explained by consultation length. Consultation length is not a significant predictor of patient satisfaction (p = .34). The adjusted R² = .000, which indicates a poor fit.

Table 4 - Simple linear regression

Independent Variable	n	Beta Coefficient	R Squared Value	Residual - Mean Square	(p) value
REALM - R score	222	.04	≤.05	15.0	.61
Consultation duration	222	.06	≤.05	15	.34
Body Mass Index	222	06	≤.05	15	.41
Parity	222	01	≤.05	15	.89
Subjective knowledge score - Measure-1	222	.06	≤. 05	15	.36
Subjective knowledge score – Measure-2	222	.21	.04	14	≤.05
Subjective knowledge score – Measure-3	208	.23	.05	15	≤.05
Patient Age	222	.01	.01	15	.14
Clinician Type	222	05	≤.05	15	.46
Clinic Type	222	.20	.04	14	≤.05
Presenting Symptom – Urge Incontinence	222	18	.03	15	≤.05
Presenting Symptom – Stress Incontinence	222	07	≤.05	15	.29
Presenting Symptom – Mixed Incontinence	222	09	≤.05	15	.19
Presenting Symptom – Prolapse	222	04	≤.05	15	.54
Presenting Symptom – Pain	222	09	.09	15	.18
Presenting Symptom – Other	222	.24	.06	14	≤.05
Accompanied at Consultation	222	.03	≤.05	15	.32
Formal Schooling Years	222	.05	≤.05	15	.44
Highest Educational Qualification	222	.08	≤.05	15	.23
Relationship Status	222	01	.01	15	.14
Work Status	222	01	≤.05	15	.15

4.4 MAIN RESULTS

4.4.1 Patient satisfaction scores

The main outcome measure for this study was the Short Assessment of Patient Satisfaction questionnaire (SAPS).

The distribution of satisfaction scores were analysed. Short Assessment of Patient Satisfaction (SAPS) scores were high for all clinics and for all clinicians involved in the study. Overall the mean Short Assessment of Patient Satisfaction (SAPS) score for the clinical consultation was 24.6/28, indicating high levels of satisfaction across all clinics and across all clinicians.

While satisfaction scores were high for all clinics they did vary slightly for each of the clinics involved in the study. In the various Urogynaecology Clinics the mean score was 24/28 (range 2-28), the Physiotherapy Clinic mean score was 26/28 (range 19-28), the Well Women's Clinic mean score was 26/28 (range 11-28) and the Pre Admission Clinic mean score was 25/28 (range 19-28).

Patient satisfaction results relating to the type of clinician that participants consulted with also varied, with satisfaction scores high for all, and similar for all clinicians. Nurses had a mean score of 26/28 (range 19-28), physiotherapists 26/28 (range 19-28) and doctors had a mean satisfaction score of 24/28 (range 2-28).

4.4.2 Consultation length

The mean consultation length in the study group was 26.5 minutes (range 7–73 minutes). There was no association in relation to satisfaction with the clinical consultation, based on consultation length (p = .34).

Consultation duration was divided into two group - a consultation time of 15 minutes or less (shorter consultation) and a consultation time of 16 minutes or longer (longer consultation). Thirty-six (16%) women had a shorter consultation time of 15 minutes or less (range 7-15 minutes) and 186 (84%) women had a longer consultation time of 16 minutes or more (range 16-73 minutes).

In the Urogynaecology Clinics the mean consultation length was 27 minutes, Physiotherapy Clinic was 31 minutes, Well Women's Clinic was 23 minutes, and Pre Admission Clinic was 19 minutes.

4.4.3 Subjective knowledge scores

Subjective knowledge estimates were high across all of the three measured time points. Subjective knowledge prior to the consultation was 8/10, increased at the post consultation measure to 9/10 and at one month it was maintained above the pre consultation score at 8.4/10.

Two hundred and twenty (99%) women completed the subjective knowledge score immediately before and immediately following the consultation. Two women left the clinic before I could ask this question and were contacted by telephone on the same day as the consultation to complete these measures. One month following the initial clinical consultation 208 (94%) women were able to be contacted by telephone to complete the subjective knowledge score. Thirteen women (6%) were lost to follow-up and one (.5%) woman had withdrawn her consent so was not contacted.

4.4.4 Health literacy measurement

A Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) test result of seven or eight out of a possible score of eight indicated adequate health literacy. A score of six or less indicated low health literacy.

Following formal health literacy testing, the Rapid Estimate of Adult Literacy in Medicine –Revised (REALM – R) literacy test mean score for all participants was 6.93 (range 0 - 8). One hundred and forty two women (64%) scored the maximum score (8/8) for the health literacy test, correctly reading aloud all of the eight scored test words. Analysis of health literacy test results showed that three (1%) women were unable to correctly read any of the eight test words, seven (3%) women read one test word, two (1%) women read two test words, four (2%) women read three test words, seven (3%) women read four words and seven (3%) women read five words. Twenty-five (11%) women were able to read six test words correctly. A total of 56 (25%) women failed the health literacy test, with a Rapid Estimate of Adult Literacy in Medicine –Revised (REALM – R) score $\leq 6/8$.

4.4.5 Participant country of birth

Study participants were asked to state their country of birth. Results showed that the 222 study participants were born in 37 different countries. A total of 130 (59%) study participants were born in Australia. A further nine (4%) women were born in India, eight (4%) women were born in Italy, eight (4%) women were born in Greece, seven (3%) women were born in Macedonia, seven (3%) women were born in England and five (2%) women were born in New Zealand. There were a further 30 countries of birth represented in the study group (Appendix 9 - Country of birth).

4.4.6 Participant preferred first language

Study participants were asked to state their preferred first language. Thirty three different language groups were nominated by the 222 study participants. A total of 144 (65%) women spoke English as their first language. A further 11 (5%) women spoke Italian, 10 (5%) women spoke Greek, seven (3%) women spoke Macedonian, four (2%) women spoke Punjabi and four (2%) women spoke German. There were a further 27 languages nominated by the women (Appendix 10 - First language).

4.4.7 Multiple regression

Multiple regression was the second step which was performed in the data analysis. Following identification of variables that were found to be significant using simple linear regression, multiple regression was used to test the association between the dependent variable (satisfaction with consultation (Short Assessment of Patient Satisfaction (SAPS total)) and the identified, statistically significant independent variables previously identified (Clinic type, Presenting symptom – Urge urinary incontinence, Presenting symptom – Other, Subjective knowledge - Measure 2 (immediately post consultation) and Subjective knowledge - Measure 3 (one month post consultation).

Results are shown in Table 7 (Table 7 - Mean, Standard Deviation, and Correlations for Short Assessment of Patient Satisfaction total and Predictor variables).

Multiple regression model summary

A multiple linear regression was calculated to predict patient satisfaction (SAPS total) based on (Clinic type, Presenting symptom – Urge incontinence, Presenting symptom – Other, Subjective knowledge – Measure 2 and Subjective knowledge – Measure 3). A significant regression equation was found (F(5, 202) = 5.10, p < .000), with an R² of .112.

Participants' predicted satisfaction (SAPS) is equal to $18.218 + .496 (IV_1) + .460 (IV_2), + 1.211 (IV_3) + .368 (IV_4) + .230 (IV_5), where Clinic type (IV^1) is coded or measured as 1 = Urogynaecology Clinic, 2 = Well Women's Clinic, 3 = Physiotherapy Clinic and 4 = Pre–$ Admission Clinic. Presenting symptom – Urge incontinence (IV²) is coded or measured as 0 = No, and 1 = Yes. Presenting symptom – Other (IV³) is coded or measured as 0 = No, and 1 = Yes. Subjective knowledge – Measure 2 (IV⁴) is measured as a scale value (range 1-10).Subjective knowledge – Measure 3 (IV⁵) is measured as a scale value (range 1-10).

Short Assessment of Patient Satisfaction (SAPS) score increased .496 (of SAPS units, SAPS score of one) for each (Clinic type) (IV_1) and -.460 for each Presenting symptom – Urge incontinence (IV_2) and 1.211 for each Presenting symptom - Other (IV_3) and .368 for each Subjective knowledge – Measure 2 (IV_4) and .230 for each Subjective knowledge – Measure 3 (IV_5).

Following multiple regression analysis Clinic type (IV_1) was a significant predictor of patient satisfaction with consultation (p = .04). There was a statistically significant association between Presenting symptom – Other (IV_3) and satisfaction with consultation (p = .05).

Table 5 - Multiple regression

Variable	В	SE B	β	t	Р
Clinic type (<i>n</i> = 222)	.56	.27	.14	2.08	.04
Presenting symptom – Urge incontinence (<i>n</i> = 222)	39	.62	05	62	.53
Presenting symptom – Other (<i>n</i> = 222)	1.28	.66	.16	1.97	.05
Subjective knowledge – Measure 2 (<i>n</i> = 222)	.39	.27	.12	1.44	.15
Subjective knowledge study – Measure 3 (<i>n</i> = 208)	.2	.2	.81	.97	.33

Variable, (n)	Mean	SD	Correlations					
Measure, (n)			Short Assessment of Patient Satisfaction total, (p)	Clinic Type (p)	Presenting symptom - Urge incontinence (p)	Presenting symptom - Other (p)	Subjective Knowledge (Measure2) (p)	Subjective Knowledge (Measure3) (p)
SAPS total (<i>n</i> = 222)	24.54	3.9	1	.19 (≤ .05)	19 (≤ .05)	.24 (≤ .05)	.21 (≤ .05)	.23 (≤ .05)
Predictor variables								
Clinic type (<i>n</i> = 222)	1.77	.99	.19 (≤. 05)	1	26 (≤ .05)	.01 (.08)	.15 (.02)	.23 (≤ .05)
Presenting symptom — urge incontinence (<i>n</i> = 222)	.38	.49	19 (≤.05)	26 (≤ .05)	1	52 (≤.05)	10 (.07)	16 (≤ .05)
Presenting symptom – other (<i>n</i> = 222)	.32	.47	.24 (≤ .05)	.01 (.08)	52 (≤ .05)	1	.20 (≤ .05)	.30 (≤ .05)
Subjective knowledge – measure 2 (<i>n</i> = 222)	9.00	1.1	.21 (≤ .05)	.14 (.02)	10 (.07)	.20 (≤ .05)	1	.56 (≤ .05)
Subjective knowledge study measure 3 (<i>n</i> = 208)	8.38	1.6	.23 (≤. 05)	.23 (≤ .05)	16 (.1)	.30 (≤ .05)	.56 (≤ .05)	1

4.5 **RESULTS SUMMARY**

Two hundred and twenty two women were successfully recruited to the study between September 2018 and December 2018. All data collection was completed in February 2019. All data were entered into a REDCap database. Results were analysed using SPSS.

In this chapter results have been reported and presented to illustrate a clear picture of the study findings. Analysis using simple linear regression demonstrated that there was no association found between patient satisfaction with clinical consultation and health literacy. There was also no association between patient satisfaction and length of clinical consultation. analysis demonstrated that there was an association between patient satisfaction with clinical consultation and subjective knowledge.

Simple linear regression confirmed an association between satisfaction with consultation and the following - Clinic type, Presenting symptom - urge incontinence, Presenting symptom - other, Subjective knowledge scores immediately following clinical consultation (Subjective knowledge - Measure 2) and Subjective knowledge one month following consultation (Subjective knowledge - Measure 3).

Multiple regression analysis showed a statistically significant association between the Short Assessment of Patient Satisfaction score (SAPS score) and Clinic type, as well as Presenting symptom – Other.

4.6 OTHER ANALYSES

No subgroups were created in this analysis

Chapter 5: DISCUSSION

5.1 KEY RESULTS

The aim of my research project was to test the association between satisfaction with clinical consultation and health literacy, to test the association between satisfaction with clinical consultation and length of consultation and to test the association between satisfaction with consultation and subjective knowledge. Study hypothesis testing has been completed and there has been no association found between health literacy and patient satisfaction with clinical consultation. There has also been no association found between length of clinical consultation and satisfaction with consultation between satisfaction with consultation and satisfaction with consultation. An association between satisfaction with consultation and subjective knowledge has been shown.

The Rapid Estimate of Adult Literacy in Medicine – Revised (REALM - R) health literacy testing procedure was completed with all study participants, according to author guidelines. The test was well tolerated, with no complaints about the testing procedure from any of the study participants. The test was quick and easy to perform. In this study 25% of the study participants failed this validated health literacy test, which was less than I had anticipated, based on previous publication data from the Australian Institute of Health and Welfare which suggests that only 41% of Australians aged 15 – 74 years have adequate health literacy levels (AIHW, 2016b).

Satisfaction with clinical consultations was high. Women who attended the Urogynaecology Clinic were a little less satisfied with the consultation than women who attended the other participating clinics, although satisfaction levels were high for all clinics involved in this study. Satisfaction with all of the clinicians who took part in the study was also high, with women attending the Well Women's Clinic having the highest level of satisfaction. In regard to presenting symptoms, women who attended for consultation and presented with urge urinary incontinence were less satisfied with the consultation than women who presented with other symptoms such as stress urinary incontinence, pelvic organ prolapse, pelvic pain or women presenting for reasons listed as other, which included those presenting for cervical screening or for assessment of anal sphincter injury, for instance. Women who presented with symptoms that were classified as other were more satisfied with the clinical consultation than women who presented with symptoms such as urge urinary incontinence or pelvic organ prolapse. Overall satisfaction scores for all consultations, and for all clinicians were high.

5.2 INTERPRETATION

Following linear and multiple regression analyses the results of my study show that there was no association found between health literacy and patient satisfaction with consultation, or with length of consultation and patient satisfaction. An association between satisfaction and subjective knowledge was shown. The objectives of the study were met.

5.2.1 Patient satisfaction

What is known about the association between health literacy and patient satisfaction with clinical consultation?

At least 18 authors have identified the link between low health literacy and adverse health outcomes. These authors all agree that people who have been found to have low health literacy are known to have an increased number and length of hospitalisations, lower utilisation of preventative health care programs and health care interventions, less knowledge of and effective management of chronic disease, increased rates of medication errors, overall poorer health outcomes, limited abilities regarding decision making and more health care costs compared to people with higher health literacy levels (Adams et al., 2013; Anger et al., 2012; Brabers et al., 2017; Edwards, Wood, Davies, & Edwards, 2012; L. A. Ferguson & Pawlak, 2011; Ganesh, 2017; Goodman, Griffey, Carpenter, Blanchard, & Kaphingst, 2015; S Hill & Sofra, 2017; Jones et al., 2016; Jordan, Buchbinder, & Osborne, 2010; MacLeod et al., 2017; Nutbeam, 2008; Roett & Wessel, 2012; Sand-Jecklin, Daniels, & Lucke-Wold, 2017; S. K. Smith et al., 2013; White, Chen, & Atchison, 2008; Yim et al., 2018).

Previous studies have shown inconsistent results in reporting outcomes regarding health literacy and its association with patient satisfaction (MacLeod et al., 2017). A positive association has been demonstrated between health literacy and increased satisfaction with consultation by four authors, with people with higher health literacy being shown to be more satisfied compared to those with lower levels of health literacy (Altin & Stock, 2016; Brabers et al., 2017; Hendriksen et al., 2011; Yim et al., 2018). Alternatively, Kandelaki (2016) and Jensen (2010) both found that people with low health literacy were more satisfied than those with higher levels of health literacy (Jensen, King, Guntzviller, & Davis, 2010; Kandelaki et al., 2016). Furthermore, MacLeod (2017) reports an association between low health literacy and lower levels of patient satisfaction, older age and poorer health (MacLeod et al., 2017). Verkissen (2014) and Roh (2016) also found that satisfaction levels were lower in patients with low health literacy (Roh et al., 2016; Verkissen et al., 2014).

One author (Goggins, 2014) measured both health literacy and numeracy and found that higher health literacy and numeracy was associated with higher inclination to be involved in problem solving, decision making and an overall more active level of participation in health care processes (K. M. Goggins et al., 2014). Findley (2015) linked higher health literacy with higher educational attainment, higher levels of income and greater engagement in paid employment, and like MacLeod (2017), also found that health literacy levels decreased with advancing age (Findley, 2015). Similar to my study findings, two further authors, Anger (2012) and Hallock (2017), failed to demonstrate any association between health literacy and patient satisfaction with health care (Anger et al., 2012; Hallock et al., 2017).

The author of the Short Assessment of Patient Satisfaction (SAPS) questionnaire (Hawthorne, 2014), reasons that dissatisfaction can occur when people's expectations and

their experiences do not match and suggests that the most important element of the consultation is a positive and constructive relationship between the patient and the clinician. According to Hawthorne (2014), this relationship can be influenced by past experiences and health care outcomes which can have an effect on both patient and clinician alike (Hawthorne et al., 2014).

Study findings in relation to published literature

My current study results are in line with Anger and Hallock's findings in that there was no association demonstrated between health literacy and satisfaction with clinical consultation. The study hypothesis proposed that women with low health literacy were predicted to be less satisfied with clinician consultations than women with higher literacy test scores. The results of my study failed to confirm this study hypothesis.

5.2.2 Satisfaction relating to clinician communication

Satisfaction levels for all consultations and for all clinicians was high in my study, regardless of health literacy test results. This result is in line with Yim (2018) who found similar results in a group of outpatients in a surgical setting (Yim et al., 2018). Yim and others have postulated that communication with all patients can be enhanced by implementation of plain language, simple explanations. Yim and others have proposed the increased use of teach back techniques along with the development and timely distribution of simple written materials to convey information to all patients, regardless of existing health literacy abilities (Anderson, KLeister, & De Rego, 2020; L. A. Ferguson & Pawlak, 2011; Griffey et al., 2015; Heijmans et al., 2015; Klingbeil & Gibson, 2018; Macabasco-O'Connell & Fry-Bowers, 2011; Mullen, 2013; Tingle, 2014; Wynia & Osborn, 2010; Yim et al., 2018).

Repetition of important aspects of the consultation, speaking slowly and encouraging patients to ask questions may also contribute to successful information exchange (Shirley & Sanders, 2013). The addition of plain language written materials may provide patients with confirmation of issued verbally discussed (Heijmans et al., 2015). The adoption of teach back techniques may allow clinicians to assess and confirm an individual patient's uptake of

information, knowledge or understanding about their condition or treatment, in a way that is less likely to cause shame or embarrassment to the patient (Anderson et al., 2020). This approach may also include the use of appropriate videos, educational posters, digital versatile discs (DVDs), practical demonstrations and pictures to convey information in a meaningful way. Teach back techniques also promote the adoption of a plain communication and language style in regard to the explanation of medical terms. Batterham (2016) also suggests that practitioners develop skills using teach back techniques to aid in effective and meaningful information exchange between patients and clinicians. Teach back techniques may increase and enhance understanding of a patient's condition or treatment options, enable more effective decision making to occur and contribute to improved patient satisfaction (Batterham et al., 2016).

Successful use of teach back techniques may be preferable to the implementation of mass health literacy testing or screening, which is also aimed at improving communication effectiveness. Batterham and others reason that a system of mass health literacy screening may cause stigmatisation, shame, anxiety and embarrassment to patients who may have low levels of health literacy. This author proposes that mass health literacy testing may not necessarily be required when an effective patient centred care approach, incorporating teach back techniques, is regularly used in the conduct of a clinical consultation (Batterham et al., 2016; Heinrich, 2012; Macabasco-O'Connell & Fry-Bowers, 2011). The creation of a clinical environment that is shame free, according to Wynia (2010) would aid in improved communication of health information (Wynia & Osborn, 2010).

My study results support this approach and I do not think that mass health literacy screening is necessary if a patient centred care approach is routinely used. This could involve the use of teach back techniques which are actively implemented and encouraged by health care organisations.

5.2.3 Patient centred care

A person's ability to acquire and understand new information can be improved and enhanced by a sensitive, personalised and tailored patient centred care approach. This approach may often result in improved levels of patient satisfaction with clinical consultations. In earlier times a more paternalistic approach to health care was often the norm, with clinicians regarded as experts who held knowledge, expertise and power over the patient and their families or careres regarding health care and health management. A paternalistic approach in the past may have often resulted in limited patient input into treatment planning and decision making processes (Gluyas, 2015; Nys, 2009; Wittink & Oosterhaven, 2018). Gluyas (2015) described three types of earlier clinician/patient relationships which include the paternalistic relationship, an informative relationship (where the clinician gives the patient information and the patient makes a decision) and thirdly an interpretive relationship which is more in line with a modern patient centred care approach (Gluyas, 2015).

In a 2010 paper, Wynia (2010, p103) stated that "Communication is one of the foundations of health care" and this author has suggested that effective clinician communication is linked to more effective health care strategies, improved levels of patient satisfaction and may contribute to improved patient health outcomes (Wynia & Osborn, 2010). A patient centred care approach proposes that each patient is an individual and ensures that clinicians take into account the preferences, ideas, values and beliefs of each individual patient, in relation to health care treatment or care and health care management. A patient centred care approach supports and actively encourages patients to make their own decisions regarding their treatment or care (Wynia & Osborn, 2010).

5.2.4 Patient satisfaction from an organisational perspective

Health care organisations and funding bodies now recognise the importance of patient satisfaction with health care delivery and have seen the benefits of a patient centred care approach. In a paper that examined person centredness from the patients' perspective, Edvardsson (2017) suggests that the patients' opinions were an important feature in the assessment of the quality of an organisation (Edvardsson, Watt, & Pearce, 2017). Satisfaction with health care, according to Pather (2010), links patient experiences with their earlier, preconceived expectations of care (Pather et al., 2010). Continuity of care is associated with higher levels of patient satisfaction (Shirley & Sanders, 2013). The published literature broadly supports and encourages overall the implementation of a patient centred care approach, with at least seven authors reporting higher levels of patient satisfaction with aspects of care when a successful patient centred care approach is employed by clinicians (Altin & Stock, 2016; Bungard et al., 2013; Delaney, 2018; Engel, Brinkman-Stopplenbung, & Nieboer, 2018; Gluyas, 2015; Kandelaki et al., 2016; Macabasco-O'Connell & Fry-Bowers, 2011; Wynia & Osborn, 2010).

Shared decision making between patient and clinician is a central tenet of a patient centred care process. In a patient centred care based consultation patients are actively encouraged to contribute to decision making regarding their treatment, care or management, according to their ability and their needs, values, and preferences. Health literacy limitations can somewhat be overcome, according to Wynia (2010), if a successful patient centred care approach is implemented by all staff across health care organisations. According to this author the lack of such an approach may contribute to poor health outcomes for people with low health literacy (Wynia & Osborn, 2010).

Clinicians who undergo specific education and training in patient centred care may contribute to increased and improved quality and safety across health care organisations (Macabasco-O'Connell & Fry-Bowers, 2011). Ongoing education of clinicians in patient centred care matters may contribute, according to Macabasco-O'Connell (2011), through encouragement of active patient participation, to improved uptake of information, optimisation of patient education levels, adherence to treatment regimens and result in increased patient involvement, satisfaction with care and improved health outcomes (Macabasco-O'Connell & Fry-Bowers, 2011).

5.2.5 Health literacy and older age

Health literacy scores were formally measured in my study and the level of low health literacy was less than expected, at 25%. The Australian Institute of Health and Welfare (AIHW) estimate that only 41% of Australians have adequate levels of health literacy, and importantly, that only 22% of older Australians (aged 60 - 74) have adequate health literacy skills (AIHW, 2016b). Older patients are more likely to report higher levels of satisfaction with consultation (Shirley & Sanders, 2013). Although the health literacy test pass rate in my study of 75% is significant, Anger (2012) has suggested that high levels of health literacy may not necessarily relate to a woman's capacity to understand complex conditions such as pelvic organ prolapse or other pelvic floor conditions (Anger et al., 2012).

This lack of understanding, according to Anger (2012) may lead to decreased satisfaction with provided treatment or care due to unrealistic expectations of the outcomes of treatment in women with high levels of health literacy. Anger (2012) has also reported that health literacy decreases with increasing age, perhaps affecting older women's understanding of their condition even more, and this author suggests that this lack of understanding may have implications for informed consent processes. Importantly, Anger suggests that a lack of understanding of pelvic floor conditions may prevent some women from seeking treatment which may result in a long term decrease in quality of life. Another impact of limited understanding of pelvic floor conditions may involve women who do seek treatment, especially for pelvic organ prolapse, but who do not completely understand the range of treatment options available to them (Anger et al., 2012).

Higher health literacy ability may enable people to take a more active role in decision making regarding their potential treatment or care. People with higher health literacy levels have been found to be better able to obtain, comprehend and apply newly gained information. Aboumatar (2013) found that though people with low health literacy may have had less knowledge and understanding of medical information, they were as interested in participating in decision making processes as those with higher levels of health literacy (Aboumatar et al., 2013). Higher levels of knowledge and comprehension associated with higher health literacy may lead to patients who are able to be more actively involved in their treatment or care, including decision making processes, according to Brabers (2017). Brabers (2017) has proposed that the ability to gather information and be able to process this information is necessary to better engage with the clinician in the decision making process, incorporating both information exchange and improvements in combined decision making (Brabers et al., 2017).

In an elderly population, according to a paper by Cohn (2017), an increased likelihood of urinary incontinence is associated with lower levels of health literacy, lack of identification of incontinence provoking factors and available treatment options, and lower levels of cognition. Cohn (2017) suggests that clinicians should directly question elderly patients regarding incontinence issues, and proposes the screening of elderly patients for both health literacy and cognitive function to better identify the prevalence of lower urinary tract symptoms (Cohn et al., 2017). Goggins (2014) reports similar findings and proposes that higher health literacy was associated with greater involvement and engagement by patients in their management, including problem solving and decision making practices (K. M. Goggins et al., 2014). In a urogynaecology study population, Sripad (2017) found health literacy levels to be high, but cautioned that older women with cognitive decline were at risk of having low health literacy. This author promotes a universal precautions approach to health care, where written materials are deliberately simplified to increase patient comprehension and satisfaction, and this style of information provision is implemented regardless of health literacy levels (Sripad et al., 2017).

5.2.6 Health literacy testing processes

In relation to health literacy testing, the Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) health literacy test has been widely validated and used to assess health literacy in various clinical contexts (Louis, Arora, & Mathiesen, 2016). This screening test has been found to be a reliable form of health literacy measurement. The REALM – R health literacy test was originally published in the Unites States of America and uses American English. Following discussion with my supervisors I left the spelling of anemia as it was originally designed by the study authors, rather than change it to the English version (anaemia) (Pat F. Bass et al., 2003). The American spelling could have either caused some confusion to women undertaking the health literacy test, or may have even made phonetic pronunciation of this test word easier. Leaving the questionnaire as originally designed ensured the REALM-R health literacy test's integrity.

In my study I found that 25% of participants had low health literacy when this measure was employed, with a REALM - R score of 6 / 8 or less, which was lower than expected. Results of health literacy testing of the study participants were higher than expected. Higher than expected rates of health literacy in the study population could have been due to the inclusion and exclusion criteria that I have applied. The lower than expected rate of poor health literacy may be related to the exclusion of women who used the services of an interpreter for the clinical consultation. Women who were excluded because they needed the services of an interpreter may possibly be more likely to have lower levels of health literacy compared to women who did not require the services of an interpreter. These women may possibly be more likely to have lower levels of health literacy compared to women who did not require the services of an interpreter. Also, women with low levels of health literacy may have been embarrassed or felt shame and on that basis perhaps declined inclusion in the study.

Following explanation of the study objectives and the careful verbal description of the health literacy testing process, there was no objection from any participant in my study to having their health literacy tested in the manner that I have previously described, using the REALM – R health literacy test. Earlier studies have suggested that patients may feel anxiety, embarrassment and shame relating to health literacy testing (Eubanks, Nodora, Hsu, & Bagley, 2017; Paasche-Orlow & Wolf, 2007; Wolf et al., 2007). Before any health literacy assessment is carried out, according to Wolf (2007), the risks to the patient must be

acknowledged regarding the effect of making public such a lack of literacy skill (Wolf et al., 2007).

Formalised health literacy testing, according to Paasche-Orlow (2007), has the potential for harm to patients in the form of shame, embarrassment, stigmatisation and a sense of alienation. These feelings of shame, stigmatisation and embarrassment caused by health literacy testing may outweigh any benefits gained by the organisation of universal or mass health literacy testing. This sense of shame could increase barriers to health care that these patients may already face when negotiating health care access and services. Paasche-Orlow (2007) suggests that a system of universal precautions would be a more effective approach rather than universal health literacy testing, to improve the transfer of health information from clinician to patient and the delivery of health care services (Griffey et al., 2015; Paasche-Orlow & Wolf, 2007; Wittenberg, Ferrell, Kanter, & Buller, 2018).

5.2.7 Measurement of health literacy

In my study, the health literacy evaluation procedure was conducted in a private area of the hospital, away from the public waiting room prior to the clinical consultation, and followed careful explanation of the test to each study participant. This may have been of benefit to women to assist them to feel at ease with the testing process.

Health literacy testing procedures that I used in my study are in line with the work of Ferguson (2011), Eubanks (2017) and Komenaka (2014). Ferguson (2011), in a study conducted in a primary care centre, suggests that formal health literacy screening should be performed to identify those with low health literacy. Ferguson (2011) examined patients' views regarding health literacy testing and found that there was no objection from study participants to the testing process. This author contends however, that the results of the formal health literacy screening did not correspond to patients' self reported reading levels, and suggests that this is a reason for the implementation of objective and universal health literacy testing of health literacy as part of routine clinical assessment in a surgical setting and used the Newest

Vital Sign health literacy test to do so. Like Ferguson, Eubanks (2017) also found the test was well tolerated and quick to perform in a surgical clinic setting. This author recruited 3,000 consecutive patients to this study, none of whom objected to the health literacy testing process (Eubanks et al., 2017). Komenaka (2014) too found no objection from participants to the testing processes, using the Newest Vital Sign health literacy test (Komenaka et al., 2014).

Ferguson (2011), Eubanks (2017) and Komenka (2014) also measured the time required for health literacy testing and report that the health literacy testing process took around two minutes, as was the case in my study using the Rapid Estimate of Adult Literacy in Medicine – Revised (REALM – R) health literacy test. Patient satisfaction with health literacy assessment was also measured by Komenaka (2014) who found that there was no decrease in patient satisfaction scores when health literacy testing was routinely employed. In my study, the REALM - R health literacy test was quick to explain and to perform, was well tolerated, with no objections from any of the 222 study participants who underwent this testing process. Following the author instructions for conduct of the REALM – R health literacy test, both the explanation of the testing purpose and procedure and the health literacy test itself were successfully completed in under two minutes.

5.2.8 Subjective knowledge

Subjective knowledge about the condition or treatment that women reported on the day of the consultation was assessed in my study. I developed a Likert scale, with a marked scale ranging from one to ten, with one representing no subjective knowledge and ten representing maximum subjective knowledge. The purpose of estimating pre consultation patient knowledge and then knowledge gained from the consultation was to examine the link between knowledge of the women's condition or treatment to patient satisfaction with the clinical consultation. Study participants may have gained knowledge in the period between consultation and knowledge estimate (at one month) by other means such as independent investigation and research.

All of the 222 study participants completed the subjective knowledge scores immediately before and immediately following the consultation. Two hundred and eight women were able to be contacted by telephone to complete the subjective knowledge score one month following the timed clinical consultation. Subjective knowledge scores at each measured time point were high, with mean scores at baseline 8/10. Following consultation the mean score rose to 9/10. This score was maintained above the baseline score at one month (mean score 8.4/10). These estimates of subjective knowledge may indicate that women felt they had successfully gained information or knowledge about their condition or treatment during the consultation process.

A consequence of higher subjective knowledge scores may be that women feel better able to and more confident regarding involvement in future planning, problem solving and decision making if they feel that they are well informed and educated about their condition or treatment (Riechel et al., 2016). Brabers (2017) has suggested that increased patient involvement in decision making in health care may result in improved patient satisfaction, treatment adherence and better health outcomes, as well as reduced patient anxiety (Brabers et al., 2017). Active involvement in decision making processes is preferred by most women and can be influenced by issues such as previous education, gender, age, ethnicity, previous experience with illness and the health care system, the relationship with the clinician and the type of decision that is required (Brabers et al., 2017). In a study of a preoperative urogynaecology population, Hallock (2017) also linked patient knowledge and existing expectations of upcoming surgery with increased satisfaction in her study of patients with pelvic floor disorders. This author found that women with greater knowledge were more satisfied with the decisions that were made regarding their upcoming surgery (Hallock et al., 2017).

Maintenance of subjective knowledge scores across the three measured time points in my study may indicate that a patient centred care approach was already being implemented by clinicians during the various clinical consultations. This may have resulted in women feeling satisfied and knowledgeable about their condition or treatment, regardless of the level of knowledge that they initially had, or that they had actually acquired, or their existing level of health literacy. Though patients may have gained knowledge in the month following the face to face consultation by other means such as independent investigation or research, these results may indicate that clinicians are already successfully transferring information to each woman in a way that the woman feels that she can adequately understand, perhaps allowing and encouraging study participants to be more actively involved in decision making processes.

Tailoring of information processes and personal interactions between clinician and patient may help to build trust and go some way to meeting the patients' unique health care needs (Brooks, Ballinger, Nutbeam, & Adams, 2017). According to Goggin (2014), involvement of patients in decision making processes may result in better health outcomes and result in higher levels of patient satisfaction (K. Goggins et al., 2016). Clinicians across all clinics may at present be successfully using a patient centred care approach, involving women in decision making processes based on their individual needs, capacity, values and preferences.

5.2.9 Clinician type

My study was designed to include various clinicians who consulted with the women involved in the study. In the Urogynaecology Clinic the women may have consulted with a nurse, a physiotherapist, a consultant urogynaecologist, a urogynaecology fellow in training, a urogynaecology resident, a urogynaecology registrar, a consultant colorectal specialist or a colorectal fellow in training. In the Physiotherapy Clinic all women consulted with a specialist women's health physiotherapist. In the Well Women's Clinic all women consulted with a specialist women's health nurse. In the Pre Admission Clinic, all women consulted with a specialist surgical nurse.

Consultation with doctors were the most common consultations in the study group, followed by nurse and physiotherapy consultations. Various Urogynaecology Clinics included

in the study were general Pessary Clinic, Urodynamics Clinic, Outpatient Clinic and Perineal Clinic. The experience levels of all of the clinicians varied from junior nurses, physiotherapists and doctors to senior clinicians across all clinical areas.

Satisfaction scores for all clinicians were high, based on results of the Short Assessment of Patient Satisfaction questionnaire (SAPS) scores. The SAPS questionnaire comprised five specific questions which related to satisfaction with aspects of clinician care (Question two explanations about treatment, Question three - the clinician checking everything during examination, Question four - treatment choices, and Question five - respect from the clinician). A further question (Question one) assessed effects of treatment or care and an additional question (Question six) related to satisfaction with the duration of the consultation (Hawthorne et al., 2014). The maximum possible satisfaction score was 28 and the minimum possible score was zero. Overall results for the SAPS questionnaire varied, with a mean satisfaction score of 25 (range 2 - 28), indicating high overall satisfaction with all clinics and with all clinicians. This, when coupled with the health literacy results where 25% of participants failed the health literacy test, may indicate that clinicians are already adopting a successful and individualised patient consultative and patient centred care approach.

5.2.10 Do clinicians overestimate their patients' health literacy?

The published literature suggests that without formal health literacy testing clinicians may fail to recognise patients who present with low health literacy, or may overestimate patients' health literacy levels much of the time. Bass (2002), Dickens (2013) and Goggins (2016) all believe that if there is overestimation of health literacy, especially in an older patient population, there is a risk to patients that consultations may be less effective and adverse health outcomes may be the result (Pat F Bass, Wilson, Griffiths, & Barnett, 2002; Dickens, Lambert, Cromwell, & Piano, 2013; K. Goggins et al., 2016). Nurses too may overestimate patients' health literacy levels, according to Wittenberg (2018). Reliance by nurses on their intuition or gut feelings, their patient's age or the patient's level of educational attainment may lead nurses to presume adequate or potentially inadequate health literacy levels. Wittenberg suggests that adequate communication is essential to the delivery of effective and quality nursing care and improved patient outcomes (Wittenberg et al., 2018).

Another paper by Easton (2013), has suggested that low health literacy can also limit people's oral communication ability during medical consultations, restricting effective information exchange between the patient and clinician, or the clinician and patient. Easton proposes that a non judgmental approach be used by all clinicians to maximise uptake of information by patients. Easton believes that clinicians will encounter people with low health literacy every day, so health information and health care systems need to be more accommodating to people with low health literacy to maximise uptake of information, improve health care outcomes and increase patient satisfaction levels both from an individual and an organisational perspective (Easton, Entwistle, & Williams, 2013).

Health literacy awareness training has been proposed for all staff, aiming to improve all clinicians' knowledge of health literacy. The aim of this training is to improve effective communication strategies. Such education may result in the implementation of relevant strategies to improve information communication and health outcomes using a patient centred care approach (Mackert, Ball, & Lopez, 2011; Wittenberg et al., 2018). Wittenberg (2018) suggests that clinician training in health literacy assessment, patient-clinician communication, education and support needs to be continuous and ongoing (Wittenberg et al., 2018).

5.2.11 Clinic type

Analysis of clinic type demonstrated that women were most satisfied with the Physiotherapy Clinic, Well Women's Clinic and Pre Admission Clinic and slightly less satisfied with the Urogynaecology Clinic, although all clinic satisfaction scores were high.

Women may have been less satisfied with the Urogynaecology Clinic compared to the other clinics for several reasons. It may be that the nature of the Urogynaecology consultation differed from a Physiotherapy Clinic, Well Women's Clinic or Pre Admission Clinic consultations where a straightforward, more structured approach to the consultation is the norm. Women presenting with symptoms of urge urinary incontinence were less satisfied than women presenting with other pelvic floor symptoms.

Women who reported symptoms of urge urinary incontinence

Women who presented with urge urinary incontinence symptoms were less satisfied overall than those who presented with other symptoms such as pelvic organ prolapse, urinary stress incontinence, anal sphincter injury or for routine cervical screening. Women attending the Urogynaecology Clinic for management of urge urinary incontinence symptoms may involve a more complex consultation process where multiple treatment options may be offered over time, which can be either conservative or surgical in nature. Treatment may be less definitive. Women with urge urinary incontinence may also suffer from more debilitating symptoms than women with other presenting symptoms. Treatment of urge urinary incontinence may be less straightforward, more complex and take place over a longer management timeframe. Treatment of urge urinary incontinence may involve women being offered several different treatments over time, some of which may prove to be less effective than others.

Investigations and treatment of urge urinary incontinence may involve invasive pelvic floor examinations, bladder testing such as urodynamic assessment, numerous bladder medications or surgical intervention. This may cause women to be less satisfied compared to women with other presenting conditions such as pelvic organ prolapse or stress urinary incontinence. These conditions may involve more direct treatment options such as physiotherapy or surgery, which could produce more effective and definitive results and which may occur over a shorter treatment timeframe.

In the Physiotherapy Clinic, Well Women's Clinic and Pre Admission Clinic the nature of the consultation is for the most part known to the woman, prior to the consultation. Though waiting times at the various clinics were not recorded, on the day of the consultations in the Physiotherapy Clinic, Well Women's Clinic and Pre Admission Clinic these clinics appeared to run to time and women seemed to have less waiting time than the patients attending the Urogynaecology Clinic. Waiting times for the Urogynaecology consultation appeared to be longer, both for an appointment to access the clinic, and on the day of the consultation. These longer waiting times could have influenced patient satisfaction scores on the day of consultation. Women attending for cervical screening (Presenting symptom - Other) had, in many cases self referred for this health screening appointment.

5.2.12 Length of consultation

Length of clinical consultation and its association with patient satisfaction, in a multidisciplinary gynaecology context, has not previously been reported. In my study, I timed the consultation length for all consultations, from the time that each clinician called the woman from the waiting room until the consultation concluded.

Four previous studies (all based in a general practice setting) have suggested that the quality of the consultation is as important as the actual consultation's duration. These studies have been based in primary care as well as hospital settings and all authors conclude that quality of consultation, not consultation duration is the important factor in maximising levels of patient satisfaction (Barratt & Thomas, 2018; Cape, 2002; Elmore et al.; Lemon & Smith, 2014). In a study involving a Nurse Practitioner, Barratt (2018) found that consultation length and patient satisfaction were not necessarily linked. Barratt found that consultation duration was not lengthened if a patient centred care style of communication, which incorporated a participatory approach to the consultation (Barratt & Thomas, 2018). Furthermore, Elmore (2016) agreed with Barratt and found that there was no association between length of consultation and patient satisfaction but did note that longer consultations are sometimes clinically required (Elmore et al.). Additionally, Lemon (2014), in a systematic review has suggested that more consultation time was beneficial to the physician as it allowed for greater exploration of patients' psychosocial issues, and allowed time for health education strategies to be discussed or a physical examination to be performed. This in turn encouraged and increased patient engagement and empowerment,

and resulted in higher levels of patient engagement in the consultation process and higher levels of patient satisfaction (Lemon & Smith, 2014). Generally Barratt (2002), Elmore (2016) and Lemon (2014) all advocate that the quality and content of the consultation, not the length of consultation was the important factor affecting patient satisfaction levels. My study found that overall satisfaction with the length of consultation in all of the clinics involved was high, regardless of the duration of the consultation. In a study looking at waiting times in general practitioner clinics, Cape (2002) proposed that perceived lack of time spent with a clinician is a major source of patient dissatisfaction (Cape, 2002).

5.2.13 Presenting symptoms

Women were asked to state the condition for which they were being treated on the day of recruitment and subsequent consultation. Urinary urgency and urinary urge incontinence (urinary incontinence related to an urge to pass urine that cannot be suppressed) were the most common self-reported presenting symptoms. Stress urinary incontinence (urinary incontinence related to increased intra-abdominal pressure such as a cough or sneeze) and mixed urinary incontinence (a combination of stress urinary incontinence and urge urinary incontinence symptoms) were also reported. Pelvic organ prolapse and pelvic pain were other presenting symptoms that women reported as the reason for attending the various participating clinics. Symptoms classified as other included women attending for cervical screening, investigation and management of obstetric anal sphincter injury and other gynaecologic conditions.

One author (Smith, 2011) suggests a link between lack of knowledge of overactive bladder physiology (these women present with urinary urgency and urinary urge incontinence symptoms), management strategies and satisfaction with health care in older women (A. L. Smith et al., 2011). Identification of low health literacy in older people is important due to this group's increased prevalence of chronic disease (Baker et al., 2000). Anger (2012) made note that pelvic floor conditions such as urinary incontinence and pelvic organ prolapse were complex and difficult conditions for older women to fully comprehend, even when health literacy levels were high. Anger (2012) also noted that pelvic floor disorders are often not freely discussed, and are often a cause of major embarrassment and shame. Anger also identified the link between lack of knowledge and fear or reticence to seek help for lower urinary tract symptoms, resulting in failure to access care, long term pain or discomfort and a poor quality of life. Women who do present for treatment of pelvic floor conditions may have lower levels of understanding of treatment options and lower levels of satisfaction with their treatment outcomes (Anger et al., 2012).

5.2.14 Australian Pelvic Floor Questionnaire

The Australian Pelvic Floor Questionnaire was used to assess women's symptoms and symptom bother on the day of the clinical consultation (Baessler et al., 2010) (Appendix 7-Australian Pelvic Floor Questionnaire). This questionnaire was developed in Australia, in a urogynaecology setting and was designed to be used as a screening measure for patients in any area of gynaecology practice. I chose this 42 item questionnaire as it comprehensively assesses symptoms in four distinct categories - bladder (15 questions), bowel (12 questions), pelvic organ prolapse (6 questions) and sexual function (9 questions) (Baessler et al., 2010).

Use of such a measure to assess symptoms and symptom bother may help to identify pelvic floor problems that are not verbally volunteered by a woman presenting for care due to embarrassment or shame, but may be significant symptoms which may require treatment or management. Embarrassment and shame may preclude some women from reporting distressing pelvic floor symptoms such as urinary and/or faecal incontinence or pelvic organ prolapse.

Use of a symptom specific questionnaire for women's health enables identification of all pelvic floor symptoms that women suffer from when they attend for consultation. In my study this questionnaire was answered by all women either while they waited for their appointment with the clinician if time permitted or immediately after their consultation. There was no objection to answering this questionnaire, although one woman found questions in the sexual function section intrusive and did not complete this part of the questionnaire. The Australian Pelvic Floor Questionnaire can also be used as a comparison measure to assess symptoms and symptom bother, or effects of treatment, if it was distributed before and after a treatment intervention, or over time.

5.2.15 Generalisability

This study had strong internal validity. This was a consequence of the study design, with the use of validated measures and the planned, random allocation of potential study participants. I took steps to minimise presentation and selection bias. In regard to external validity, I recruited a wide age range of study participants (aged 19 – 93 years), who consulted with various clinicians. The study participants were recruited from across all of the targeted hospital clinics.

The study group was not intended to be generalisable to the whole population as the study group included a female gynaecological population only, in the northern and western suburbs of an advanced economy in Melbourne, Australia. However, the population did not seem to differ from other similar clinical populations in any systematic way. The two participating hospitals are part of Australia's public health care system which provides free treatment to all eligible patients. I used the Australian Pelvic Floor questionnaire to show that the study sample is representative of women attending the two hospitals for obstetric or gynaecological care.

The Australian Pelvic Floor Questionnaire was selected for use as it gathers extensive, specific, subjective information on patient symptoms and symptom bother relating to aspects of pelvic floor dysfunction, in one single measure. The study population of adult women in an obstetrics or gynaecology context is not seen to differ from other study populations of women in such a context. The clinical variables described in these other publications were similar to my study population (age, body mass index, parity).

Publications by Melbourne based authors include Lee (2013, 2015), Schierlitz (2012), Ow (2016), Lim (2006), Murray (2016) and Frawley (2010). These authors included only female participants in Australian gynaecology and urogynaecology populations who had comparable age, parity and body mass index measures (J. K.-S. Lee et al., 2013; J. K. S. Lee, Rosamilia, Dwyer, Lim, & Muller, 2015; Lim, Cornish, & Carey, 2006; Ow et al., 2016; Schierlitz et al., 2012). Authors Lee, Ow, Schierlitz and Lim are urogynaecologists who are based in urogynaecology clinical settings in Melbourne. Murray (2016), in a nurse led study found similar parity and BMI but an older patient age group in her urogynaecology based study (Murray, Thomas, & Pollock, 2016). Frawley, in a physiotherapy study of women with pelvic organ prolapse, found similar age, parity and BMI (Frawley, Phillips, Bø, & Galea, 2010). Frawley's study was conducted in a general gynaecology hospital setting.

5.3 STUDY STRENGTHS

There were several strengths to my study.

5.3.1 Study design to minimise bias

I took great care in the design and implementation of the study processes and procedures to minimise selection, social desirability and presentation bias. I developed a planned, random allocation of potential study participants which I implemented so as to minimise selection bias as much as possible. Only women who had already presented for their appointment were approached and invited to participate, which minimised social desirability bias. I assured women that their participation in the study was voluntary. I did not coerce women in any way to participate in the study. I made no payment or inducement to any of the women for any aspect of their study involvement. Additionally, other than a short time commitment, there was no associated cost to the patient related to their participation.

5.3.2 Recruitment timeframe

Initially I proposed that the recruitment phase of my study may take 16 – 20 weeks to complete. I went on to recruit women to the study over a 13 week timeframe only. Women who participated were recruited from all of the clinics targeted for inclusion in the study. Participants consulted with all the clinicians that were proposed for inclusion in the study,

including doctors, nurses and physiotherapists at both of the participating hospitals. Data entry and follow-up telephone calls were completed in a timely manner one month after the initial consultation.

5.3.3 High completion rates in the study

Completion rates in the study were high due to my attention to detail and my control of the research environment. To ensure completeness of data I paid particular attention to the study participants' movements within the clinic on the day of recruitment and clinical consultation. When the clinician called the woman from the waiting room I noted which consulting room the women went to for consultation. I then waited outside the consulting room door for them to complete their consultation and I walked with them as they returned to the reception area of the clinic. While they queued to see the clinic receptionist to make their next appointment I was able to hand them the Short Assessment of Patient Satisfaction questionnaire to complete, along with the subjective knowledge Likert scale. These two measures were able to be completed in under five minutes before the participant left the clinical area of the hospital.

By using these strategies I was able to collect the data from most of the women at the initial consultation visit. Of the 222 participants involved, two women left the hospital before I was able to ask them to complete the Short Assessment of Patient Satisfaction (SAPS) questionnaire and the second subjective knowledge score (Subjective knowledge - Measure 2). As I had obtained a telephone number for future contact I was able to call these women on the same day as their consultation and complete these study measures by telephone.

Another reason why I was able to ensure completeness of data was that I was careful to only ever be observing two women in a participating clinic session at any given time. This allowed me to keep control of where these women were within the clinic, who they consulted with and which room they went to for their consultation. I was also able to time each clinical consultation's duration. I was therefore able to approach the women when their consultation was finished to complete the post consultation study measures.

5.3.4 Participants were representative of Melbourne women's hospitals

The study population overall was representative of women attending for obstetric or gynaecological assessment or treatment at both of the study hospitals. The age range of study participants was broad, with women aged 19 – 93 years included in the study. All of the targeted clinical areas were included, along with various clinicians including nurses, doctors and physiotherapists.

5.3.5 Study completion rates

Overall study completion rates were high. All women signed written consent forms, provided demographic and clinical details and completed health literacy testing. Due to my control of the research environment I was able to complete all study questionnaires on the day of the participants' clinic attendance. Telephone follow-up was undertaken at one month and I was able to contact most women following the initial clinical consultation to complete the final element of the study. Only one woman withdrew her consent to participate during the course of the study. I respected her wishes and I therefore did not contact her for follow-up.

5.3.6 Study measures that were used

All of the study measures that I used had been previously validated.

The measures that I used in the study could be broadly applied to any patient group within any medical discipline (Rapid Estimate of Adult Literacy in Medicine – REALM - R health literacy test, Short Assessment of Patient Satisfaction (SAPS) questionnaire and subjective knowledge scores using a Likert scale. In this study, only the Australian Pelvic Floor Questionnaire was discipline specific and designed for use in a gynaecology population.

5.4 STUDY LIMITATIONS

There were several possible limitations to my study.

5.4.1 Subjective knowledge estimation using a Likert score

When I asked women to estimate subjective knowledge regarding their condition or treatment I used a self developed measure (a 10 point Likert scale). While the study participants seemed to have had no problem using this measure, the study may have been improved had I used an existing measure to assess levels of a patient's subjective knowledge. I could also have piloted the Likert scale that I developed before I used it in the study group.

The problem with finding an existing measure was the range of clinics and presenting symptoms that were involved in the study. A symptom specific measure may have suited some women, but may have been unsuitable for others. To enhance the study's results it may have been better to locate a generic subjective knowledge measure, rather than using a self developed measure.

5.4.2 Making participation available to women who use interpreters

An additional and important limitation of the study is that it was only available to women who spoke English and did not require the services of an interpreter during the consultation process (either provided formally by the hospital, or provided by an accompanying person such as a family member or friend).

The exclusion of women who made use of an interpreter has limited the assessment of health literacy in the many women who present for consultation at the hospitals involved who speak a language other than English. No measure of these women's health literacy or their satisfaction with the clinical consultation could therefore be made. Satisfaction scores among these women may have been different to scores provided by women who did not require an interpreter for the consultation process. Involving the women who speak a language other than English would have enriched the study further.

Of the 277 women who were identified and were approached and invited to participate, 20 (7%) women were excluded because they did not speak English or did not speak English sufficiently and required the services of an interpreter. This is a significant

number of women who were excluded due to their spoken language. Their opinions and levels of satisfaction with the clinical consultation may have been valuable information to obtain, both from a personal perspective and as an organisational quality measure. In future, I would ensure that more effort is made to be inclusive of women whose language is other than English.

At the study hospitals there are approximately 171 language groups represented across the patient populations (Mercy Health, 2018/2019). Translation of all study materials including patient information, study measures and consent documents into 171 languages was not financially or practically feasible. In the future it may be possible to include women in the more common language groups other than English (the most common other languages spoken in my study group were Italian, Greek and Macedonian) in a further study. Translation of the study materials into common languages could have been feasible and affordable and these women would therefore have been able to be included in the study. Little is known about the women who were ineligible to participate or the women who declined to participate in this study. Without consent being given by the non-participating or ineligible women, the only personal information that was available to me was which clinic they were scheduled to attend and whether or not they were booked for consultation with an interpreter provided by the hospital, which is noted on the hospital's electronic appointment system. Women who declined to participate were asked to nominate the reason that they declined involvement. Reasons given were many and varied, and there was no systematic reasons evident for non-participation in the study.

Little is known about satisfaction with consultation when patients consult with various clinicians such as doctors, nurses or physiotherapists. Most published studies examine only consultations between patients and doctors, rather than other clinician consultations, in regard to satisfaction.

5.4.3 Minimum reading time of thirty minutes and consent to participate

During recruitment to the study women were handed the Patient Information and Consent document containing all details of the study and study processes to read, or have read to them. I allowed a reading time of 30 minutes.

A minimum reading time period of 30 minutes was given before each woman was further approached to enquire if she wished to participate in the study and to gain her written consent. This waiting time may have been too short for some women to read and understand, and to consider their options regarding participation in the research study. The women may have felt rushed into making a decision without adequate time to consider their options. A longer time for consideration regarding participation may have been of benefit to some women, allowing them time to consider their participation, reflect on their possible options regarding participation and to ask any questions about the study or study processes.

There was a high response rate for inclusion in the study. The issue of reading time did not appear to be an issue. The women did not report being hurried into a decision regarding their involvement in the study. Additional time for consideration of participation in the study may have made some women feel more comfortable and at ease, and perhaps reduced their levels of anxiety.

5.4.4 Not all collected data were used in the analysis

Various demographic and clinical data were collected from all of the study participants. Not all of these collected data were used in the study's primary data analysis. I collected information on relationship status, work status, highest level of educational attainment, parity, body mass index and whether the woman was accompanied at the consultation. I also asked women if they were sexually active. These demographic and clinical variables were not used in the analysis. Asking these questions may have potentially caused embarrassment, anxiety or distress to some women. The collection of these variables that were not useful to the study reflects my inexperience with the research study design. In future research ventures I would pay additional attention to thinking the study design through, and then only collecting information from participants that were essential to the study.

5.4.5 Possible limitations of the Short Assessment of Patient Satisfaction (SAPS) questionnaire

The selection of the Short Assessment of Patient Satisfaction questionnaire (SAPS) as the main outcome measure could possibly be seen as a limitation in this research study (Hawthorne et al., 2014). The questionnaire has been validated. While the questionnaire has been previously cited 13 times in the literature, it has not been widely used by researchers since its publication in 2014. Following a library database search, there were only two published papers identified which have used the Short Assessment of Patient Satisfaction (SAPS) questionnaire as an outcome measure (Goyal et al., 2018; Vaughan et al., 2019).

Using the Short Assessment of Patient Satisfaction measure, Goyal (2018) categorised satisfaction scores into two group (highly satisfied / satisfied and highly dissatisfied / dissatisfied), depending on total satisfaction scores (Goyal et al., 2018). The Short Assessment of Patient Satisfaction questionnaire's validity was discussed by Vaughan (2019). This author questioned whether the Short Assessment of Patient Satisfaction (SAPS) questionnaire was valid outside of the context in which the questionnaire was developed (a continence clinic) (Vaughan et al., 2019).

While the Short Assessment of Patient Satisfaction questionnaire has had limited previous use, it was found to be most suitable for my study, based in an obstetrics or gynaecology context. This seven item satisfaction questionnaire covered aspects of the consultation such as overall patient satisfaction, as well as further features such as personal exchange between the clinician and the patient and satisfaction with the duration of the consultation. Most questionnaires considered for use in this study measured patient satisfaction with the clinical consultation from a doctor or physician perspective only. I wanted to find a satisfaction measure for my study that could be used to measure satisfaction after patients consulted with any clinician including nurses and physiotherapists. The Short Assessment of Patient Satisfaction questionnaire allowed me to do so.

Many questionnaires that I considered for use in this study were condition specific and did not suit the range of patients (obstetrics, gynaecology, pre admission, conservative physiotherapy management) attending the various clinics under observation in my study. Use of the Short Assessment of Patient Satisfaction (SAPS) questionnaire allowed for the measurement of satisfaction with consultation across any health discipline and was not confined to doctor and patient consultations only. This allowed its use in other consultations, including physiotherapy and nurse consultations in addition to usual medical consultations.

A further advantage of the Short Assessment of Patient Satisfaction (SAPS) questionnaire over other available measures was its ease of use. It consisted of a single page questionnaire comprising seven multiple choice questions (covering seven domains), and took around one to two minutes to complete by the study participants themselves (or a family member, friend or staff member) immediately following the clinical consultation.

5.4.6 The study population was limited to adult women only

As the study group was limited to adult women only, no conclusions can be drawn across the whole of the population. In a future study stronger results may be able to be generated by including both men and women to gain insight into health literacy of the population as a whole.

5.4.7 Only one reviewer completed the scoping review of the literature

A limitation of the scoping review is that I was the lone reviewer. Although I consulted with a university librarian regarding the search methodology, the selection of relevant papers and the review processes may have been more robust if two or more reviewers were involved in the selection of the publications and the quality appraisal and review processes. Selection bias may have been a problem and could have been reduced if more than one reviewer had been involved in the scoping review. A recommendation for future studies would be to involve at least one other reviewer in the selection and review processes to ensure that bias was minimised.

5.4.8 Scoping review search terms

A further limitation of the scoping review is the selection of search terms intended to identify publications related to consultation length. On review of the database search results only two papers were identified which examined length of consultation and patient satisfaction. The two papers were not identified and examined in the initial review. The search terms may not have been sensitive enough to identify relevant papers, or there may have been an issue with how the papers were indexed. The search terms used in the search strategy included 'consultation time' OR 'waiting time' OR appointment. Using these search terms in the search strategy, I would have expected papers on consultation length to be identified in the database searches. These search terms may not have been sensitive enough to identify relevant papers, or there may have been an issue with how the papers were indexed.

On review of the database search results only two papers were identified which examined length of consultation and patient satisfaction. The two papers were not identified and examined in the initial review. One paper by Lemon (2014) was a literature review so was not included in the analysis as it did not meet the inclusion criteria. A further paper by Cape (2002) met the criteria for inclusion and was added to the scoping review. In a future review more care would be taken to select terms that are sensitive enough to identify publications of interest.

5.5 RECOMMENDATIONS FOR FURTHER RESEARCH INTO THIS TOPIC

5.5.1 Further study follow-up could have been undertaken

If future research was undertaken into this area, patient satisfaction scores could have been assessed at another time point. In my current study, no further follow-up beyond one month was sought regarding consultation satisfaction scores using the Short Assessment of Patient Satisfaction questionnaire (SAPS). When the study participants were contacted by telephone one month following the consultation (to assess Subjective knowledge - Measure 3) the Short Assessment of Patient Satisfaction questionnaire (SAPS) could have once more been used to provide another satisfaction score at a time when women had had a chance to reflect on the entire consultation process and consider the manner in which it was undertaken. This additional information could have been simple, quick and easy to collect and may have provided further insight into the participants' satisfaction with consultation, over a longer timeframe. I do not think that asking participants to complete this questionnaire on a second occasion would have caused them any anxiety, embarrassment or distress. It would not have taken a significant amount of time to add this questionnaire at this time point. A second estimate of patient satisfaction with consultation asked at a later time may have further enriched the study.

Since the study was completed I have held discussions with the Multicultural Services Manager at Mercy Health regarding a follow-up study which would involve women who speak a language other than Englsih and require the services of an interpreter, in some of the more common languages seen (the most common spoken languages were Italian, Greek, Macedonian and Punjabi).

5.5.2 Clinic waiting times in relation to satisfaction scores

Clinic waiting times to see the clinician on the day of the consultation were not formally measured in this study, therefore, any association between longer clinic waiting times and lower clinic consultation satisfaction scores or clinician satisfaction scores was not captured. The patients attending the Urogynaecology Clinic appeared to have a longer clinic waiting time and this could possibly have influenced their satisfaction scores relating to both the clinic and/or the clinician that was involved in the consultation. In a future study, patient waiting times for scheduled consultations could be measured for any possible link between clinical consultation satisfaction scores.

Chapter 6: OTHER INFORMATION

6.1 FUNDING

This study has been supported by La Trobe University in the form of an Australian Government Research Training Program Stipend Scholarship that I have been awarded. There has been no other funding received for the conduct of this study.

Chapter 7: CONCLUSION

A scoping review of the published literature was undertaken in 2019, in order to understand the range of already published literature that covered my topic. Fourteen studies met the stated selection criteria and their quality was appraised. There was no consistency of results in regard to health literacy and satisfaction with clinical consultation. Studies did not consistently report an association between increased satisfaction and higher or lower levels of health literacy. Three distinct themes were identified as patient satisfaction, patient centred care and health literacy. An individualised and patient centred care approach to health service delivery was associated with higher patient satisfaction levels. Quality analysis of selected papers revealed a broad range of results.

This observational study was conducted over a three month period in 2018. Recruitment to this research study was limited to women only. Two hundred and twenty two women were recruited to the study, and 208 completed all of the study requirements. Simple linear regression and multiple regression analyses were conducted and there was no association found between patient satisfaction and health literacy or patient satisfaction and length of consultation. There was an association found between satisfaction and subjective knowledge. Satisfaction scores for both clinics and clinicians were high. Women who presented with urge urinary incontinence were less satisfied with the clinical consultation compared to women who presented with other lower urinary tract symptoms such as stress urinary incontinence, pelvic organ prolapse or conditions classified as other. Formal health literacy testing was conducted and one quarter of women in the study group were found to have low levels of health literacy.

Though low health literacy has been found to be common in the study group, broad based mass health literacy testing may not necessarily need to be performed. Rather, a patient centred care approach, personally tailored to the abilities, needs, values and preferences of individual patients has been shown to be the most effective type of approach to all clinical consultations in regard to patient satisfaction. Adoption of teach back techniques has been shown to be effective in transferring information to patients. This kind of consultation approach acknowledges the preferences, ideas, values and beliefs of each individual patient in our care. A patient centred care approach often results in high levels of patient satisfaction with consultation.

The completion of this research study adds weight to the existing body of knowledge that suggests that women's satisfaction with consultation is not necessarily associated with health literacy. A successful patient centred care approach is more likely to result in higher patient satisfaction, regardless of health literacy levels. The quality of the consultation, not the duration of the consultation is important. The development and timely distribution of simple, understandable and tailored written materials, using a universal health literacy precautions approach, and including the use of teach back techniques, may be the most effective method of successfully conveying relevant information to all patients, regardless of existing health literacy levels. This has implications for both clinicians and health care organisations. Improvements in health literacy can have a positive impact on overall health outcomes for individual patients as well as benefits for the broader health care organisation.

Appendices

Appendix 1– Scoping Review – Publications retained for analysis	:
	23
Appendix 2- Scoping review - Quality appraisal	:
	27
Appendix 3 – Data log	28
Appendix 4 – Data collection sheet	<u>:</u>
	29
Appendix 5 – Ethics approvals	:
	30
Appendix 6 - SAPS –Short Assessment of Patient Satisfaction questionnaire	39
Appendix 7 – Australian Pelvic Floor Questionnaire	
	41
Appendix 8 – Permissions	
	46
Appendix 9 - Country of birth	: 52
Appendix 10 - First language	-
	53

Author	Intervention type	Study population	Number of	Aims of the study	Methodology	Outcome measures	Important results
			participants				
Altin et al,	No intervention	Primary practice	1125	Not specifically stated,	Nationwide cross	Commonwealth Fund	Patients with higher levels of health literacy and those
2016		(Germany)		but background	sectional survey	International Health	who experienced a more patient centred care approach
				information stated	(telephone	Policy Survey, open	to health care were more likely to be satisfied with their
				subjective health	interviews)	ended question	general practitioner's care.
				literacy and patient		regarding health	
				centred care and their		status, Brief Health	
				association with		Literacy Screen	
				satisfaction		(BHLS), Consumer	
						assessment of	
						Healthcare Provider	
						and Systems (CAHPS)	
Anger et al,	Assessment of	Urogynaecology and	36	To explore the	Cross sectional	Incontinence Severity	Patients had low recall of pelvic floor diagnoses and poor
2012	health literacy	Urology Clinic		relationship between	survey - Pilot study	Index, Questionnaire	understanding of complex pelvic floor conditions despite
		(United States of		age, diagnosis type,		for Urinary	high health literacy scores. Lack of understanding of
		America)		health literacy and		Incontinence	complex conditions may have implications for consent,
				disease understanding		Diagnosis, Test of	and affect post-operative satisfaction with treatment due
						Functional Health	to unrealistic expectations. Increasing age was associated
						Literacy in Adults	with poorer health literacy.
						(TOFHLA)	
Arora et al,	No intervention	Gynaecology/	52	To assess patient	Cross sectional	The European	Standard of medical care provided, frequency of doctors'
2010		Oncology Clinic		satisfaction with	survey	Organisation for	visits, exchange of information, friendliness of staff, and
		(Australia)		gynaecology/oncology		Research and	state of the room ranked highly on the patient satisfaction
				hospital inpatient		Treatment of Cancer	scales.
				services		(IN-PATSAT32)	
						questionnaire	
						(modified version,	
						additional 16 items)	

Appendix 1 – Scoping Review – Publications retained for analysis

Author	Intervention type	Study population	Number of	Aims of the study	Methodology	Outcome measures	Important results
			participants				
Barber et al,	No intervention	Gynaecology/	208	To examine associations	Cross sectional	The Patient	Patient satisfaction scores are associated with non-
2016		Oncology Clinic,		between non	survey	Satisfaction	modifiable demographic, financial and geographic factors.
		(United States of		modifiable patient		Questionnaire	Satisfaction was not associated with technical quality of
		America)		factors and satisfaction		(PSQ-18)	care or time spent with the doctor.
Beattie et al,	Physical care	Physiotherapy Clinic,	1502	To examine associations	Cross sectional	Measuring Patient	Patients who had care provided by a single clinician were
2005	provided by one or	(United States of		between longitudinal	survey	Satisfaction with	three times more likely to report complete satisfaction
	more	America)		continuity of care and		Physical Therapy Care	than those whose care was provided by more than one
	physiotherapists			patient satisfaction		(MRPS)	clinician. These authors suggest that efforts be made to
							ensure continuity of care from providers to increase
							patient satisfaction with treatment and care.
Bungard et al,	Anticoagulant	Anti-coagulant Clinic,	1687	To assess patients'	Prospective postal	25 item written survey	The majority of patients were satisfied with the care they
2013	therapy	(Canada)		perception of care	survey	utilising 5 point Likert	received. More than two-thirds preferred to continue
				delivery in		scales	receiving care by the anti-coagulant clinic, rather than by
				anticoagulation clinics			their GP.
Cape, 2002	No intervention	Mental health clinic	160	To test whether	Observational	General Health	Patients gave estimates of the consultation's duration.
				consultation duration	study, naturalistic	Questionnaire (GHQ),	Patient satisfaction did not necessarily relate to
				affects patient	study	length of consultation,	consultation duration (p = 0.131), but was associated with
				satisfaction		Satisfaction	patient estimated consultation duration (p = 0.001). Also
						Questionnaire	there was an association between patient perception of
							the consultation's duration and its actual length (p =
							0.001). Quality rather than duration is important in
							relation to patient satisfaction.
Hallock et al,	No intervention	Urogynaecology	150	To investigate	Observational	Satisfaction with	Knowledge and understanding of upcoming surgery are
2017		Clinic, (United States		preoperative	study	Decision Scale – Pelvic	important components of patient decision making and
		of America)		satisfaction and		Floor Disorder (SDS-	satisfaction. Measurement of patient understanding may
				informed consent for		PFD), adapted	allow clinicians to address preoperative expectations and
				surgery		Informed Consent	satisfaction with the proposed surgery which may result in
						Questionnaire (ICQ),	higher satisfaction levels post-operatively.
						3-item measure for	

Author	Intervention type	Study population	Number of	Aims of the study	Methodology	Outcome measures	Important results
			participants				
						HL, Single-item anxiety	
						measure, 5 free text	
						questions	
Hendriksen et	Introduction of	Gynaecology/	245	To analyse the	Cross sectional	Patient satisfaction	Patient satisfaction did not differ significantly between
al, 2011	nurse practitioners	Oncology,		satisfaction levels of 3	survey	questionnaire (specific	groups 1 and 3 (notified by a gynaecologist or nurse
		Colposcopy Clinic,		groups of women –		questionnaire not	practitioner prior to the colposcopy appointment), though
		(Netherlands)		patients informed by		stated)	group 2 patients (notified by a gynaecologist immediately
				doctor, nurse or nurse			prior to the colposcopy) were less satisfied. The highest
				practitioner			level of satisfaction was in Group 3 (nurse practitioner
							group).
Kandelaki et	No intervention	National patient	232,518	To evaluate patient	Cross sectional	First national patient	Most satisfied were men, individuals with low levels of
al, 2016		survey, (Sweden)		centred care and	survey	survey conducted	education and those whose first language was Swedish.
				satisfaction with health		between 2009-2010	Less satisfied were women, those with higher education
				care			or those not native to Sweden.
Kenton et al,	Reconstructive	Urogynaecology	79	To determine patient	Cross sectional	Pelvis Floor Distress	Satisfaction, alleviation of symptoms, and quality of life
2007	pelvic surgery	Clinic, (United States		readiness for pelvic	survey	Inventory (PFDI-20),	are strongly associated with patients' expectations and
		of America)		surgery		Urinary Distress	preparedness for surgery. Women who are better
						Inventory (UDI) Pelvic	prepared report higher levels of satisfaction post-
						Organ Prolapse	operatively, as well as a greater level of symptom
						Distress Inventory	reduction and an improved quality of life.
						(POPDI), Patient	
						Global Impression of	
						Improvement (PGI-I),	
						Pelvic Organ Prolapse	
						quantification system	
						(POPQ), standing	
						cytometrogram	
						measurement	
Mallinger et	Information topics	Women with breast	182	To examine the	Cross sectional	Patient perception of	Satisfaction with treatment information was high, with

Author	Intervention type	Study population	Number of	Aims of the study	Methodology	Outcome measures	Important results
			participants				
al, 2005		cancer, (United		relationship between	survey	patient centeredness	satisfaction related to information on surgery highest.
		States of America)		patient centred care		instrument (based on	Satisfaction with breast cancer survivorship information
				and satisfaction with		a previous instrument	was widely reported. Women were highly satisfied with
				information provided		which was not stated),	information related to follow-up and on-going cancer
						Primary Care	surveillance. Low satisfaction was reported by women in
						Assessment Survey	relation to risk of breast cancer recurrence.
						(PCAS)	
Radu et al,	No intervention	Obstetrics/gynaecol	150	Assess demographic	Observational	Demographic	Satisfaction with the clinic's gynaecological services is
2018		ogy Clinic, (Romania)		characteristics in	survey	characteristics,	neutral (9.48), orientation towards the consumer scored
				relation to		satisfaction (Likert	very satisfied (20.71). These results were analysed against
				organisational		scale)	demographic factors such as rural/urban, level of
				satisfaction			education, income, civil status, environment of origin and
							marital status. There was no analysis based on age.
Torres et al,	No intervention	Post-menopausal	106	To understand the	Cross sectional	shortened Test of	A positive relationship was found between both health
2009		women, Family		relationship between	survey	Functional Health	literacy and knowledge about hormone replacement
		Clinic, (United States		health literacy and		Literacy in Adults	therapy, and between health literacy levels and self-
		of America)		other factors in		(sTOFHLA) in English	efficacy regarding hormone replacement therapy. Health
				postmenopausal		and Spanish, 11-	literacy levels may affect patient decision making in regard
				women attending a		question decision	to hormone replacement therapy.
				family clinic		efficiency scale, 2-	
						question behavioural	
						intent, regarding HRT-	
						17-question hormone	
						therapy questionnaire	

Author	Date of publication	Were the criteria for inclusion in the sample clearly defined?	Were the study subjects and the setting described in detail?	Was the exposure measured in a valid and reliable way?	Were objective, standard criteria used for measurement of the condition?	Were confounding factors identified?	Were strategies to deal with confounding factors stated?	Were the outcomes measured in a valid and reliable way?	Was appropriate statistical analysis used?	Overall appraisal - Include, exclude, seek further information
Torres, R et al	2009	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Include
Altin, S.V et al	2016	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Include
Anger, J.T et al	2012	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Include
Arora, V et al	2010	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Include
Barber, E.L et al	2016	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Include
Beattie, P et al	2005	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Include
Bungard, T.J et al	2013	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Include
Hallock, J.L et al	2017	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Include
Hendriksen, M.T et al	2011	Yes	Yes	Unclear	Unclear	Unclear	Unclear	Yes	Yes	Include
Kandelaki, K et al	2016	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Include
Kenton, K et al	2007	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Include
Cape, J	2002	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Include
Mallinger, J.B et al	2005	Yes	Yes	Yes	Unclear	Unclear	Unclear	Yes	Yes	Include
Radu, G et al	2018	No	Unclear	Unclear	Unclear	No	No	No	Yes	Include

Appendix 2 - Scoping review - Quality appraisal

Appendix 3 – Data log

aste	X Cut Copy - Format Painter Clipboard		• 11 ⊞ • 2 nt	× A [*] A [*] ≡			' Wrap Text Merge & Cer		al ▼ % * €.0 .00 .00 →.0 Number 54	Conditional Form Formatting ▼ Tab	
V11	¥ :)	$\times \checkmark f_x$									
4	A		В	с	D	E	F	G	Н	I	J
Da	te		Clinic	PatientID	Time	Random	Approached	d Participate?	Reason	Cliniciar	StudyID
	Tuesday, 11	September 2018	PHYS		09:00	56	YES	YES		Р	2
	Tuesday, 11	September 2018	PHYS		09:00	1	YES	YES		Р	1
	Tuesday, 11	September 2018	PHYS		09:30	10	NO				
	Tuesday, 11	September 2018	PHYS		10:00	60	NO				
_	Tuesday, 11	September 2018	PHYS		10:30	38	YES	YES		P	3
_	Tuesday, 11	September 2018	PHYS	-	10:30	123	NO				
-	Tuesday, 11	September 2018	PHYS		11:00	87	NO				
6	Tuesday, 11	September 2018	PHYS	a.	11:30	<mark>102</mark>	NO				
	Tuesday, 11	September 2018	PHYS		11:30	67	NO				
2	Tuesday, 11	September 2018	PHYS	1	09:00	7	NO				
	Tuesday, 11	September 2018	PHYS	1	12:00	129	NO				
	Tuesday, 11	September 2018	UROG		13:30	164	YES	YES		Ρ	4
	Tuesday, 11	September 2018	PHYS		13:30	12	NO				
;	Tuesday, 11	September 2018	PREA		13:30	122	YES	YES		N	6

Consultation interview data collection sheet						
Clinic (circle one) UROG GYNAE-ONC PHYSIO PRE ADMISION WWC	StudyID No		Patient	label		
Interview Date						
//		-				
Consent(circle when complete)	Current age	Parity	He	ight	Weight	BMI
Signed Collected Filed	(yrs)		(0	cm)	(kg)	
First Language				npanied ′) (N)	Accompani 1 Family men 2 Friend 3 Professional	nber
Educational Background (total years of formal school)						
Highest qualification (circle one)	Primary school	High School	Trade	Diploma	Degree	Higher Degree
Relationship status (circle one)	Single	Married	Living wi	th partner	Divorced	Widow
Work status (circle one)	Full Time	Part Time	Volu	Inteer	Homemaker	Seeking Work
Pre Consultation Likert	1 2	3 4	5	6 7	8	9 10
Pre Consultation Questionnaires completed (circle as appropriate)	Australian	PF Questior (Y) (N)			REALM-R (Y) (N)	SAPS (Y) (N)
REALM-R Results	Fat	Flu		Osteoporosis		Jaundice
	Fatigue	Directed	Colitis	Anaemia	Constipation	n/8
Consultation	Duration	mins				
Post Consultation Likert	1 2	3 4	5	6 7	8	9 10
Permission to Contact By Phone in 1 Month	Yes No	Phone No				
Telephone Followup Likert Date//	1 2	3 4	5	6 7	8	9 10

Appendix 4 - Data collection sheet

Appendix 5 - Ethics approvals



Mercy Hospitals Victoria Ltd Level 2, 12 Shelley Street Richmond Vic 3121 Phone: +61 3 8416 7777 Fax: +61 3 8416 7888 mercyhealth.com.au

20 August 2018

Ms Christine Murray Mercy Hospital for Women 163 Studley Road Heidelberg VIC 3084

Dear Ms Murray,

Re: 2018-041: The association between health literacy and patient satisfaction with consultation: an observational study.

I am pleased to advise that the Mercy Health Human Research Ethics Committee has reviewed and **approved and endorsed** of the above research proposal at the 14^{th} August 2018 meeting.

In particular the following documents were approved:

Document	Version	Date
Research Methodology	1	received 28 June 2018
PICF	1	received 28 June
Section E	1	received 28 June
The Short Assessment of Patient Satisfaction - SAPS Questionnaire	-	received 28 June
The Australian Pelvic Floor Questionnaire	Ξ	received 28 June
Data Collection Sheet	V1	received 28 June

The Mercy Health Human Research Committee has approved this research until 14th August 2019.

Mercy Hospitals Victoria Ltd ACN 614 116 013 ABN 74 762 230 429 Page 1 of 3



The Human Research Ethics Committee is constituted and functions in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007- updated May 2015).

In accordance with the NHMRC Guidelines, approval is subject to:

- Immediate notification to the Administrative Officer, Human Research Ethics Committee and sponsor, of any unforeseen events that may affect the continuing ethical acceptability of the project;
- 2. Notification and reasons for ceasing the project prior to its expected date of completion;
- 3. The completion of a progress report at 6 months and then annually for the duration of the project.
- Human Research Ethics Committee approval of any proposed modifications to the project;
- 5. The submission of a final report and papers published on completion of the project.

Please also note:

6. The Principal Investigator upon leaving the Institution must inform the Human Research Ethics Committee as to the nominated person to replace him/her.

In future correspondence please quote the given project number: 2018-041.

Extensions:

If an extension of ethics approval is required, the HREC office must be contacted <u>before</u> the ethics approval runs out. Your request must be accompanied with a current progress report.

Progress Report:

Continuation of ethics approval is contingent on submission of an annual progress report. Failure to comply with this requirement may result in suspension of this research. A progress report form has been emailed with this letter.

Amendments:

Amendments to approved research can be made at any time. Amendments must be submitted with a Mercy Health Amendment Request Form and copies of any additional or amended documentation with tracked changes. A blank Amendment Request Form has been emailed with this letter.

Page 2 of 3



If you have any queries, please do not hesitate to contact Ms Natasha Rooney, Administrative Officer Mercy Health Human Research Ethics Committee on 8458 4808 or email <u>ethics@mercy.com.au</u>.

Yours sincerely,

Sim Chary

Mr Tim O'Leary Chair, Mercy Health Human Research Ethics Committee



Mercy Hospitals Victoria Ltd Level 2, 12 Shelley Street Richmond Vic 3121 Phone: +61 3 8416 7777 Fax: +61 3 8416 7888 mercyhealth.com.au

01 October 2018

Ms Christine Murray Mercy Hospital for Women 163 Studley Road Heidelberg VIC 3084

Dear Ms Murray,

Re: 2018-041: The association between health literacy and patient satisfaction with consultation: an observational study.

I am pleased to advise that your request for updated documentation to this approved research has been considered and is supported.

This approval is effective immediately and enables you to continue the study but is subject to the endorsement of the Mercy Health HREC.

In particular, the following is approved:

Document	<u>Version</u>	Date
Additional Site Request Werribee Mercy Hospital	-	Received 23 August 2018

The full Human Research Ethics Committee will be advised of these amendments at its next meeting to be held on the **9th October 2018**. You will receive a formal letter of endorsement from the Mercy Health HREC following this meeting.

Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of this research.

Should you require an extension of ethics approval, the HREC office must be contacted <u>before</u> the ethics approval runs out and your request must be accompanied with a current progress report.

Mercy Hospitals Victoria Ltd ACN 614 116 013 ABN 74 762 230 429 Page 1 of 2



In accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007), approval is subject to:

- Immediate notification to the Administrative Officer, Human Research Ethics Committee and sponsor, of any serious adverse effects on participants;
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- The completion of a progress report annually for the duration of the project;
- Human Research Ethics Committee approval of any proposed modifications to the project;
- The submission of a final report and papers published on completion of the project.

Please also note:

- Consent Forms must be available for audit by the Human Research Ethics Committee and retained for the period required by law;
- The Principal Investigator upon leaving the Institution must inform the Human Research Ethics Committee as to the nominated person to replace him/her.

If you have any queries, please do not hesitate to contact me on 8458 4808.

Yours sincerely,

NP

Natasha Rooney Administrative Officer, Mercy Health Human Research Ethics Committee

Page 2 of 2



Mercy Hospitals Victoria Ltd Level 2, 12 Shelley Street Richmond Vic 3121 Phone: +61 3 8416 7777 Fax: +61 3 8416 7888 mercyhealth.com.au

01 October 2018

Ms Christine Murray Mercy Hospital for Women 163 Studley Road Heidelberg VIC 3084

Dear Ms Murray,

Re: 2018-041: The association between health literacy and patient satisfaction with consultation: an observational study.

I am pleased to advise that your request for updated documentation to this approved research has been considered and is supported.

This approval is effective immediately and enables you to continue the study but is subject to the endorsement of the Mercy Health HREC.

In particular, the following is approved:

Document	<u>Version</u>	Date
Additional Site Request Werribee Mercy Hospital	-	Received 23 August 2018

The full Human Research Ethics Committee will be advised of these amendments at its next meeting to be held on the **9th October 2018**. You will receive a formal letter of endorsement from the Mercy Health HREC following this meeting.

Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of this research.

Should you require an extension of ethics approval, the HREC office must be contacted <u>before</u> the ethics approval runs out and your request must be accompanied with a current progress report.

Mercy Hospitals Victoria Ltd ACN 614 116 013 ABN 74 762 230 429 Page 1 of 2



Mercy Hospitals Victoria Ltd Level 2, 12 Shelley Street Richmond Vic 3121 Phone: +61 3 8416 7777 Fax: +61 3 8416 7888 mercyhealth.com.au

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Mercy Hospitals Victoria Ltd ACN 614 116 013 ABN 74 762 230 429 Page 1 of 2



In accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007), approval is subject to:

- Immediate notification to the Administrative Officer, Human Research Ethics Committee and sponsor, of any serious adverse effects on participants;
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- The completion of a progress report annually for the duration of the project;
- Human Research Ethics Committee approval of any proposed modifications to the project;
- The submission of a final report and papers published on completion of the project.

Please also note:

- Consent Forms must be available for audit by the Human Research Ethics Committee and retained for the period required by law;
- The Principal Investigator upon leaving the Institution must inform the Human Research Ethics Committee as to the nominated person to replace him/her.

If you have any queries, please do not hesitate to contact me on 8458 4808.

Yours sincerely,

NP

Natasha Rooney Administrative Officer, Mercy Health Human Research Ethics Committee

Page 2 of 2



Research Office

7 September 2018

То	Susan McDonald
From	University Human Ethics Committee
Reference Number	MercyHospitalforWomen2018-041
Project title	The association between health literacy and patient satisfaction with consultation: an observational study
Subject	Externally Approved Project
Date	7 September 2018

The externally approved project submitted above was reviewed and **noted** by the University Human Ethics Committee Chair.

Please note that all requirements and conditions of the original ethical approval for this project still apply.

Should you require any further information, please contact the Human Research Ethics Team on: T: +613 9479 1443| E: humanethics@latrobe.edu.au.

Warm regards,

David Finlay Chair, University Human Ethics Committee

Externally Approved New Application letter version dated 21 February 2018

Page 1 of 1

The Short Assessment of Patient S	atisfaction - SAPS Questionnaire
Q1. How satisfied are you with the effect of your treatment/care? Very satisfied0 Satisfied1 Neither satisfied nor dissatisfied2 Dissatisfied3 Very dissatisfied4	Q2. How satisfied are you with the explanations the doctor/other health professional has given you about the results of your treatment/care? Very dissatisfied0 Dissatisfied1 Neither satisfied nor dissatisfied2 Satisfied3 Very satisfied4
Q3. The doctor/other health professional was very careful to check everything when examining you. Strongly agree0 Agree1 Not sure2 Disagree3 Strongly disagree4	Q4. How satisfied were you with the choices you had in decisions affecting your health care? Very dissatisfied0 Dissatisfied1 Neither satisfied nor dissatisfied2 Satisfied3 Very satisfied4
Q5. How much of the time did you feel respected by the doctor/other health professional? All of the time0 Most of the time1 About half the time2 Some of the time3 None of the time4	Q6. The time you had with the doctor/other health professional was too short. Strongly agree0 Agree1 Not sure2 Disagree3 Strongly disagree4

Appendix 6 - Short Assessment of Patient Satisfaction questionnaire

Q7. Are you satisfied with the care you received in the hospital/clinic?
Very satisfied0
Satisfied1
Neither satisfied nor
dissatisfied2
Dissatisfied3
Very dissatisfied4

The Australian Pelvic Floor Questionnaire			
BLADDER FUNCTION			
1. How many times do you pass urine in the day? 0 up to 7 1 between 8-10 2 between 11-15 3 more than 15	2. How many times do you get up at night to pass urine? 0 0-1 1 2 2 3 3 more than 3 times	 3. Do you wet the bed before you wake up at night? 0 never 1 occasionally (less than once per week) 2 frequently (once or more per week) 3 always (every night) 	
 4. Do you need to rush or hurry to pass urine when you get the urge? 0 can hold on 1 occasionally have to rush (less than once per week) 2 frequently have to rush (once or more per week) 3 daily 	 5. Does urine leak when you rush or hurry to the toilet or can't you make it in time? 0 not at all 1 occasionally (less than once per week) 2 frequently (once or more per week) 3 daily 	 6. Do you leak urine with coughing, sneezing, laughing or exercising? 0 not at all 1 occasionally (less than once per week) 2 frequently (more than once per week) 3 daily 	
 7. Is your urinary stream (urine flow) weak, prolonged or slow? 0 never 1 occasionally (less than once a week) 2 frequently (once or more per week) 3 daily 	 8. Do you have a feeling of incomplete bladder emptying? 0 never 1 occasionally (less than once a week) 2 frequently (once or more than once a week) 3 daily 	 9. Do you need to strain to empty your bladder? 0 never 1 occasionally (less than once a week) 2 frequently (once or more per week) 3 daily 	

Appendix 7 – Australian Pelvic Floor Questionnaire

10. Do you have to wear pads because of urinary leakage? 0 none - never 1 as a precaution 2 when exercising or during a cold 3 daily	11. Do you limit your fluidintake to decrease urinaryleakage?001before going out23always	 12. Do you have frequent bladder infections? 0 no 1 1-3 per year 2 4-12 per year 3 more than one per month
13. Do you have pain in your bladder or urethra when you empty your bladder?0never1occasionally (less than once a week)2frequently (once or more than once a week)3daily	14. Does the urine leakage affect your routine activities like recreation, socialising, sleeping, 	 15. How much does your bladder problem bother you? 0 not at all 1 slightly 2 moderately 3 greatly

BOWEL FUNCTION			
16. How often do you	17. How is the consistency 18. Do you have to strain a		
usually open your bowels?	of your usual stool? to empty your bowels?		
0 every other day	0 soft 0 firm 0	0 never	
or daily	hard (pebbles)	1 occasionally (less than	
1 less than every 3	2 watery	once a week)	
days	1 variable	2 frequently (once or	
2 less than once a		more than once a week)	
week		3 daily	
0 more than once a			
day			
19. Do you use laxatives to	20. Do you feel	21. When you get wind or	
empty your bowels?	constipated?	flatus, can you control it or	
0 never	0 never	does wind leak?	
1 occasionally (less	1 occasionally (less	0 never	
than once a week)	than once a week)	1 occasionally (less than	
2 frequently (once	2 frequently (once	once a week)	
or more than once a	or more than once a	2 frequently (once or	
week)	week)	more than once a week)	
3 daily	3 daily	3 daily	

22. Do you get an	23. Do you leak watery	24. Do you leak normal stool	
overwhelming sense of	stool when you don't mean	when you don't mean to?	
urgency to empty your	to?	0 never	
bowels?	0 never	1 occasionally (less than	
0 never	1 occasionally (less	once a week)	
1 occasionally (less than	than once a week)	2 frequently (once or	
once a week)	2 frequently (once	more than once a week)	
2 frequently (once or	or more than once a	3 daily	
more than once a week)	week)		
3 daily	3 daily		
25. Do you have a feeling	26. Do you have to use	27. How much does your bowel	
of incomplete bowel	finger pressure to help	problem bother you?	
of incomplete bowel emptying?	finger pressure to help empty your bowels?	problem bother you? 0 not at all	
1	8 I I		
emptying?	empty your bowels?	0 not at all	
emptying? 0 never	empty your bowels? 0 never	0 not at all 1 slightly	
emptying? 0 never 1 occasionally (less	empty your bowels? 0 never 1 occasionally (less than	0 not at all 1 slightly 2 moderately	
emptying? 0 never 1 occasionally (less than once a week)	empty your bowels? 0 never 1 occasionally (less than once a week)	0 not at all 1 slightly 2 moderately	
emptying? 0 never 1 occasionally (less than once a week) 2 frequently (once	empty your bowels? 0 never 1 occasionally (less than once a week) 2 frequently (once or	0 not at all 1 slightly 2 moderately	
emptying? 0 never 1 occasionally (less than once a week) 2 frequently (once or more than once a	empty your bowels? 0 never 1 occasionally (less than once a week) 2 frequently (once or more than once a week)	0 not at all 1 slightly 2 moderately	

PROLAPSE SYMPTOMS			
28. Do you have a	29. Do you experience	30. Do you have to push back	
sensation of tissue	vaginal pressure or	your prolapse in order to void?	
protrusion or a lump or	heaviness or a dragging	0 never	
bulging in your vagina?	sensation?	1 occasionally (less than	
0 never	0 never	once a week)	
1 occasionally (less	1 occasionally (less	2 frequently (once or	
than once a week)	than once a week)	more than once a week)	
2 frequently (once	2 frequently (once	3 daily	
or more than once a	or more than once a		
week)	week)		
3 daily	3 daily		

31. Do you have to push back your prolapse to empty your bowels? 0 never 1 occasionally (less than once a week) 2 frequently (once or more than once a week) 2 doily	32. How much does your prolapse bother you? not applicable, do not have a prolapse 0 not at all 1 slightly 2 moderately 3 greatly
3 daily	

SEXUAL FUNCTION			
33. Are you sexually	If you are not sexually	34. If you are not sexually	
active? (No scoring of this	active, please continue to	active, please tell us why: (No	
question)	answer questions 34 and	scoring of this question)	
no	42 only	do not have a partner	
less than once per		I am not interested	
week		my partner is unable	
once or more per			
week			
daily or most days			
35. Do you have sufficient	36. During intercourse	37. Do you feel that your vagina	
natural vaginal lubrication	vaginal sensation is:	is too loose or lax?	
during intercourse?	0 normal / pleasant	0 never	
0 yes	1 minimal	1 occasionally	
1 no	1 painful	2 frequently	
	3 none	3 always	
38. Do you feel that your	39. Do you experience pain	40. Where does the pain during	
vagina is too tight?	with sexual intercourse?	intercourse occur?	
0 never	0 never	0 not applicable, I do not	
1 occasionally	1 occasionally	have pain	
2 frequently		1 at the entrance to the	
3 always	2 frequently	vagina	
	3 always	1 deep inside, in the	
		pelvis	
		2 both at the entrance	
		and in the pelvis	

41. Do you leak urine during sexual intercourse?	42. How much do these sexual issues bother you?
0 never	not applicable, I do not
1 occasionally	have problems
2 frequently	0 not at all
3 always	1 slightly
	2 moderately
	3 greatly

Appendix 8 - Permissions

1/17/2020

Mail - CHRISTINE MURRAY - Outlook

Re: research project

Bass III, Pat <PBassi@lsuhsc.edu> Tue 30-Jan-18 2:32 AM To: CHRISTINE JUNE MURRAY <19281527@students.latrobe.edu.au> It is freely available. Good luck with your project. Thanks

Ricky

Pat F. Bass III, MD, MS, MPH Professor of Medicine and Pediatrics Chief Medical Information Officer LSU Health Shreveport P: 318-675-6490 C: 318-573-9413 F: 318-675-8150

On Jan 28, 2018, at 3:31 PM, CHRISTINE JUNE MURRAY <<u>19281527@students.latrobe.edu.au</u>> wrote:

EXTERNAL EMAIL: EVALUATE Dear Dr. Bass,

I am a Professional Doctorate (Doctor of Nursing) student from La Trobe University in Melbourne, Australia.

I am preparing to conduct a study examining the link between health literacy and satisfaction in baby boomer women attending a Urogynecology Unit at Mercy Hospital for Women here in Melbourne where I work.

I would like to test the patients' health literacy using the REALM-R and seek your permission to use this tool.

Kind regards,

Christine Murray La Trobe University Melbourne Australia Ph: +61 411 270 740

https://outlook.office.com/mail/inbox/id/AAQkADU4ZjEzMGFkLTIhOTYtNDkyNS1iYjViLWRkMWlyNTYzYVM2NQAQAKRQC7wQJaVFlau2ldFsCJ... 1/1

1/17/2020

AW: Permission to use questionnaire

Baessler, Kaven <kaven.baessler@charite.de> Sun 04-Feb-18 6:21 AM To: CHRISTINE JUNE MURRAY <19281527@students.latrobe.edu.au> Cc: chrismaher@urogynaecology.com.au <chrismaher@urogynaecology.com.au> Dear Christine, we are absolutely happy for you to use the questionnaire! Good luck with your research! Cheers Kaven

PD Dr. med. Kaven Baessler Diploma in Urogynaecology (Royal Australian and New Zealand College of Obstetricians and Gynaecologists) Gastwissenschaftlerin an der Charité

Von: CHRISTINE JUNE MURRAY [19281527@students.latrobe.edu.au] Gesendet: Donnerstag, 1. Februar 2018 22:56 An: Baessler, Kaven Betreff: Permission to use questionnaire

Dear Dr Baessler,

I am a Professional Doctorate (Doctor of Nursing) student from La Trobe University in Melbourne, Australia.

I am preparing to conduct a study examining the link between health literacy and satisfaction in baby boomer women attending a Urogynecology Unit at Mercy Hospital for Women here in Melbourne where I work.

I would like to use the female pelvic floor questionnaire (that you developed with Chris Maher) to collect symptom and bother details from participants and seek your permission to use this tool in my research project.

Kind regards,

Christine Murray La Trobe University Melbourne Australia Ph: +61 411 270 740

https://outlook.office.com/mail/search/id/AAQkADU4ZjEzMGFkLTihOTYtNDkyNS1iYjViLWRkMWIyNTYzYWM2NQAQAPzE7uc7zKFEmR880v0... 1/1

1/17/2020

RE: Permission to use questionnaire

Dr Christopher Maher <chrismaher@urogynaecology.com.au> Sun 04-Feb-18 6:35 PM To: 'Baessler, Kaven' <kaven.baessler@charite.de>; CHRISTINE JUNE MURRAY <19281527@students.latrobe.edu.au> Good luck with the research Chris cm

From: Baessler, Kaven [mailto:kaven.baessler@charite.de] Sent: Sunday, 4 February 2018 5:21 AM To: CHRISTINE JUNE MURRAY <19281527@students.latrobe.edu.au> Cc: chrismaher@urogynaecology.com.au Subject: AW: Permission to use questionnaire

Dear Christine, we are absolutely happy for you to use the questionnaire! Good luck with your research! Cheers Kaven

PD Dr. med. Kaven Baessler

Diploma in Urogynaecology (Royal Australian and New Zealand College of Obstetricians and Gynaecologists)

Gastwissenschaftlerin an der Charité

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1/17/2020

RE: Survey author

Susan McDonald <S.McDonald@latrobe.edu.au> Tue 28-Nov-17 3:23 PM To: CHRISTINE JUNE MURRAY <19281527@students.latrobe.edu.au> Cc: Richard Gray <RGray@latrobe.edu.au> Hi Chis, this means the author is happy for the researcher to use the SAPS as long as you acknowledge the author of the SAPS who was G Hawthorne. That is a great outcome S

Susan McDonald Professor of Midwifery (Women's and Infants Health) La Trobe University/Mercy Hospital for Women Mercy Hospital for Women, Level 2 163 Studley Rd Heidelberg, Victoria 3084

Phone +61 3 84584945 Mobile: 0400519461 Fax: +61 3 84584222 Email: <u>s.mcdonald@latrobe.edu.au</u> or <u>sue.mcdonald@mercy.com.au</u> PLEASE NOTE: I am generally at Mercy Hospital for Women on Mon,Tues, Thurs and at the Judith Lumley Centre Wed and Friday (Ph 94798731)

From: CHRISTINE JUNE MURRAY Sent: Tuesday, 28 November 2017 1:10 PM To: Susan McDonald <S.McDonald@latrobe.edu.au> Cc: Richard Gray <R.Gray@latrobe.edu.au> Subject: Re: Survey author

Hi Sue and Richard,

On the bottom of the Hawthorne publication of the SAPS questionnaire this statement regarding copyright is at the bottom of the first page.

0895-4356/\$ - see front matter Copyright. ? 2011. Copyright in the SAPS is held and will continue to be held in perpetuity by the authors with a license to the Commonwealth of Australia. Researchers are welcome to use the SAPS subject to acknowledgement/citation of the authors' rights in the usual way. http://dx.doi.org/10.1016/j.jclinepi.2013.12.010

Where it states 'subject to acknowledgement/citation of the authors' rights in the usual way' what does this statement mean please? Can I use the questionnaire with acknowledgement of the author or is something else required?

Chris

From: Susan McDonald Sent: Tuesday, November 28, 2017 1:04:36 PM To: CHRISTINE JUNE MURRAY Cc: Richard Gray Subject: RE: Survey author

Yes, I know. I made the same comment. A bit weird that it should still be active 3 years on !!

https://outlook.office.com/mail/search/id/AAQkADU4ZjEzMGFkLTIhOTYtNDkyNS1iYjViLWRkMWlyNTyzYVM2NQAQACtniT34t0E%2Bi%2F6Tw... 1/3

1/17/2020

Susan McDonald Professor of Midwifery (Women's and Infants Health) La Trobe University/Mercy Hospital for Women Mercy Hospital for Women, Level 2 163 Studley Rd Heidelberg, Victoria 3084

Phone +61 3 84584945 Mobile: 0400519461 Fax: +61 3 84584222 Email: <u>s.mcdonald@latrobe.edu.au</u> or <u>sue.mcdonald@mercy.com.au</u> PLEASE NOTE: I am generally at Mercy Hospital for Women on Mon,Tues, Thurs and at the Judith Lumley Centre Wed and Friday (Ph 94798731)

From: CHRISTINE JUNE MURRAY Sent: Tuesday, 28 November 2017 12:20 PM To: Richard Gray <<u>R.Gray@latrobe.edu.au</u>>; Susan McDonald <<u>S.McDonald@latrobe.edu.au</u>> Subject: Re: Survey author

Hi Sue,

It all makes sense now although I wonder why his email did not bounce back to me...

I will investigate the copyright issues on both Graeme Hawthorne's questionnaire and the REALM-R literacy test (Bass).

Chris

From: Richard Gray Sent: Monday, November 27, 2017 12:37 PM To: Susan McDonald; CHRISTINE JUNE MURRAY Subject: Re: Survey author

Oh dear, that's very sad ...

R

From: Susan McDonald <<u>S.McDonald@latrobe.edu.au</u>> Date: Monday, November 27, 2017 at 12:03 PM To: CHRISTINE JUNE MURRAY <<u>19281527@students.latrobe.edu.au</u>> Cc: Richard Gray <<u>R.Gray@latrobe.edu.au</u>> Subject: Survey author

Hi Chris, mystery solved about Graeme Hawthorne.... He died in 2014. We probably need to look at whether his Q was copyrighted or not and work from there. His widow eveidently works in Population Health @UniMelb S

Susan McDonald Professor of Midwifery (Women's and Infants Health) La Trobe University/Mercy Hospital for Women Mercy Hospital for Women, Level 2 163 Studley Rd Heidelberg, Victoria 3084

Phone +61 3 84584945

https://outlook.office.com/mail/search/id/AAQkADU4ZjEzMGFkLTIhOTYtNDkyNS1iYjViLWRkMWlyNTYzYVM2NQAQACtniT34t0E%2Bi%2F6Tw... 2/3

1/17/2020

Mail - CHRISTINE MURRAY - Outlook

Mobile: 0400519461 Fax: +61 3 84584222 Email: <u>s.mcdonald@latrobe.edu.au</u> or <u>sue.mcdonald@mercy.com.au</u> PLEASE NOTE: I am generally at Mercy Hospital for Women on Mon,Tues, Thurs and at the Judith Lumley Centre Wed and Friday (Ph 94798731)

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Country of birth	Frequency, $n = 222$	%
Australia	130	58.6
Belgium	1	.5
Cambodia	1	.5
Canada	2	.9
China	2	.9
Croatia	4	1.8
Cyprus	1	.5
England	7	3.2
Germany	4	1.8
Greece	8	3.6
Holland	1	.5
Hong Kong	2	.9
India	9	4.1
Indonesia	1	.5
Ireland	1	.5
Italy	8	3.6
Lebanon	2	.9
Lithuania	1	.5
Macedonia	7	3.2
Malta	3	1.4
Nepal	1	.5
New Zealand	5	2.3
Northern Ireland	1	.5
Paraguay	1	.5
Persia	1	.5
Philippines	1	.5
Portugal	2	.9
Russia	1	.5
Scotland	3	1.4
Slovenia	1	.5
Sri Lanka	2	.9
Sudan	1	.5
Sweden	1	.5
Vietnam	2	.9
Yugoslavia	2	.9
Zambia	1	.5
Zimbabwe	1	.5
Total	222	100.0

Appendix 9 - Country of birth

First language	Frequency, $n = 222$	%
English	144	64.86
Italian	11	4.95
Greek	10	4.5
Macedonian	7	3.15
German	4	1.8
Punjabi	4	1.8
Maltese	3	1.35
Hindi	3	1.35
Croatian	3	1.35
Cantonese	3	1.35
Spanish	2	.9
Russian	2	.9
Vietnamese	2	.9
Mandarin	2	.9
Lebanese	2	.9
French	2	.9
Dutch	1	.45
Cambodian	1	.45
Dinka	1	.45
Gujarati	1	.45
Sinhalese	1	.45
Albanian	1	.45
Hokien	1	.45
Bemba	1	.45
Shona	1	.45
Slovak	1	.45
Farsi	1	.45
Nepalese	1	.45
Arabic	1	.45
Slovenian	1	.45
Serbian	1	.45
Polish	1	.45
Swedish	1	.45
Total	222	100

Appendix 10 – First language

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