DEVELOPING AN INTERVENTION TO IMPROVE INFORMED DECISION MAKING FOR ONCOLOGY PATIENTS IN SOUTH AFRICA

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A thesis submitted to the Faculty of Health Sciences, School of Clinical Medicine, Department of Medicine, University of the Witwatersrand in fulfilment of the requirements for the degree of Doctor of Philosophy (PhD)

Johannesburg, 2024

DECLARATION

I, Charmaine Louise Blanchard, declare that this thesis is my own original, unaided work. It is being submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa, for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted before for any degree nor examination at any other university or institution.

Dr CL Blanchard

Date: September, 2024

DEDICATION

To my very special family for all their unwavering support

Mike, Andrew, Erin, Liam and Arthur

ETHICS COMMITTEE APPROVAL

This research was approved by the Human Research Ethics Committee (HREC), of the University of the Witwatersrand. (Clearance Certificate Number: M200986) (APPENDIX A).

ACKNOWLEDGEMENTS

I am deeply indebted to my supervisors Prof Shane Norris, Prof Moosa Patel and Prof Holly Prigerson, for their ongoing support and mentorship through this PhD journey in developing the knowledge and skills to plan and execute the studies and to ultimately write up this thesis. I am also deeply grateful to Dr Maureen Joffe, for her faith in me, her unwavering support, continuous encouragement and occasionally, admonishments, which have kept me on track throughout this process. I am also extremely grateful for the expert support of Prof Patricia McInerney for all her assistance with the systematic review process, for the excellent teaching of statistical analysis from Dr Oluwatosin Ayeni, and support and assistance with the review by Dr Witness Mapanga. I wish to thank the awesome research team who assisted with the interviews under the stressful circumstances around the COVID pandemic, and the fire at CMJAH: Keletso Mmoledi, Rev Gloria Mokwatle, Sihle Sibiya, Yvonne Shengetelo, Victor Shandukani, Nonhlanhla Mkwanazi, Samke Makhanya. I also wish to thank Siobhan De Lange, who coded the transcripts with me and for all our very insightful conversations. I am deeply grateful to all the oncology staff and patients who participated in our studies, without whose generous input, this would not have been possible. Without the generous financial sponsorship of the Cassandra Miller-Butterworth Fellowship, for which I am extremely grateful, this journey would not have been possible - as well as the continued support from the NORA/DELTAS African multi-country research projects.

Lastly, but most importantly, I cannot express enough my gratitude for my family’s unwavering support. With their sacrifice of time and their belief in me, I was able to embark on and complete this journey.

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THESIS MATERIAL AND CONTRIBUTIONS

Together with my supervisors, I conceptualised the three studies and developed the protocol. I led the three studies and participated in data collection. I assisted research interviewers with the quantitative data collection, and managed data quality. I supervised the in-depth interviews which were conducted by multilingual interviewers, and I conducted the focus group discussions with the nurses and doctors of the oncology clinics. With assistance from my supervisors and an epidemiologist, I conducted the quantitative analysis, and I led the qualitative analysis.

FUNDING AND AWARDS

This thesis was funded by the following:

Cassandra Miller-Butterworth Wits Clinician Scientist PhD Fellowship

Funded in part by the German Federal Ministry of Education and Research 01KA2220B.

Funded in part by the Science for Africa Foundation to the Developing Excellence in Leadership, Training and Science in Africa (DELTAS Africa) program [Del-22-008] with support from Wellcome Trust and the UK Foreign, Commonwealth & Development Office and is part of the EDCPT2 programme supported by the European Union

PUBLICATIONS AND PRESENTATIONS

Findings of the studies completed in the course of producing this thesis were presented at 3 scientific meetings. Two papers were submitted for publication, and a third is being drafted.

Presentations at symposia and conferences

Wits 13th Cross Faculty Postgraduate Symposium 2022

Measuring oncology patient health literacy to inform the development of an intervention for informed treatment decision making. (Poster presentation)

Multinational Association of Supportive Care in Cancer Annual Meeting June 22 – 24, 2023

Improving Informed Cancer Treatment Decision Making in South Africa. (Poster Presentation)

AORTIC 2023 2 – 6 November 2023

Development of Cancer Treatment Decision Interventions for Africa: Contributions from High Income Countries. (Presentation)

Publications

A cross-sectional study of health literacy, information needs, decision control preferences and decisional conflicts of oncology patients in South Africa.

Charmaine L. Blanchard, Oluwatosin Ayeni, Ros Dowse, Maureen Joffe, Moosa Patel, Holly G. Prigerson, Shane Norris. Submitted to Pan African Medical Journal. In review.

A mixed methods review of oncology treatment decision support interventions amongst vulnerable populations.

Charmaine L. Blanchard, Patricia McInerney, Witness Mapanga, Maureen Joffe, Moosa Patel, Holly G, Prigerson, Shane Norris. Submitted to MDM Policy and Practice.

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ACRONYMS

AORTIC: African Organisation for Research and Training in Cancer

BCT: Behaviour Change Techniques

cART: Combination antiretroviral therapy

CHBAH: Chris Hani Baragwanath Academic Hospital

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

COVID: Coronavirus Disease (SARS-CoV-2DA: Decision aid

DC: Decision conflict

DCP: Decision Control Preferences

DCS: Decision Conflict Scale

DELTAS: Developing Excellence in Leadership

DESI: Decision support intervention

DNA: Deoxyribonucleic acid

FGD: Focus Group Discussion

GAD-7: Generalised Anxiety Disorder 7

HCP: Healthcare providers

HIC: High Income Countries

HIV: Human Immunodeficiency Virus

HL: Health literacy

HLSF: Health Literacy Skills Framework

HPCSA: Health Professions Council of South Africa

HRB: Health Related Behaviour

IDM: Informed decision making

IM: Intervention Mapping

IMHL: Integrated Model of Health Literacy

IOM: Institute of Medicine

IPDAS: International Patient Decision Aids Standards

KZN: KwaZulu Natal

LMIC: Low- and Middle-Income Countries

MMSR: Mixed Methods Systematic Review

MRC: Medical Research Council

NORA: Network for Oncology Research in Sub-Saharan Africa

NSD: No significant difference

ODSF: Ottawa Decision Support Framework

OG: Option Grid

PCC: Patient centred care

PhD: Doctor of Philosophy

POG: Picture Option Grid

PtDAs: Patient decision aids

SDM: Shared decision-making

SSA: sub-Saharan Africa

TDF: Theoretical Domains FrameworkTTI: Theory of Triadic Influence

UC: Usual Care

UK: United Kingdom

UMIC: Upper Middle-Income Countries

USA: United States of America

VCE: Values Clarifying Exercise

WHO: World Health Organisation

ABSTRACT

Introduction

Patients making cancer treatment decisions face several challenges including grappling with difficult terminology and deliberating different options based on the information provided and their own values while experiencing high levels of stress. Informed cancer decision making by South African patients in the public healthcare sector, is further complicated by the constrained resources in the oncology clinics limiting the time available for consultations with the oncologists. Language and socio-cultural barriers impact on the patient’s ability to make fully informed treatment decisions, which are legally and ethically required. While decision aids (DAs) exist in high income countries (HICs) to assist patients to make informed cancer treatment decisions, there are no studies reporting the development of cancer treatment DAs in South Africa.

Aim

The aim of this thesis was to develop a decision support intervention (DESI) to improve cancer patient informed treatment decision making.

Methods

This thesis applied the Intervention Mapping (IM) framework to the development of the DESI. The three objectives of the thesis related to the first step of the IM process namely a needs assessment to develop the logic model of the problem. The first objective was to assess the effectiveness of decision aids (DAs) in addressing vulnerable patient-reported decision needs by conducting a mixed methods systematic review to understand the synergies and gaps between the DAs and the patients’ needs. For the second objective a quantitative study was undertaken to measure the South African patient’s health literacy (HL), factors associated with HL, their decision control preferences (DCPs), and to assess their decision needs. The study enrolled 124 patients diagnosed with cancer at three tertiary level oncology clinics in South Africa (two in Gauteng and one in KwaZulu Natal). For the third objective a qualitative study was undertaken to understand the patient experiences of making cancer treatment decisions and the oncology staff perceptions of the decision-making process. In-depth interviews with 30 patients and eight focus groups with oncology staff were conducted at the same clinical sites as the quantitative study. The results of the three studies were triangulated to provide a logic model of the problem which informed the next steps of the IM process, resulting in an evidence-based theory driven intervention program.

Results

The systematic review identified significant gaps between the DAs and the vulnerable patients’ decision support needs, particularly relating to communication in the consultation and providing counselling and coaching support for decision-making. The 124 South African patients at the study sites in Gauteng and KwaZulu Natal had mostly marginal (69%) to limited (11%) health literacy, positively associated with their level of education (OR 2.2, 95% CI 0.58 – 8.55 for high school and OR 14.6 95% CI 2.2 – 96.61 for tertiary education) and socio-economic status (OR 4.1, 95% CI 1.03 - 15.98, for the wealthiest tertile). The patients reported high information needs (71%) despite reporting understanding a lot of what the doctors explained (77%) and feeling comfortable a lot, asking questions (82%) in the consultation. Most patients (82%) preferred an active decision-making role. The qualitative study findings confirmed the high levels of information needs, but most patients did not ask questions in the consultation and often played a passive role in decision-making. Language and cultural differences between the patients and the oncologists were identified by oncology staff as major barriers to informed decision-making, and support from the patients’ families, the oncology nurses and the palliative care teams addressed some of the patients’ decision needs. Following the logical, iterative process of the IM framework a locally relevant decision support intervention program was developed.

Conclusion

Patients have high levels of cancer and treatment information needs and wish to be active participants in their treatment decision making yet often lack the self-efficacy to engage in treatment deliberation with their oncologists. Language and cultural discordance between the patient and oncologist compounded by the time pressures of the clinic, are barriers to effective patient-centred communication in the consultation. It is vital that adequate training is provided to oncologists to improve culturally sensitive patient-centred communication when supporting cancer patients to make informed treatment decisions.

PREFACE

Looking back, I realise that patient centred care and communication has been a part of my DNA since medical school days. As a student, I enjoyed the patient interaction as much as I enjoyed the academic and clinical learning on the wards. As an intern, a patient-centred approach beyond solely the clinical history and examination resulted in me always being behind with my never-ending tasks in busy hospital units, but it also led to me advocating for my patients' wishes to be heard, especially when medical interventions were no longer adding to their quality of life.

During my community service in a rural primary level hospital during the rapidly expanding HIV epidemic without cART (combination antiretroviral therapy) I became increasingly distressed, feeling helpless to offer any treatment for patients in the wards. They wanted to go home, but their families couldn't cope. Searching for information to at least, manage their symptoms more effectively, led me to palliative care. Through my palliative care postgraduate training and experiences in a hospice inpatient unit, I learned valuable communication skills. These were not acquired in one teaching session, but over time observing seniors, and practicing myself. For my palliative care diploma portfolio, I naturally focussed on communication between doctors, patients and families and reflecting on personal experiences with a family member who died of cancer.

Working as a palliative care specialist at Chris Hani Baragwanath Academic Hospital (CHBAH), I found that patients who were referred to our palliative care centre, knew very little about their cancer, often still expecting a cure. Families of patients at home were equally unaware of the terminal nature of their loved one's illness and, often brought them back to hospital for treatment, rather than managing end of life care at home as and when feasible. We subsequently conducted a research project investigating cancer patient palliative care needs at CHBAH. Patients were asking questions about their cancer, the treatments and the possibility of cure – while their treating doctors estimated that they had less than 6 months to live.

Being an academic centre, meant that our clinical team at the CHBAH Palliative Care Centre participated in teaching palliative care and communication skills to medical students. While I was grateful that we at least had a few hours in the curriculum to teach some communication skills, I felt that there was too little time devoted to this vital aspect of patient care. A few hours of teaching in the early years of medical school did not translate into improved clinician communication on the wards.

My experiences in palliative care taught me that patients often received oncology treatments, of which they had little knowledge, and which may not add significantly to their quality of life nor be congruent with patients' values. While our staff often blamed doctors for not explaining to patients, when I questioned the doctors, they explained that they had told the patient, sometimes more than once. Why were patients telling us that they were not told? Either they were hoping for a different diagnosis or prognosis, as may happen, or doctors do explain to patients the details of their cancer and its treatments, but patients often do not remember or understand the information shared with them.

When considering a topic for my PhD, patient centred care and communication was my natural choice. To narrow down my options for a feasible project, I chose to focus on patient informed oncology treatment decision-making. Drawing from my experiences both practicing in public hospitals and teaching at the University of the Witwatersrand Medical School in Johannesburg, South Africa, I aim to design an effective, yet feasible intervention to aid patients' informed treatment decision-making. I realise that this is an ambitious aspiration, given the myriad of challenges to effective clinician-patient communication in our oncology clinics, however, just because it seems impossible, does not mean that we should not try.

The structure of the thesis is as follows:

Part 1. Introduction

Chapter 1 provides a background to cancer patient decision-making, and factors that contribute to patients making informed treatment decisions. The chapter ends with a theoretical framework on which the PhD study is based and outlines the aims and objectives.

Chapter 2 discusses the rationale for using the intervention mapping approach to developing the decision support intervention and rationale and methodology selection applied for each separate sub-study.

Part 2. Empirical chapters

Each chapter is a report of the three individual sub-studies and expands on the papers submitted for publication, while at the same time dealing with specific aspects of the conceptual model employed for the thesis overarching objectives.

Chapter 3 covers the systematic mixed methods review of decision support interventions.

Chapter 4 includes a cross-sectional study of patients’ health literacy, information needs, decision control preferences and satisfaction with their treatment decisions.

Chapter 5 provides an in-depth study of cancer patient experiences of treatment decision making consultations, their facilitators, and barriers to making informed decisions; and of oncology clinic staff perceptions of facilitators and barriers to patient informed decision making.

Part 3. Integration of findings, recommendations, and conclusions

Chapter 6 provides a synthesis of the findings of the three sub-studies together with recommendations from a stakeholder group for the development of an effective and feasible cancer treatment decision-making support intervention.

PART1

CHAPTER 1: INTRODUCTION

"To achieve the possible, we must attempt the impossible again and again."

(Herman Hesse)

Chapter 1 . Background

South African cancer patients face numerous challenges to making informed decisions about their treatments. Cancer treatment decisions are primarily determined by clinical factors. However, within the contexts of constrained resources, large patient volumes and additional patient and oncologist related factors in low- and middle-income countries (LMICs) treatment decision-making is not only determined clinically [1]. Patient's limited health literacy poses a significant barrier to their effective cancer treatment decision-making [2], [3]. Many patients struggle to understand medical information and terminology. Oncologists fail to provide clear comprehensive and understandable information to patients about their diagnosis, treatments, and prognosis, which further exacerbates the situation [4]. Patients feel emotionally overwhelmed by their recent diagnosis, impacting on their ability to absorb and process information, and fully participate in decision making [5]. The lack of patient centred care and of involving patients in their decision making in South Africa contributes to disempowering patients to make meaningful treatment decisions, and to adhere to treatment plans [6].

The Ottawa Decision Support Framework (ODSF) has identified and categorised patients' healthcare decisional needs and proposes three strategies to support patients' informed decision making (Stacey, 2020). Decisional needs include dealing with uncertaintly and decisional conflict when making difficult decisions and having adequate knowledge, resources and support to make an informed decision. Decisional conflict results from uncertainty about goals of treatment, potential treatment outcomes and side-effects and anticipating potential decisional regret. Providing adequate knowledge of treatments, pros and cons and clarifying personal values regarding treatment outcomes may mitigate decision conflict. Support and resources include emotional and instrumental support from healthcare providers, family, friends and the community. Unclear decisional roles or a mismatch between a patient's preferred role and actual role may add to decisional conflict or regret. Decision control preferences range from a patient actively making a decision without any input from the doctor or family to sharing the decision role with either the doctor or family or both, to passively allowing either the doctor or family to make the decision for them, without their input [7], [8].

Strategies suggested by the ODSF to support decision making include clinical counselling by a qualified healthceare provider, using decision aids (DAs) before or within the consultation, and providing decision coaching [9]. Clinical counselling includes the disclosing of the diagnosis, providing the treatment options, providing decision support with a DA or through decision coaching and facilitating the implementation of the decision direcelty or through referral to other health professionals. A DA is a condition-specific, evidence-based tool which provides information to support the patient's informed decision making. A DA may include a values clarifying exercise ontended to reduce decision conflict by assisting patients to identify which treatment option best matches their values and outcome priorities. Decision coaching is the non-directive guidance provided in-person or digitally to prepare patients to deliberate on treatment options with the healthcare providers. Decision support interventions may include any combination of strategies to support patients to make informed treatment decisions.

Developing a context-appropriate intervention to support South African cancer patient treatment decision-making is imperative for addressing the decisional challenges facing patients and oncologists. An intervention that incorporates concepts of health literacy, shared decision-making, and a patient-centred approach that can accommodate large patient volumes and short patient-oncologist interaction times, can significantly improve the decision-making process for South African cancer patients.

1.1. Cancer treatment decision making

Richard Street states that: "Higher quality health care decisions are grounded in the best available evidence (biomedical), are consistent with patient values and preferences (psychosocial) and are feasible to implement (psychosocial)" [10]. While feasibility is often viewed from a provider perspective, the treatment also needs to be feasible for patients to implement. The biopsychosocial approach to medicine means that doctors should treat patients across all dimensions of care, i.e., biomedical and psychosocial.

Persons diagnosed with cancer are required to make important decisions while processing the news of a life-altering event with its concomitant emotional distress that affects cognitive abilities [11], impacting on informed decision-making. Cancer treatment decisions are particularly complex when multiple treatment options exist, with variable risks of serious side effects and uncertainty regarding expected clinical outcomes [12]. Oncologists make treatment decisions based on evidence from clinical trials, from clinical guidelines and considering expert opinion, as well as personal experience [13]. Clinically related factors are considered such as the characteristics of the malignancy, the stage of the cancer, the patient's performance status, co-morbidities and age. For some cancers variable treatment options are available, each with side effects of differing severity and complications, which adds to the uncertainty in decision making.

Decisions are impacted by the healthcare resources available, which may either limit choices or add to the complexity. In high income countries (HIC), oncologists may have a choice of numerous cancer treatments to offer, while in LMICs, scarce resources will limit the treatments available [14]. Goals of treatment are also crucial factors in decision making [13], [15]. While some treatments may be expected to result in remission of cancer, others may, without cure, control the disease progression extending lifetime, but, at the expense of quality of life. Thus, the oncologist and the patient need to consider the trade-off between quantity of life versus quality of life when making treatment choices. In LMICs, with most patients presenting late for diagnosis [16] and with limited treatment options, treatment intent is less likely to be curative, but may be provided to palliate symptoms or as life-extending therapy[17]. This approach requires a balance between risks and benefits of treatment in terms of quality of life, which includes social impacts of accessing treatments on the patient and family.

In South Africa, considered an upper middle-income country (UMIC), there is a significant disparity in access to health resources with more than 80% of the population utilising the public health system which does not have the resources typically available in upper middle-income countries [18], [19], [20]. This situation limits oncologists' choices of cancer treatments available [14]. Additionally, patients accessing the public sector health facilities are more likely to reflect the sociodemographic characteristics of middle to low-income countries where late presentation to health facilities and diagnosis of later stages of cancer impacts on goals of treatment [19], [20].

Besides clinical factors and healthcare resources, the personal characteristics of the decision-makers play a role in the treatment decision-making process [13]. There are two potential decision-makers – the oncologist and the patient, and in many circumstances, a patient's family, or caregiver [1], [21]. In addition to the personal and professional demographic characteristics of the decision-makers, communication styles, culture and beliefs are amongst a complex mix of factors impacting on the treatment decision-making discussion [9], [13]. The Western concept of individual autonomy in decision making is not always shared by traditional African and South African cultural beliefs, which adopt a communitarian approach to decision making. The patient may not make a decision in isolation and may need to consult with their family before a final decision is made[22,23]. Additionally the biomedical concept of health is a Western construct not typicallyt shared by the African holistic view of health which includes a spiritual dimension often addressed by African tradional healers [22]. The multicultural and multilingual environment of our country and the legacy of historical imbalances in access to tertiary education means that doctors and patients at tertiary facilities all too frequently do not share common levels of education, languages, or cultures [4], [23]. Thus, the personal and professional characteristics of decision-makers in cancer treatments in South Africa will play a significant role in the process.

The South African National Health Act requires that patients are adequately equipped to give informed consent, and that the required information should be disclosed in a language the patient understands and with consideration for the patient’s literacy level [24], [25]. Furthermore, while informed consent is the minimum requirement for patients making decisions about their healthcare, South African health professionals are urged to implement shared decision making as a patient-centred extension of informed consent [24]. Given the endemic challenges to patients making informed decisions or giving informed consent to treatments, it is important that we explore solutions that will improve cancer patient informed treatment decision-making.

1.2. Informed decision making

Informed consent is both an ethical imperative respecting a patient’s autonomy and a legal requirement intended to limit the doctors’ liability for adverse events [26], and requires that the doctor provides information to the patient about the treatment, the risks and benefits, including of not having treatment, and the expected outcomes. The patient must be capable of signing consent and voluntarily agree to the procedure [27]. Informed decision making requires adequate information exchange between the patient and healthcare provider, and deliberation of options leading to a mutually agreed treatment choice [28], [29]. To make an informed treatment decision, a patient needs to first recognise that a decision must be made, structure the decision options and outcomes, evaluate these according to facts and personal preferences before finally deciding [30]. Patient knowledge and understanding of their illness, stage, prognosis, and treatment options, including the risks, benefits, and expected outcomes are essential to enable informed decisions. However, in LMICs cancer patients' low levels of education and health literacy, inadequate provider communication and meaningful engagement of the patient, within an unsupportive health care environment, may contribute to poorly informed decision-making [4], [31], [32].

It is common that patients with advanced cancer have differing estimations of prognosis to that of their doctors, which impacts on their treatment decision-making [33]. A study of American patients with advanced colorectal or lung cancer, found that 93% opted for palliative chemotherapy, most of whom, had unrealistic expectations of cure. In South Africa, oncology nurses expressed opinions that patients receiving non-curative chemotherapy were clinging to the hope of a miracle or cure, despite what they were told by the oncologists [34]. However, some patients, on hearing a poor prognosis may refuse palliative treatment intended to improve quality of life, based on fear, fatalism and cultural beliefs [23], [35]. Our recent oncology palliative care study at Chris Hani Baragwanath Academic Hospital (CHBAH), revealed that most patients (77%) did not wish for an estimation of time left to live, while only 3% reported having had a conversation with their doctors about prognosis. However, most reported preferring comfort care (73%) over life-extending care at end of life and 66% wished to die at home. Despite these preferences, more died in hospital (63%) [36]. Patients preferring comfort care at the end of life but not wishing to discuss prognosis with their doctors and hoping for cure in the face of advanced stage cancer, provides a challenge to culturally sensitive conversations and appropriate treatment decision making for late-stage cancers, particularly in time-constrained settings.

1.3 Patient health literacy and its impact on decision making

Patient health literacy (HL) impacts on how well they understand their health needs, seek assistance for their illnesses and follow recommended treatment regimens [37]. Adequate HL is associated with fewer cancer related patient needs at diagnosis, improved patients' understanding of the severity of their cancer and an increased likelihood of choosing appropriate treatment [37], [38], [39], [40], [41], [42], [43]. Inadequate HL negatively impacts on decision making through poor understanding of medical terminology, inability to process information accurately and poor patient-provider communication [44], [45]. Key concepts underpinning HL are the ability to access, understand and appraise health information to make health related decisions [46], requiring a multidimensional capacity to read, write, understand, and apply information to make decisions [47]. The USA Institute of Medicine (IOM) defines HL 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” [46]. The World Health Organisation (WHO) broadens the definition to include: “the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health [48]”. Nutbeam, 2008, highlights essential functional, interactive, and critical skills, each adding a layer of complexity to the HL required to make decisions [49].

The Integrated Model of Health Literacy (IMHL) includes similar competencies to those listed by the IOM and the WHO, but also identifies three determinants of HL: personal, situational, and societal/environmental [47]. The Health Literacy Skills Framework (HLSF) of Squiers et al., 2012, include the impact of health-related stimuli as well as other mediating factors acting on the pathway between HL and health outcomes [50]. Mediators of HL include social support, emotional state, motivation, and self-efficacy [50], [51], [52], [53], [54], and while social support acts as a mediator between HL and health outcomes, it is also positively associated with HL itself [55], [56]. Age, education level, English literacy, socioeconomic status, employment status language spoken at home, and rural/urban living are the most identified determinants of HL, both in HICs and LMICs [57], [58], [59], [60].

Nutbeam, 2008, observes that the IOM views low HL as a risk to be managed to allow for improved health-related decisions and clinical outcomes, while the WHO definition views HL as an asset gained through health education and communication, which empowers individuals to take responsibility for their health decisions and subsequent outcomes [46]. Given the decisions to be made along the continuum of cancer care from detection to diagnosis and treatment, interventions to support cancer patients should strive to transform HL from a risk factor to an asset through appropriate education and coaching. This will empower patients to not only consent to, but to make informed choices regarding their cancer and treatments.

1.4. Shared decision making

While informed consent or informed decision making is the minimum requirement for patients making decisions about their treatments, there has been a growing universal trend toward the implementation of shared decision making (SDM) [24], [61]. Shared decision making is a process of information exchange between patient and healthcare provider, a discussion of preferences based on the information shared and reaching a consensus regarding the treatment decision [62], [63]. Given the complexity of cancer treatment decisions where multiple treatment options may be available; including the option of no treatment; or where there may be considerable risk of serious adverse events especially where there is no clear evidence regarding expected outcomes [63], SDM is potentially an appropriate model for patients and oncologists to deliberate on options and to reach consensus regarding the best treatment choice [45], [64], [65].

However, the SDM model makes the assumption that patients wish to engage in information exchange, deliberation of options and collaboratively making a decision. Some patients may prefer not to engage in SDM [66], [67]. While most patients a reported to prefer more information, some have variable information needs, both in content and amount of information[66], [68], [69], [70]. This preference may be determined by cultural or personal factors such as overwhelming emotions. An informed patient may, however, still not participate in a discussion of preferences and consensus building. Acquiring adequate functional health literacy skills and accessing information to make treatment decisions are not sufficient for patients to participate in shared decision-making without addressing the power imbalance between the patient and oncologist [64]. Some barriers to sharing power in decision making include presumptions about the patient or oncologist roles, patients undervaluing their own expertise, oncologist communication styles, lack of perceived need to prepare for decision making and insufficient decision support [64], [71], [72]. Patients may consider SDM to mean being fully informed about their cancer and treatments but not to participate in the actual decision making [73]. Besides improving functional health literacy to improve patients' knowledge, equal attention is required to develop the interactive and critical domains to empower patients to engage meaningfully in shared decision making [46]. However, SDM is not only transactional with mutual sharing of information and deliberation of options to reach a mutually agreed decision. Shared decision making is also relational involving not only respect for a patient's autonomy but also for the person [69]. Human communication is about the message and the relationship such that in providing information and discussing options, the doctor should also pay attention to the therapeutic relationship. While acknowledging the patient's vulnerability, the doctor needs to be aware of their own power and their vulnerabilities. The SDM process is embedded within the concepts of patient centred care. An oncologist's patient-centred communication requires an exchange information with the patient, to respond appropriately to emotions within the consultation while managing uncertainty and to enable informed treatment decision making [28]. This is achieved through a patient-centred approach, fostering a therapeutic relationship and enabling patients to take ownership of their health decisions [28]. Shared decision making is the integration of evidence-based best medical practice with patient centred communication skills, resulting in optimum patient-centred outcomes [74].

1.5. Patient-centred care

As with the growing global focus on shared decision making, patient centred care is increasingly embraced as the standard of good quality care [75], [76], [77]. Reviews of studies conducted in HICs show that patient centred care is associated with increased patient satisfaction with care, improved patient enablement and functioning, and increased ability of caregivers to care for patients at home [78]. Patient centred care, according to the IOM is care that is "respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions" [79]. The WHO has identified patient centred care as a core competency of all healthcare workers to improve quality of care [80]. Mead and Bower, 2000, identified five dimensions of patient centred care, namely, 1) biopsychosocial perspective, 2) the "patient as person", 3) sharing power and responsibility, 4) therapeutic alliance and 5) the "doctor as person" [77]. Langberg et al., 2019, reported that from 80 articles, 'Mead's' dimensions of sharing power and responsibility and therapeutic alliance appeared most frequently, with "doctor as person" was addressed the least [75]. In this review, co-ordinated care emerged as a new theme, in addition to 'Mead's' five dimensions. Based on their findings, Langberg et al., 2019, suggested a 3-dimentional framework to improve the operationalisation of patient centred care, namely 1) "understanding of the patients' experience of the illness in their life situation" combining 'Mead's' first two dimensions and 2) "the professional's relationship with the patient", combining dimensions 3 and 4, and adding 3) "co-ordination of care in the system". (Figure 1.1).

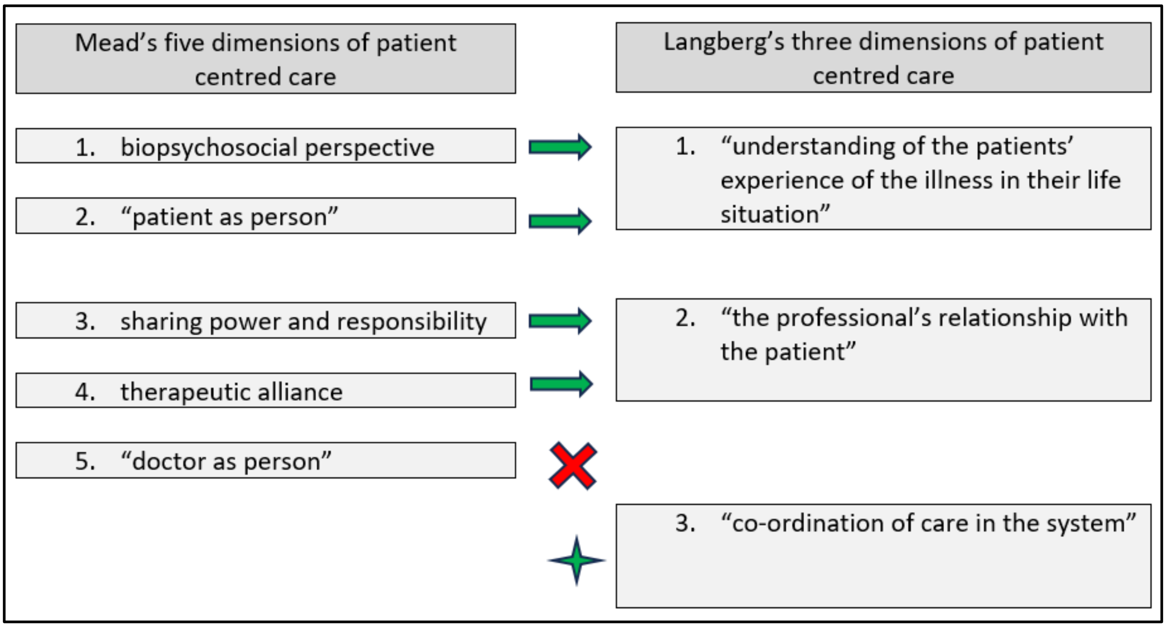


Figure 1.1: Dimensions of patient centred care

'Langberg's' dimensions, while intended to ease operationalisation of patient centred care, risks losing sight of the "doctor as person" in the consultation, with a skewed focus on the patient as a client requiring quality care when accessing the health services. Not only are doctors' personal attributes important but there is a risk of a subjective bias, arising from emotional distress when dealing with patients for whom options may be limited, or for whom cure is not possible. The scarce mention of this dimension in patient centred care articles, as demonstrated in the review, may result from a lack of awareness or acknowledgement of the importance of the doctor as a person in the therapeutic relationship in the biomedical literature [75]. A doctor's own emotional response when engaging with patients for whom options for cure are limited or unavailable and when faced with patient distress, may impact on their quality of communication, information sharing and addressing patients' emotions [81], [82]. This aspect of the "doctor as person" in the patient-centred relationship risks being unacknowledged and inadequately addressed. While patient centred care may be considered as the standard of good quality clinical care, it may not always be welcomed by patients [67], [83]. Patients with lower education, different cultures and more anxiety may not prefer a patient centredness. Patients who do not have adequate health literacy or health capital may not engage in the consulation exacerbating potential vulnerabilities. In such cases, a patient centred approach requires intuition and judgment on the oncologists' part to tailor their approach which may not include all of the proposed behaviours. A patient centred approach, based on the premise of patient autonomy may also not be implementable in societies which adopt a communitarian philosophy whereby one's personhood is inextricably linked to others in the community, as evidenced in the concept of "Ubuntu" in Africa ("I am because we are") [84]. For many non-Western cultures, family play a vital role in healthcare decision making, which challenges the notion of patient centred autonomy.

In sub-Saharan Africa, there is little research to guide the conceptualisation of locally relevant patient centre care interventions, possibly because of the traditional communitarian approach to decision making. Reported challenges to patient centred care , include poor communication, disempowered patients, inadequate human and infrastructure resources at health facilities, poor staff motivation to provide patient centred care and lack of accountability or disciplinary action for those who abuse patients[80]. However, positive reports note that patients treated for HIV seem to experience better patient centred care than women giving birth, which may reflect the focus on training of staff managing HIV patients to assess and manage the psychosocial aspects of care to enhance adherence [80].

In South Africa patient centred care is embodied within the Batho Pele ('People First') framework for health care. The principles include consultation, service standards, access, courtesy, information, openness, and transparency as well as redress [85]. South African patients' experiences indicate only partial compliance with these principles at all levels of the health-care system [85],[86] with several reported barriers to patient centred care [87],[88]. Without adequate patient centred care which contributes to shared decision making, it will be difficult to achieve patient informed treatment decision making based on their preferences.

1.6 Conceptual framework for informed cancer treatment decision making

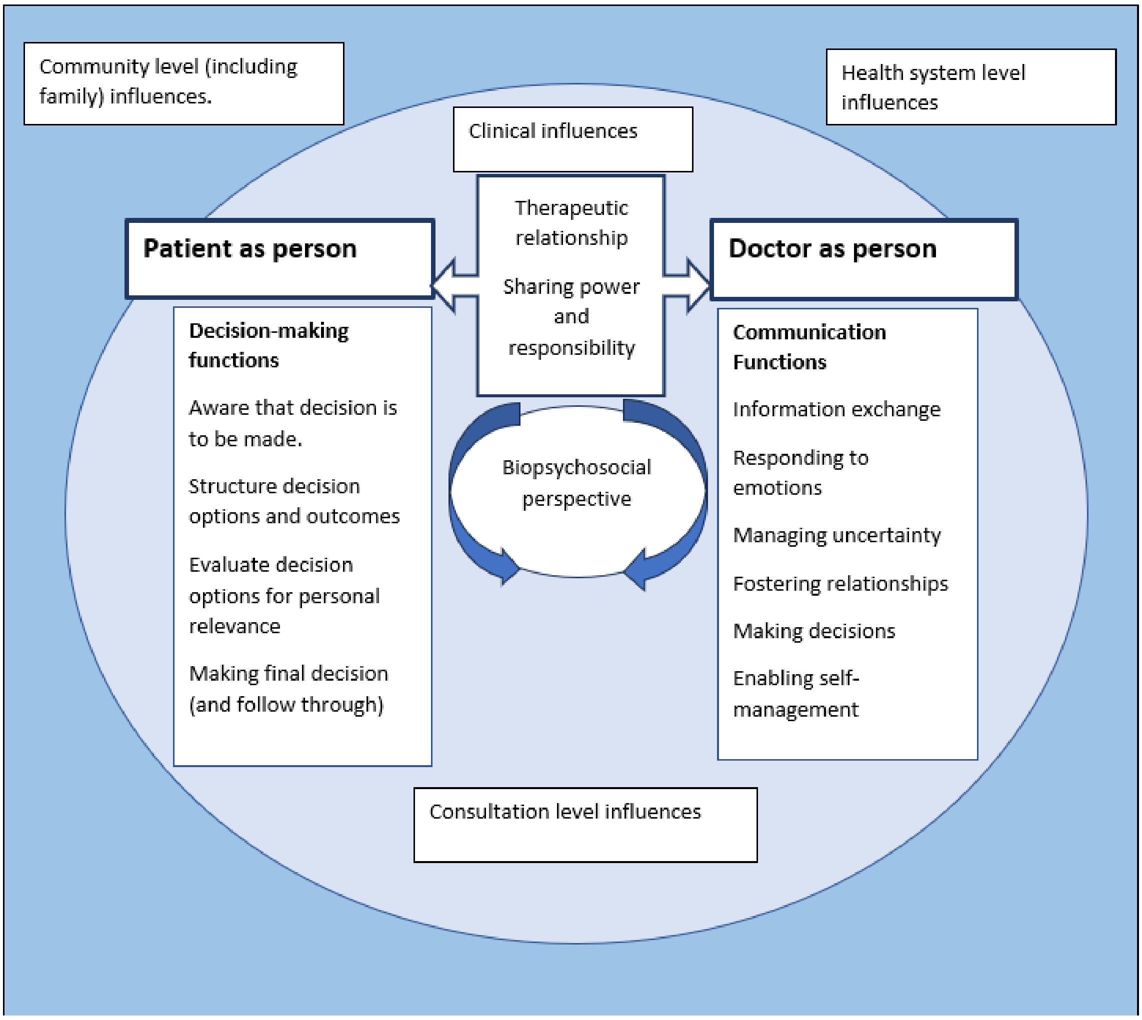


Figure 1.2: Conceptual framework of informed cancer treatment decision-making

Figure 1.2 summarises the components of an oncologist-cancer patient consultation required to achieve a shared cancer treatment decision which integrates patient centred communication and evidence-based practice to achieve the best outcome for the patient. The framework combines Woudstra's decision-making functions required of the patient with Epstein and Street's oncologist communication functions within the framework of Mead's patient centred care domains [28], [30], [77].

Patient-related factors impacting on the process include sociodemographic aspects, knowledge and health literacy, communication skills and emotional distress. Oncologist-related factors include knowledge, communication style, sociodemographic aspects as well as emotional influences. The patient's clinical condition and the health-system resources will determine what treatments are appropriate and available, while support from the family or community will play a role in treatment choices. Each sub-study of this PhD will explore elements of the conceptual framework, to further refine the final conceptual model to inform the intervention development. Figure 1.3 below, gives a visual representation of the findings from the literature of facilitators and barriers to informed treatment decision-making. A review of SDM amongst racial and ethnic minorities in HICs found that low-

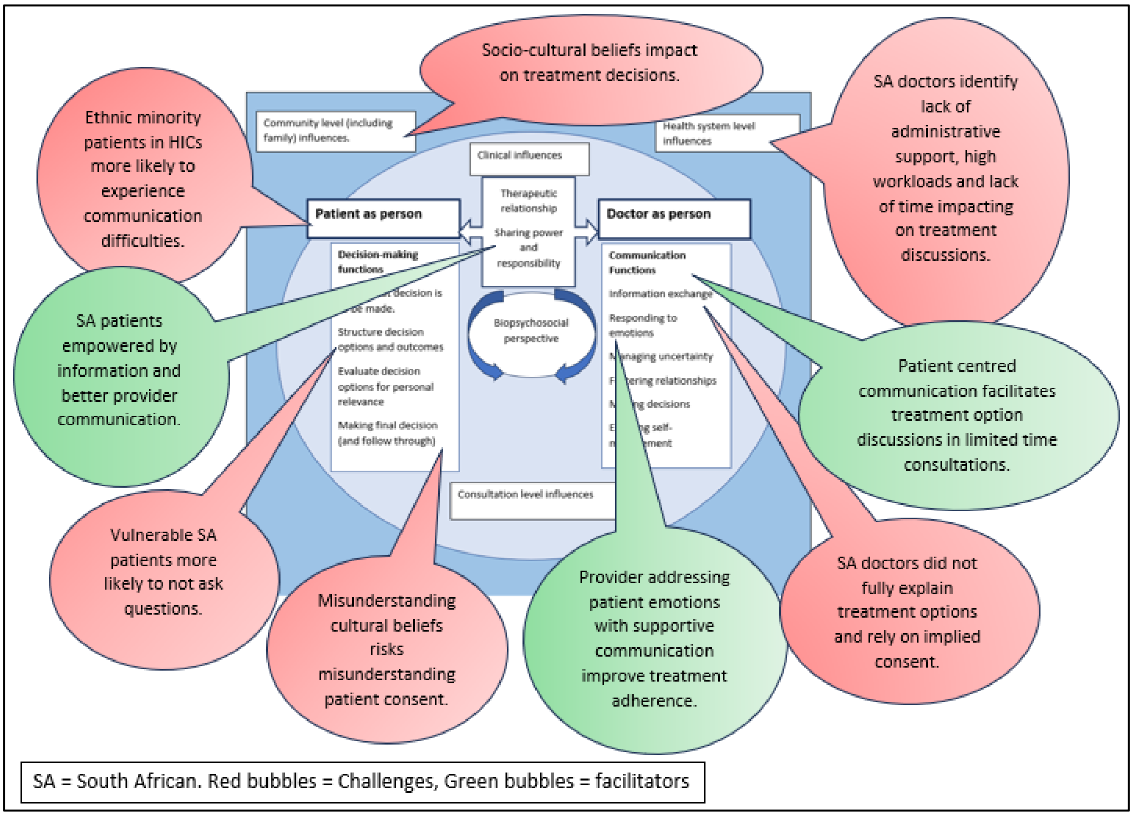


Figure 1.3: Challenges and facilitators of informed decision-making

acculturated patients were more likely to experience communication difficulties, have lower self-efficacy which could resulted in less participation in treatment discussions [62]. Providers communication style was a significant factor in cancer treatments received, and greater provider interaction resulted in improved knowledge, less decision conflict and more appropriate treatment decisions. Providers who were sensitive to patients' emotions and provided supportive communication improved adherence to treatment.

South African cancer patients feel empowered when receiving adequate information about their cancer and poor communication with health professionals was disempowering [6]. In public healthcare facilities in Durban, KZN a study found that doctors did not fully discuss treatment options while more than 50% relied on implied or presumed consent [4], [89]. Doctors identified language barriers, lack of administrative support such as interpreters, high workloads and restricted time for discussion impacting negatively on informed consent. Vulnerable patients, being more likely not to ask questions, risked making uninformed decisions.

Multi-disciplinary healthcare providers in a tertiary level service in KZN reported difficulties communicating diagnosis, treatment and prognosis in one consultation with patients when deciding on treatment for osteosarcoma, a cancer with a very poor prognosis for which treatment often included amputation [90]. Strategies to communicate bad news included first assessing patients' emotions and knowledge of their cancer, and an awareness of cultural influences on treatment decisions. Patients' cultural beliefs as well as the language used for cancer in isiZulu presented unique challenges requiring further sensitivity on the part of the HCPs when discussing the need for a swift intervention.

In Gauteng, a study of patient socio-cultural beliefs impacting healthcare found that patients did not raise sociocultural issues in consultations and providers usually did not enquire, which resulted in a misunderstanding of patients appearing to refuse treatments, which would have been avoided with culturally sensitive consultations. The author recommends a patient-centred approach to treatment discussions with patients [91].

1.7. Literature review: Treatment decision aids to improve informed decision making.

To facilitate informed SDM, several patient treatment decision aids (PtDAs) exist, which include educational literature with pictures, photos and diagrams, videos and audio recordings, decision grids and interactive web-based tools [92]. Decision aids (DAs) developed for colorectal, lung and breast cancers improved patient knowledge, prognostic understanding, and satisfaction with communication with no harmful effects such as increased anxiety or diminished hope [93], [94]. A study of older women making breast cancer treatment decisions found that a complex decision support intervention consisting of an online algorithm, booklet, and a brief DA about breast cancer treatment choices resulted in improved shared, and informed decision making and resulted in clinically more appropriate choices [95].

Patient-centred communication with compassion

A study comparing the use of a PtDA, or oncologist training in communication and SDM, or a combination of both, found that the oncologist training was more effective in increasing observed and reported SDM than the use of a PtDA alone. Combining the 2 interventions did not multiply the effect, although a combined intervention did result in shorter consultation times for SDM by 5 minutes [96], an important outcome for time-constrained consultations. Emotion-oriented silence or emotion-oriented speech has been found to enhance patient's information recognition after a consultation, even for patients with poorer health literacy [97]. Davis et al. comment that it is more feasible to teach healthcare providers (HCPs) effective communication skills than to improve the patient's literacy skills [98]. Use of simple language, a teach-back method as well as supplementing any printed information with pictures and stories are some recommendations for the consultation.

Ethnic minority patients in high income countries

Informed discussions and enhanced provider communication improved decision making for ethnic minority breast cancer patients in the USA [99]. Interventions which included producing personalised summaries of information and treatment preference clarification before the consultation facilitated patient centred discussion with the doctor. Educational material in various formats improved prostate cancer patients' informed decision making and decision self-efficacy, however self-administered DAs demonstrated mixed efficacy in increasing cancer and treatment knowledge.

A randomised cluster-controlled trial of two in-consultation DAs including people with low socio-economic status (SES), resulted in improved SDM for all patients, although SDM was still lower amongst patients with lower SES before accounting for clustering [100]. Success of the DAs varied across surgeons while socio-demographics varied across sites, possibly meaning that individual surgeon and patient factors may have influenced the outcomes. Patients with low SES reported levels of SDM that were higher than observed levels, suggesting that when evaluating SDM as an outcome, patients with low self-efficacy may over-estimate their active participation in the process. There are very few documented trials of DAs for cancer treatment decision making in LMICs, with none in South Africa.

Development of cancer patient decision support interventions

To develop an effective intervention which facilitates informed cancer treatment decision making in South Africa, it is important to deepen our understanding of factors that impact on cancer patient treatment decisions. Early interventions to improve patient participation in decision making in non-Western countries across all clinical domains have not progressed to wider implementation [101]. Effective intervention implementation requires a rigorous process of development, from an in-depth needs analysis to developing a theory-based implementation program and evaluation plan [102], [103]. While many decision support interventions have been developed using a decision-making theoretical framework such as the Ottawa Decision Support Framework (ODSF), or the International Patient Decision Aids Standards (IPDAS) Collaboration checklist [101], [104], [105], no studies have been found to report using a theory-based intervention and evaluation plan.

The scarcity of documented studies of the development and successful implementation of cancer patient informed treatment decision support in LMICs and South Africa represents a significant gap in providing patient-centred cancer care. Additionally, the lack of studies reporting theory-based implementation plans coupled with the disappointing lack of progress to wider implementation in LMICs, make it imperative to move beyond the use of theoretical frameworks for developing the intervention structure and to utilise theory driven strategies to guide a successful intervention plan.

1.8. Study rationale

South African cancer patients face significant challenges to making informed treatment decisions. Our complex population demographic of multiple languages and cultures, added to the previous Apartheid history of oppression of most people intersects with the limitations of the healthcare system to provide adequate patient-centred care. A uniquely South African intervention is required to support cancer patient informed treatment decision-making.

1.9. Overall aim and objectives

The overall aim of the study is to combine the published evidence of best practices with a needs assessment of local factors which impede or facilitate cancer patient informed decision making to inform the development of a feasible implementable decision support intervention to enable oncology patients in South Africa to make informed treatment decisions throughout the illness continuum.

Key Hypothesis

Providing patient-centred decision support will address South African cancer patients' significant decisional needs and facilitate their informed cancer treatment decisions.

1.9.1 Study objectives and research questions.

Objective 1

To critically review published trials and other experimental studies for effectiveness and patient experience of interventions to improve cancer patient shared treatment decision making.

1. How effective are current treatment decision support interventions to assist cancer patients to make informed, values-based treatment decisions?
    a. What are the reported experiences of patients making cancer treatment decisions?
    b. How effectively are decision support interventions addressing the cancer patient decisional needs?

Hypothesis.

Decision support interventions will improve vulnerable patient informed decision making and address important patient reported decision needs.

Objective 2

To describe oncology patient health literacy, factors associated with health literacy, information needs, decision control preferences and patient perceived therapeutic alliance.

1. What is the health literacy of the patients attending the oncology clinics at three academic hospitals in South Africa, and what are the sociodemographic factors associated with adequate health literacy?
2. What are the oncology patient reported information needs, decision control preferences, and perceived levels of therapeutic alliance?

Hypothesis.

Patients will have high levels of information need, will prefer either a shared decision-making role with family or a passive decision role and will report high levels of respect for and trust in doctors.

Objective 3.

To understand the cancer patient experience of, and the healthcare provider perceptions of treatment decision-making; and the facilitators and barriers that impact on patient informed decision making.

1. What is the patient reported knowledge of cancer and treatments, sources of information, and what are their experiences of making treatment decisions, including barriers and facilitators to making informed decisions?
2. What are the perceptions of oncology doctors and nurses of cancer patient decision-making experiences, including barriers to and facilitators of patient informed cancer treatment decision making?

PART 1

CHAPTER 2: METHODOLOGY

"Research is to see what everybody else has seen, and to think what nobody else has thought."

Albert Szent-Gyorgyi

Chapter 2 . Methodology

This chapter commences with a brief description of the South African legal framework for informed decision making and cancer patient care and rights. It also describes study site contextual settings (Section 1). In subsequent sections the overarching methodology of the PhD is discussed, exploring the theory to justify the selected methodologies for the individual sub-studies. Section 2 covers the intervention mapping methods selected to develop the decision support tool. Section 3 discusses the mixed methods systematic review process and the rationale for selecting this methodology for the review. Section 4 covers the theory of mixed methods studies to justify the use of this methodology for the needs assessment for this PhD (i.e., the empirical quantitative and qualitative study chapters). Section 5 briefly describes the integration of the results to inform the intervention development. Section 6 covers data management for the empirical studies, before ending with the ethical considerations in Section 7.

2.1. Study context and setting

2.1.1. Informed decision-making legislation and guidelines in South Africa

South Africa has legislation and guidelines regarding informed consent for any health-related procedure or treatment. Informed consent is the legal requirement of healthcare staff to ensure that patients make informed decisions about their healthcare.

The National Health Act (NHA) 61, 2003 requires that every patient is informed of their health status, the required diagnostic tests and available treatments including the benefits, risks and consequences of each option. They are to be informed of the right of refusal of options with the concomitant implications, risks and obligations associated with refusal [106]. The patient must be informed in a language that they understand and in a manner that considers their literacy level. As discussed in section 1.2, informed consent only requires a doctor to give the patient information and for the patient to voluntarily give consent, which is the minimum requirement of the National Health Act, however there is no requirement of an exchange of information or deliberation on options available, including the option of no treatment.

The Health Professions Council of South Africa (HPCSA) expands the scope of informed consent, to assess the patient’s needs and priorities, which include culture, occupation and beliefs which may impact on their decision [107]. Doctors should check the patient’s understanding and need for further information. To provide up-to-date understandable information for patients, written materials, pictures and other aids should be used to explain complex concepts. Inviting family members or other trusted caregivers is encouraged and using staff to assist with translation as well as further discussion is suggested. While the HPCSA extends the doctor's responsibility to ensure that a patient understand the information, there is no clear mention of the need to deliberate options with the patient in the process of making a decision.

The National Cancer Strategic Framework for South Africa, recommends a multidisciplinary approach to cancer care, including the representation of all relevant professionals in an oncology multidisciplinary team. This team should also include psychosocial team members to provide support for cancer patients across the entire trajectory of illness [108]. While there is no specific mention of decision making support, these multidisciplinary teams may provide support from the time of diagnosis which could include treatment decision making.

The National Patients' rights charter published by the Department of Health [4], [109] is displayed in all health facilities informing patients of their rights to receive information to make an informed decision about their health. However persons who are vulnerable and dependent on the healthcare providers for their treatment, and who may also have low health literacy may not act on their right to information.

2.1.2. Study sites

Gauteng

The empirical studies for this thesis were conducted at two tertiary academic hospital oncology sites in Gauteng and one in KwaZulu Natal. Sites were conveniently selected because of access to trained research teams. However, sites in two geographically different locations were purposively included to represent different populations and oncology clinic settings. These study sites fall within the resource-constrained Public Health Sector, which serves the majority (around 80%) of South Africans, mainly from socioeconomically disadvantaged communities [110].

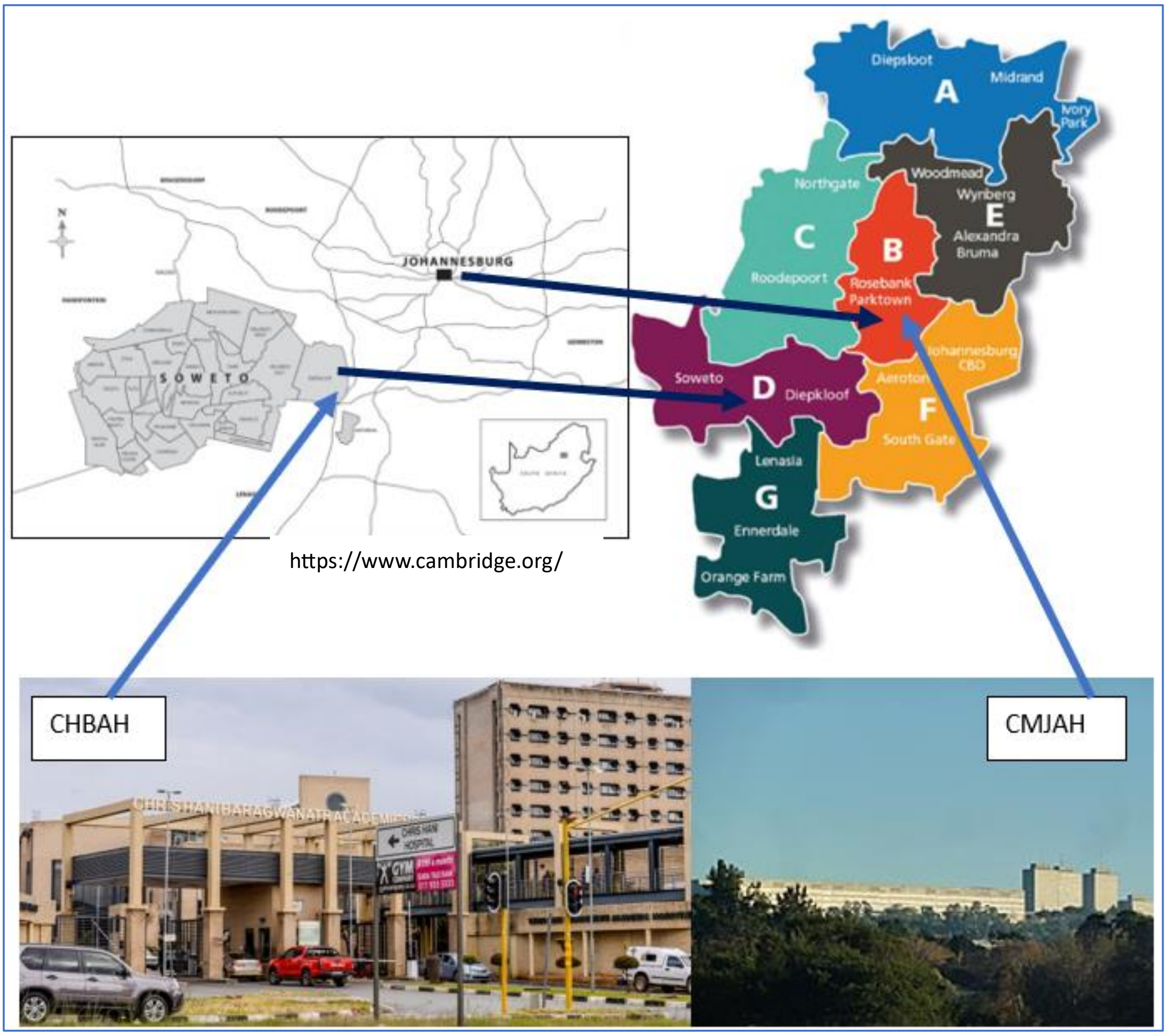
Gauteng is geographically the smallest province in South Africa, but the most populous at 16.10 million in 2022 (27% of total population of South Africa), and wealthiest (contributing 33% of the country's GDP) [111][112], [113]. Because of its relative wealth, Gauteng experiences the highest immigration in the country, from international and provincial sources, with over 1 million immigrants expected from 2021 – 2026 [113]. The population of Gauteng is mostly urban (90%), is multilingual with Isizulu being the most spoken language at 20% followed by English, Afrikaans, and Sesotho. Adult literacy in Gauteng is the highest in South Africa at 95% [114].

Johannesburg is the most advanced commercial city in Africa, and the economic hub of South Africa. The city is home to almost 5 million people, 36% of the Gauteng population [115]. Despite its wealth, Johannesburg has an unemployment rate of 25%. Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) is in Parktown, just north of the inner city of Johannesburg (Figure 2.1). The 1088-bed hospital provides tertiary and specialist level services to patients referred from secondary level hospitals in surrounding districts and from other provinces. CMJAH provides central hospital medical and haematological oncology as well as radiation oncology services [116]. At the time of the quantitative data collection for this thesis, the oncology services were disrupted by a fire in April 2021. This resulted in a complete closure for several months of medical and radiation oncology services at the hospital.

Soweto is a conglomeration of about 87 townships covering an area of 200km^2, with a population of about 1.8 million. Soweto has a long history of forced migrations, largely due to the Apartheid policies, dating back to 1905. A haphazard construction of townships through the 20th century has resulted in high economic inequality, ranging from very affluent areas to extremely poor families living in squatter camps. The population of Soweto consists almost entirely of black people at 98%, with an unemployment ranging from 45% - 65% [117] Chris Hani Baragwanath Hospital (CHBAH) is located on the far Eastern border of Soweto in the more affluent suburb of Diepkloof (Figure 2.1). It is the largest tertiary level hospital in South Africa with about 2800 beds and serves the urban and peri-urban areas of Soweto, surrounding districts and patients from neighbouring provinces. However, some patients travel from as far as the Eastern Cape province (about 850km) in the South-Eastern region of South Africa.

Until 2021, only haematology oncology services were provided. In 2021, a donor-funded medical oncology unit, called the Soweto Comprehensive Cancer Centre was opened. There is no radiation oncology service at CHBAH, and patients are referred to CMJAH (just under

20km distance) for radiation treatment. The fledgling oncology unit was initially overwhelmed by patients referred from CMJAH in the first months after the 2021 fire at that hospital, coinciding with the time that of the quantitative surveys were conducted for this thesis.



https://www.cambridge.org/

Figure 2.1: Gauteng - Chris Hani Baragwanath Academic Hospital and Charlotte Maxeke Academic Hospital

KwaZulu Natal

KwaZulu Natal (KZN), is the second most populous province of South Africa with 11.54 million people, comprising 19% of the country's population. KZN produces the second highest proportion of the country's GDP at 16% [111]. IsiZulu is most spoken by 83% of the population, with adult literacy at 87%. KZN has a large rural population (52%), with the remaining 48% living in urban areas.

Pietermaritzburg in the Msunduzi municipality, is the provincial capital and is the economic hub of the uMgungundlovu district of KZN. Unemployment in the district is at 29% [118]. The population of the municipality is 820 00 (2022), with only 41% having completed grade 12 and 15% having a tertiary qualification [119]. Grey's hospital (Figure 2.2) is a 530-bed tertiary level institution providing specialist level services to the population of Pietermaritzburg and the largely rural Western areas of KZN with a population of about 3.5 million [120]. The oncology clinic at the hospital provides medical, haematological and radiation oncology services.

The individual differences in clinic settings and operational procedures are described in chapters 4 and 5.

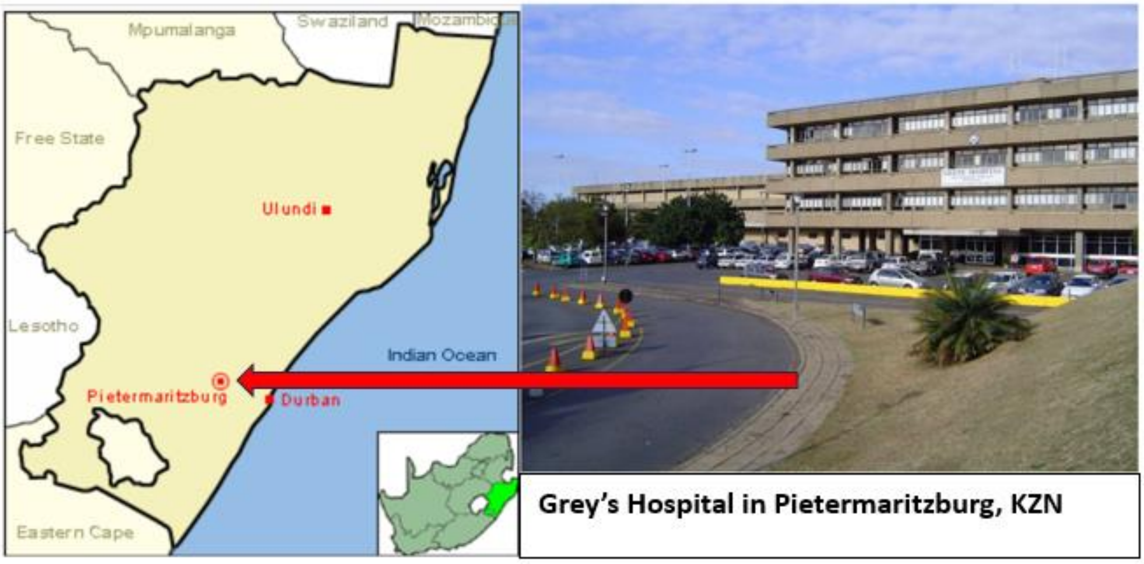


Figure 2.2: Greys Hospital in Pietermaritzburg, KZN

2.2. Intervention development methodology

Developing an effective health service intervention requires the application of a complex iterative process to ensure an implementable intervention which is effective, yet acceptable and feasible for the resource-constrained context of SA, to be adopted as normal practice. This chapter describes the overarching study methodology, the mixed methods systematic review and empirical study methodologies and designs, data management approaches and ethical considerations.

Two intervention development methodologies exist: The Medical Research Council (MRC) Developing and evaluating complex interventions framework [102], [103], [121] and the Intervention Mapping (IM) framework [122]. The MRC framework describes the intervention development method as four broad phases: (i) development, (ii) feasibility/piloting, (iii) evaluation and (iv) implementation; with recommended processes to complete each phase. The **development phase** includes problem identification and needs assessments, stakeholder involvement, drawing on existing theory and frameworks to inform the intervention, developing an intervention theory, understanding the context in which the intervention will be implemented, then to design and refine the intervention. The IM framework provides a clear map of six recommended steps starting from identifying the problem, to designing and implementing a solution. These steps include 4 intervention development steps, namely (i) a needs assessment to develop a logic model of the problem, (ii) based on the evidence, formulation of the program objectives, (iii) program design using evidence-based methods and theories of behavioural and environmental change, (iv) intervention development resulting in an implementable program (intervention). Steps 5 and 6 encompass the implementation and evaluation strategies, namely (v) develop a program implementation plan and, (vi) develop an evaluation plan. I elected to use the IM approach as it gives clear steps and tasks to follow for designing an intervention for cancer patient informed treatment decision making. The 6-step intervention mapping steps and tasks are summarized in Table 2.1.

Table 2.1: Intervention Mapping framework steps

Intervention Mapping Methodology [122]
Logic Model of problem: Step 1 - *a careful description of the problem to enable intervention planning*. 1. Conduct needs assessment to create a logic model of problem. 2. Describe context for intervention (population, setting, community). 3. State program (intervention) goals.
Program outcomes and objectives – Logic model of change: Step 2: *articulate the desired health promoting behaviours and environmental conditions.* 1. State expected outcomes – behaviour and environment. 2. Specify performance objectives for expected outcomes. 3. Select determinants for outcomes (behavioural and environmental changes needed). 4. Construct matrices of change objectives. 5. Create logic model of change.

Intervention Mapping Methodology [122]
Program Design: Step 3: *discuss intervention ideas and select behavioural change theory and evidence-based methods and strategies for the identified changes needed.* 1. Generate program themes, components, scope, and sequence. 2. Choose theory and evidence-based change methods. 3. Select/design practical applications to deliver change methods.
Intervention development: Step 4: *the various applications selected in Step 3 are organized and produced.* 1. Refine program structure and organisation. • Prepare plans for program materials. • Draft messages, materials and protocols. • Pre-test, refine and produce materials.
Program Implementation Plan: Step 5: *guides the development of implementation approaches.* 1. Identify program users. 2. State outcomes and performance objectives for program use. 3. Design implementation strategies for the intervention. 4. Implement the strategy.
Evaluation plan: Step 6: *enables process and effectiveness evaluations of the implementation strategy.* 1. Write effect and process evaluation questions. 2. Develop indicators and measures for assessment. 3. Specify the evaluation design. 4. Complete the evaluation plan.

Intervention mapping emphasises the importance of theory and evidence in intervention planning, is well suited to interventions which target both personal and environmental elements of behaviour change and has been successfully utilised in developing and implementing many complex health interventions [123], [124], [125]. An intervention to improve cancer patient informed treatment decision making in South Africa is complex in terms of the difficulty of the decisions to be made, the interaction of the different role-players, the health system context and greater environment. The systematic review and empirical studies of this PhD focus on the first step of intervention development, by conducting a needs assessment, to inform program outcomes and objectives and a logic model of change.

The linking of the pertinent individual elements of this study is illustrated in Figure 2.3. The needs assessment follows an iterative process where the results of a preceding study are explored further in the next study, to refine the conceptual model based on locally identified needs, challenges and facilitators of informed cancer treatment decision making. The systematic review (chapter 3, paper 1) provides the evidence from the literature for the effectiveness of current decision support interventions to address patient reported needs to make informed values-based decisions. Based on the literature review of this thesis and the findings of the systematic review, the empirical quantitative study (chapter 4, paper 2) explored factors associated with informed decision making and treatment choices. The systematic review findings and the quantitative study findings informed the qualitative study enquiry (chapter 5, paper 3) to interrogate the quantitative findings and add additional depth of needs elements. These consolidated findings informed the design of an intervention to improve patient informed cancer treatment decision making. The next steps beyond the scope of this thesis is to work with a multi-disciplinary inclusive stakeholder group to develop the tools of the intervention to be tested in a pilot study.,

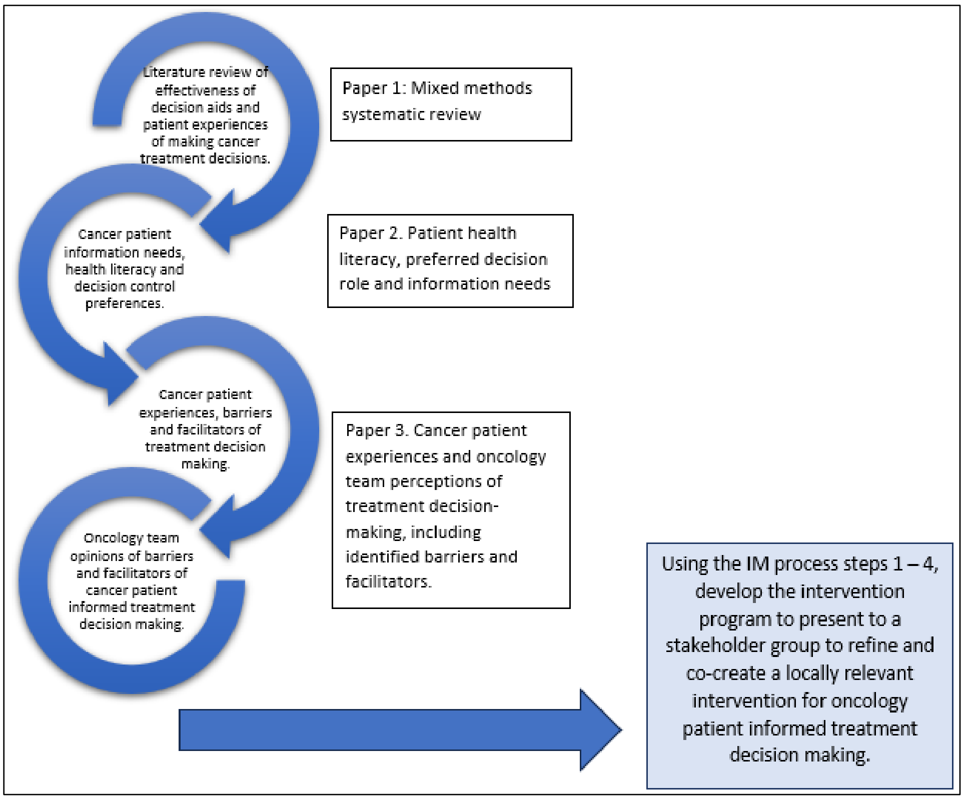


Figure 2.3: Conceptual map of the research process

The next sections address the methodologies of the individual sub-studies (chapters 3-5) of this PhD.

2.3. Mixed methods systematic review of the effectiveness of decision support interventions and patient decision-making experiences

Mixed methods systematic reviews (MMSRs) are becoming increasingly popular to inform public health or clinical policy, particularly for complex interventions [126]. Conceptually, MMSRs bring together two ontological research paradigms: i) a positivist ontology paradigm (which contends that there is an external objective reality which exists independently of peoples beliefs about or understanding of it) which is commonly associated with quantitative research studies and ii) a constructivist ontology paradigm associated with qualitative research studies [127] (which posits that individuals' views are directly influenced by their experiences, and it is these individual experiences and views that shape their perspective of reality). A greater breadth and depth of understanding is achieved by combining quantitative and qualitative data or integrating evidence from quantitative and qualitative studies, into one systematic review. The most common framework for data synthesis for this type of review is the convergent design which includes either integrated or segregated methods of data management [127], [128]. The integrated method is suitable for a MMSR with one research question which is answered utilising data from both quantitative and qualitative studies. The convergent integrated method (used for my systematic review) is best suited to MMSRs with two related research questions, where the data from quantitative and qualitative studies are independently synthesised followed by the integration of the evidence from each synthesis.

The MMSR provides a comprehensive approach to understanding the complexities of the intervention required to support patient cancer treatment decision making. This review provides a holistic understanding of the objective outcomes of interventions and subjective patient experiences of treatment decision making allowing for the identification of potential gaps between intervention effectiveness and patient experiences. The integration of the evidence from the qualitative and quantitative syntheses provides a robust foundation for developing interventions that are responsive to patient needs.

For the MMSR for this study, I followed the convergent segregated method to answer the questions: 1) What is the effectiveness of cancer treatment decision support interventions to improve patient decision outcomes? (quantitative studies) and 2) what is the experience of cancer patients making treatment decisions? (qualitative studies). The evidence of each synthesis was integrated to identify which interventions address patient reported needs and where there are gaps to be addressed when designing a decisions support intervention (figure 2.4). A detailed description of the review methods is provided in chapter 3.

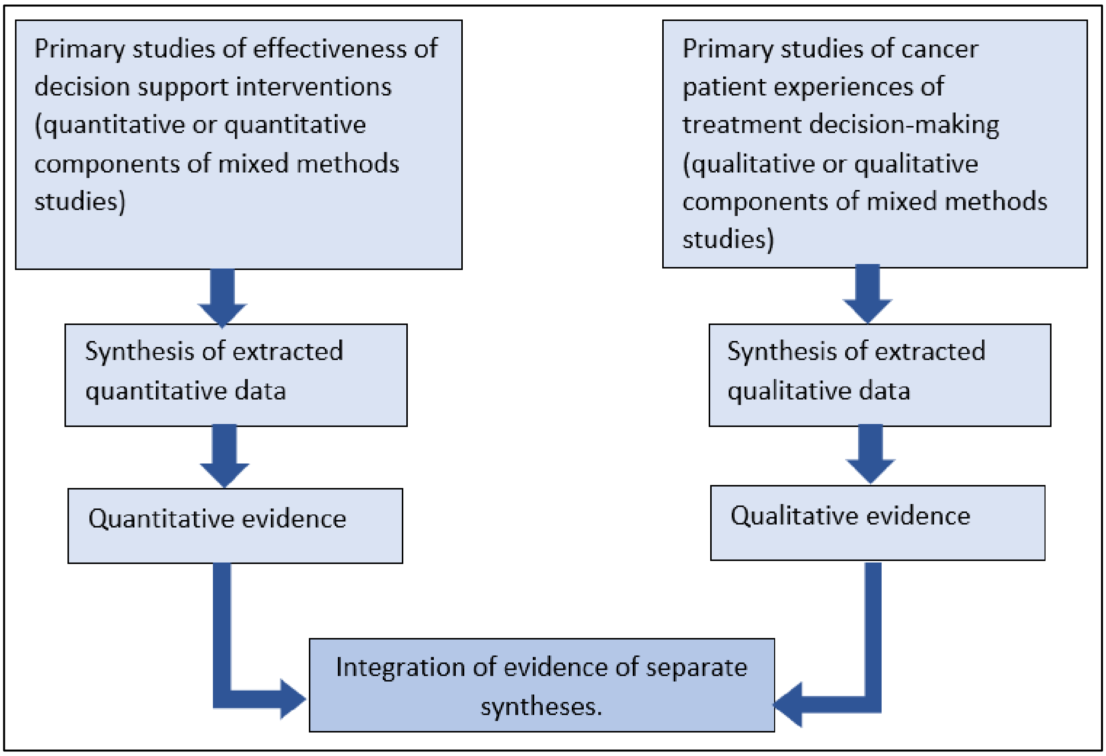


Figure 2.4: Convergent segregated research design for the mixed methods systematic review*

*[127]

2.4 Mixed methods (qualitative and quantitative) studies to understand South African patients' needs to make informed cancer treatment decisions

Oncology professionals practice within a complex dynamic system, dealing with life-threatening illnesses and accompanying uncertainties. Treatment decisions require patients and oncology staff from diverse social contexts to interact and find common ground. Working within such a context requires a philosophically pragmatic approach to decision making based on best scientific evidence, but also reflecting on environmental (in this case scarce provider resources and large patient volumes), social and emotional factors impacting on treatment decisions. Given these circumstances, a similar pragmatic philosophy which endorses the notion of theory development directly from practice, is best suited to guide research of factors affecting cancer treatment decision making. This approach recognises that truth is multifaceted and best understood from both an objective and subjective stance, requiring an iterative process of shifting between deduction and induction to ultimately apply insights gained back into practice [129], [130]. A constructivist mixed methods paradigm of views and assumptions about the nature of reality/ truth which integrates both quantitative (positivist) and qualitative (interpretivist) methods was best suited to research originating from a pragmatic philosophy [129], [130], [131]. This philosophy places an emphasis on actionable knowledge, recognises the interconnectedness between experience, knowing and acting, and views inquiry as an experiential process.

Mixed methods research is defined by Tashakkori and Creswell as: “Research in which the investigator collects and analyses the data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or program of inquiry”[132]. Mixed methods methodology provides a comprehensive view of a phenomenon by incorporating positivist quantitative methods and interpretivist qualitative methods into one study. The limitations of each approach are offset by the strengths of the other, increasing the validity of the results. Through triangulation, results of one method may be corroborated by the other (convergent triangulation), strengthening the confidence in the findings. Divergent results may indicate that the phenomenon is more multifaceted, and with further enquiry, could expand understanding and add to theory development [129], [130], [133]. To adequately answer the research questions and fulfil the objectives of the needs analysis, I selected a constructivist mixed methods approach utilising a sequential studies design, starting with a quantitative study to provide generalizable findings followed by a qualitative study to verify domain elements of the quantitative study and to potentially add additional context elements to the conceptual framework selected for informing the investigator (PhD student) and stakeholder group for intervention development and strategies to select for subsequent implementation evaluation. Findings from these empirical studies were further triangulated against the mixed methods systematic review findings as discussed in 2.5.

2.4.1 Quantitative study

A non-experimental descriptive study design was used for the quantitative study. This design is suitable for an exploratory study of the phenomena of choice. Participants with a diagnosis of cancer who were to discuss their treatment options with oncologsts in specialist clinics were purposively selected to assess their decisional needs. A cross-sectional survey using validated tools was used to collect data. The data was analysed using simple descriptive statistics and a regression analysis to test the association between participant sociodemographic variables and health literacy. Chapter 4 contains the detailed description of the methodology for the quantitative study.

Steps to ensure the validity and reliability of the results were considered when designing the study. Internal validity is defined as the extent to which a concept is truly measured by an instrument, while external validity refers to the generalisability of the findings to the whole population [130], [134].

Threats to internal validity include the duration of the study, with events over time potentially affecting the dependant variables, sampling strategy or unreliable survey instruments. This cross-sectional study was planned to be completed over 8 weeks which would have limited the potential impact of time on the results. The sample size was calculated to allow for representability of the results within the populations sampled. The survey instruments were all validated for use in South Africa, or widely used in low literacy populations in LMICs. The health literacy instrument was translated into IsiZulu, the most commonly spoken South African language to reduce errors due to interpretation of the English instrument by the interviewers and participants. All interviewers attended training by the PhD researcher to ensure that the surveys were uniformly applied and uniformly translated, and that the data was accurately captured. Daily data cleaning was applied to address any queries immediately to ensure accurate data capturing.

Threats to external validity include unrepresentative samples, the researcher’s expectations which may subtley be communicated in the interview, or the participant’s responses reflecting what they think the researcher wants to hear. The study sample was purposively selected to represent the study population and recruited from three different sites to capture the variability of geography and associated sociodemographic factors, however, they may not be generalisable to the greater population of South Africa. The interviewer training included awareness of how phrasing could impact on how participants answer questions, and that participants should be assured that there are no “wrong” answers, and that confidentiality would be maintained.

2.4.2 Qualitative study

Based on a phenomenological paradigm, an exploratory qualitative research design was used for exploring cancer patient and oncology staff experiences of treatment decision making. Semi structured in-depth interviews were conducted with patients with cancer who were receiving chemotherapy in the oncology clinics. Focus group discussions were conducted with oncology nurses and doctors in the clinics. Chapter 5 contains the detailed description of the methodology of the qualitative study. While qualitative research is inherently subjective in nature, strategies may be employed to limit biases and to establish trustworthiness. The trustworthiness of qualitative research depends on four key criteria: credibility, transferability, dependability and confirmability [135]. Credibility is enhanced by prolonged engagement with participants, researcher reflexivity and triangulation of methods and sources. For this study, while the interviews and FGDs were a once off interaction with the participants, which may have been a limitation, however, the interviewers tried to build rapport with the participants at the start of, and during the interviews. The PhD researcher was careful to reflect on and document any possible biases which may impact on interactions with participants and which may influence the analysis of the data. By interviewing patients, and doctors and nurses separately, the shared information could be corroborated, reducing the potential biases from a single method of data collection. Transferability was enhanced by providing clear contextual and sampling information. Dependability was enhanced by documenting the research process steps and maintaining an audit trail of decisions. Objectivity was confirmed by engaging colleagues not involved in the research process to check the analysis outcomes and interpretations of the results and by maintaining a reflexive journal.

2.5. Integration of the mixed methods studies results

The results of the mixed methods studies were integrated together with the findings of the MMSR to answer the overarching question of the thesis. Based on these integrated findings the conceptual framework selected for the thesis (Chapter 1, figure 1.2) was subsequently refined to reflect these new insights. Together the findings were used to develop the logic model of the patient informed decision-making problem as the first step of the IM process. This model is used to inform the next steps of the intervention development. Details of this process are discussed in chapter 6.

2.6. Data management

For the systematic review (chapter 3), the papers sourced though the search of the databases were loaded onto COVIDENCE©, for screening and data extraction [136]. Results of the screening process, and critical appraisal as well as the data extracted were downloaded onto Microsoft excel spreadsheets and stored on the author’s password protected laptop computer.

For the quantitative study (chapter 4), the consent forms and the interview forms were filed separately and stored in a locked cupboard in the author's office. The quantitative interview and survey data were uploaded and stored on a secure, password-protected REDCap database, hosted by the University of the Witwatersrand [137]. All captured data was checked for accuracy, missing variables and where necessary corrected by the interviewers and the author as the interviews progressed. De-identified data was downloaded from REDCap and analysed using STATA 14 [138]. Data manipulation included, as required, recoding and transforming of variables, and creating new indicator variables for analysis.

The consent forms and demographic questionnaires for the in-depth interviews and focus group sessions were filed separately and stored in a locked cupboard in the author's office. The recordings of the in-depth interviews and focus groups were downloaded onto the author's password protected laptop computer. The transcriptions and translations conducted by a research consulting service, were stored on the same computer. Transcripts and demographic information were uploaded to Dedoose [139], a password protected application for coding and analysis. The transcripts were coded and analysed by the author and a co-investigator, and the emerging themes were reviewed with the supervisors.

2.7. Ethical considerations

For the systematic review, an ethics waiver from the University of the Witwatersrand's Human Research Ethics Committee (Medical) was obtained (HREC Waiver: W-CBP-211108-01). For the PhD protocol and the mixed methods studies, ethics approval was obtained from the Witwatersrand's Human Research Ethics Committee (Medical) (HREC clearance number: M200986) (APPENDIX A)

All participant questionnaires were coded to maintain anonymity, and all data collected was used only for research purposes.

PART 2

EMPIRICAL CHAPTERS

Gaining knowledge is the first step to wisdom.
Sharing it, is the first step to humanity.

(Unknown)

Chapter 3 . A mixed methods review of oncology treatment decision support interventions amongst vulnerable populations. (Paper in review)

3.1. Background

A cancer diagnosis is a life-altering experience for the patient and any family members. From it follow intense emotions that can interfere with the processing of medical information and making optimal treatment choices [140],[141]. Cancer treatment decisions may be especially complicated with multiple treatment options and the considerable risk of serious adverse events, particularly where there is no clear evidence regarding expected outcomes [142]. Cancer treatment decision making occurs within the milieu of the patient's serious illness, personal circumstances and emotional state, physician characteristics and communication skills, and the demands imposed on both by the clinical environment [143]. In many low to middle income countries (LMICs) cancer patients' low levels of education and health literacy, inadequate provider communication and meaningful engagement of the patient, within an unsupportive health care environment, may contribute to poorly informed decision making [57], [144], [145].

Decision aids (DAs) developed in high income countries (HIC) to improve cancer treatment decisions for colorectal, lung and breast cancers, improve patient knowledge, prognostic understanding and their satisfaction with communication with limited negative impacts on anxiety or patients' hope [146],[147]. Training oncologists to effectively facilitate medical decision making has been reported to improve SDM [148],[149]. Interventions developed in HICs may not be feasible in LMICs, given the differing demographics and resources, however vulnerable populations in HICs have similar experiences to patients in LMICs when accessing and interacting with healthcare services [62], [105]. While there is little evidence of implementation of decision support aids from sub-Saharan Africa and LMICs, examining the effectiveness of decision support interventions (DESI) implemented within vulnerable populations in HICs may provide information useful to develop interventions in LMICs. Vulnerable populations include elderly persons, culturally diverse or minority ethnic groups, rural dwelling people, people with low education or low health literacy, and socioeconomically disadvantaged groups [150], [151].

When designing an intervention to support patients to make informed cancer treatment decisions, it is important to understand patient decision-making experiences and their perspectives of effectiveness of DESIs. A preliminary search in PubMed in September 2021, did not identify any reviews integrating the effectiveness of DESIs with the patient experience of decision making.

3.2. Purpose

The objective of this review was to understand the synergies and gaps between decision support interventions (DESIs) and patient decision-making needs. This mixed methods review incorporated quantitative evidence of effectiveness studies and qualitative evidence of oncology patient experiences of cancer treatment decision making with or without decision support tools. The review questions were: 1) How effective are decision support tools in improving knowledge of cancer and treatments, and supporting patients based on their decision role preference to make informed decisions, 2) What were the challenges to, and facilitators of supported informed cancer treatment decision making for vulnerable patients? We focussed on studies including vulnerable populations within HICs, as a proxy for populations of LMICs.

3.3. Methods

We conducted a mixed methods review for its suitability to explore what works to support complex cancer treament decision making, and how and why it works [152]. The integration of quantitative and qualitative evidence provides a deeper understanding of factors that will impact the development and implementation of complex interventions in differing contexts. The systematic review was conducted in accordance with the JBI methodology for mixed methods systematic reviews [153].

3.3.1. Data sources

We searched the following databases: PubMed, Medline, CINAHL, PsycINFO, Cochrane Library and Global Health, SCOPUS, and ProQuest. The recommendation of JBI is to search the widest reasonable range of databases to ensure comprehensiveness of the review. Databases which would yield papers from quantitative and qualitative studies were included. Databases which could not be accessed were not included [126]. Search terms included: (Cancer OR oncology OR neoplasms OR malignancy) AND (shared decision making OR informed decision making OR Patient decision making OR patient clinician communication

OR joint decision making) AND (decision aid OR decision support OR decision intervention OR decision tool). For the qualitative review, the search term (patient experience OR patient perception OR patient view OR patient participation OR patient centred care OR patient preference OR patient involvement OR patient satisfaction) was added. The research string was adjusted for each database searched.

3.3.2. Inclusion criteria

We included quantitative and qualitative studies of patients 18 years or older diagnosed with adult-onset cancer. The quantitative component considered studies that included the following outcome measures: Patient knowledge of cancer and treatments, decision support and decision conflict, shared decision making, and distress or anxiety. The qualitative component examined the patient reported experiences of barriers to, and facilitators of cancer treatment decision making . Quantitative studies comprised randomised controlled trials, and other non-randomised studies of effectiveness of a decision aid or intervention. Qualitative studies included study designs based on phenomenology, grounded theory, action research and descriptive research. Mixed methods studies were included if quantitative or qualitative data could be clearly extracted. Due to the limitations of resources, only papers published in English were considered. Patient decision aid trials were first registered in the Cochrane collection library from 1999 with a sharp increase in the number of patient decision aids registered from 2001 [154]. Therefore, papers from 2000 to 30 September 2021 were included.

3.3.3. Study selection

The electronic search results were downloaded into COVIDENCE$^{©}$, a systematic reviews production tool to remove duplicates, screen titles and abstracts and full texts [155]. Five reviewers screened title and abstracts against the inclusion and exclusion criteria. Training was provided for all reviewers to ensure that the objectives of the study and criteria for selection of studies were understood. Studies for which two reviewers had reached consensus were either excluded or included for full text screening. Any disagreements on inclusion were resolved at weekly meetings. Full texts were similarly screened. Two independent reviewers assessed the full text studies for methodological validity prior to inclusion in the review. For quantitative studies and for qualitative studies (and the respective components of mixed methods studies), we used the standardized critical appraisal instruments from JBI[126] . Any disagreements between two reviewers were resolved through discussion, with no conflicts requiring resolution by a third reviewer. The results of the critical appraisal may be found in APPENDICES C - E. The results of the search are summarised in Figure 3.1, complying with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram [156].

3.3.4. Data extraction

Two reviewers extracted all publication details, methodologies, and details about the study populations from all eligible papers. Further extracted information included details of interventions and results of specified outcomes from quantitative studies, and themes and subthemes with supporting quotes from qualitative studies.

There were no papers reporting studies from LMICs. Because the results of this review are to be utilised to develop a DESI amongst largely vulnerable populations in South Africa, we decided on a sub-analysis reviewing studies which included vulnerable adult populations from HICs, who may face similar challenges to accessing healthcare as people within LMICs [62], [105]. We selected all studies which were conducted with vulnerable cancer patients, or those with a proportion of vulnerable patients for which a sub-analysis of outcomes was conducted.

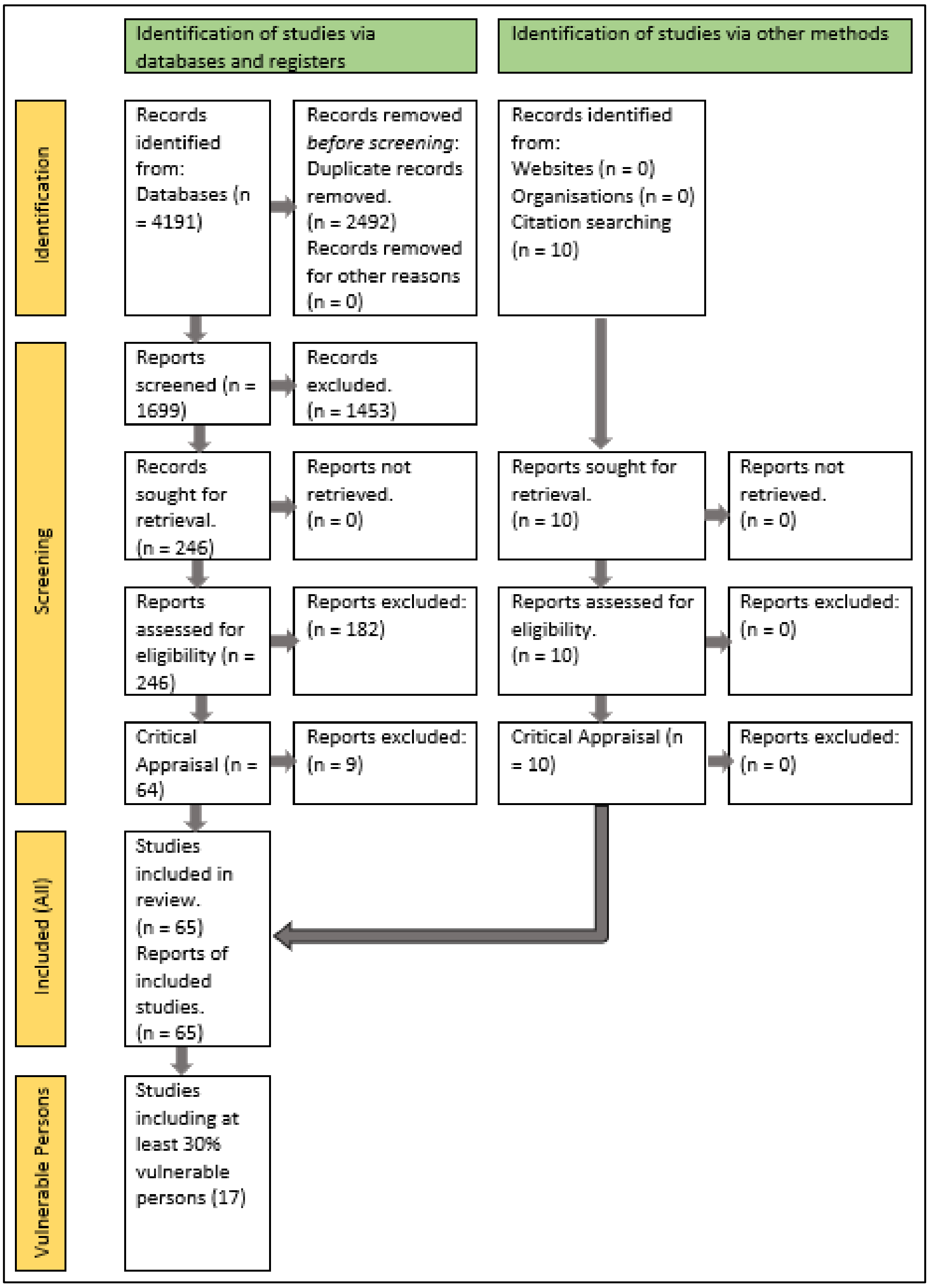


Figure 3.1: PRISMA flow diagram of the study selection

(PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses)

3.3.5. Data synthesis and integration

Utilising the JBI convergent segregated methodology for mixed methods systematic reviews [153], we synthesised the quantitative and qualitative evidence separately, followed by an integrated synthesis. Due to the heterogeneity amongst quantitative studies, we conducted a narrative analysis of outcomes of DESI implementation. For the qualitative studies, we pooled the extracted findings which we categorised and collated to produce our synthesised findings, according to the JBI meta-aggregation approach [153]. The findings of the quantitative and qualitative syntheses were juxtaposed to identify synergy and gaps between outcomes of DESIs assessed and patient reported decision-making experiences.

3.4. Results

Using Covidence© [155], 4191 studies were screened, 2492 duplicates were removed. Of the remaining 1699 studies, 65 papers were potentially eligible for inclusion in the review (Figure 3.1). We included an extra 10 papers identified through citation screening. Following critical appraisal of the eligible papers, we extracted data from 37 quantitative papers, 26 qualitative studies and two mixed methods studies [157],[158]. Applying our criteria for papers including vulnerable populations, we finally included 17 papers, of which ten were quantitative studies of effectiveness and seven were qualitative studies of patient experiences of treatment decision making.

3.4.1. Study characteristics

Nine quantitative papers reported results from eight RCTs [95] [100], [159], [160], [161], [162], [163], [164], [165], [166] (Table 3.1). Two papers were published from one study [160], [161]. One paper reported results from an analytical cross-sectional study [166]. All were conducted in HICs, the majority in USA [100], [160], [161], [163], [164], [165], [166] , one each in Saudi Arabia [159], the Netherlands [162] and the UK [95]. Five quantitative papers focussed on localised prostate cancer[160], [161], [162], [163], [166], four on localised breast cancer [100], [164], [165] and one on metastatic colorectal cancer [159].

All seven qualitative studies were conducted in HICs: four in the USA [167], [168], [169], [170], and one each in the UK [171], Canada [172] and Australia [173] (Table 3.2). Five studies utilised individual participant interviews[167], [168], [170], [171], [173] and two conducted focus group discussions[169], [172] for data collection.

Table 3.1: Characteristics of the quantitative studies of effectiveness

Lead Author, year, study design, country of study	Title of paper	Setting and study population	Study population demographic details
Aeshah I. AlSagheir[174] 2020 RCT Saudi Arabia	Comparing the use of Arabic decision aid to usual care. A multicentre randomized controlled trial for Arabic speaking metastatic colorectal cancer patients in Saudi Arabia	Metastatic colorectal cancer patients attending any one of the 4 main oncology centres in Saudi Arabia.	N = 92 Language: Arabic age 56.1 (SD 12.3) male 62 (67.4%) Married/partner. 66 (71.7%) Education: Illiterate - 16 (17.4%), Less than high school - 33 (35.9%), High school - 16 (17.4%), Diploma/College graduate/Postgraduate: 27 (29%) Income: <5000 SAR: 29 (31.5%), 5000 - 10000 SAR: 41 (44.6%), 10001 - 15000 SAR: 13 (14.1%), > 15000 SAR: 9 (9.8%)
Berry, DL[160] 2013 RCT USA	The Personal Patient Profile-Prostate decision support for men with localized prostate cancer: A multi-centre randomized trial	6 institutions (urology, radiation oncology, or multi-disciplinary clinics in 4 geographically distinct areas. Men with newly diagnosed with T1 or T2, (localized) prostate cancer. All men required to read English or Spanish at ≥ grade 6 level.	N = 494 Age: DA 63 (45-86). Control 62 (40 - 84) Minority/multiple race: 75 (15.2%) Spanish/Hispanic/Latino: 15 (3%)
Berry, DL[161] 2018 RCT USA	Decision Support with the Personal Patient Profile-Prostate: A Multicentre Randomized Trial.	Urology and radiation clinics English and Spanish speaking men with newly diagnosed localized prostate cancer	N = 392 enrolled (276 analysed) Age: DA < 60 66 (33.3%), >/= 60 132 (66.7%), control <60 59 (30.4%), >/= 60 135 (69.6%) Race: Black 113 (29%), white (Hispanic) 12 (3%), white (non-Hispanic) 240 (61%) Married/relationship: DA 140 (70.7%), control. 140 (72.2%)

			Education: > high school 310 (79%), </= high 77 (20%)
Cuypers, M[175] 2018 RCT (Longitudinal regret…) Holland	Impact of a web-based prostate cancer treatment decision aid on patient-reported decision process parameters: results from the Prostate Cancer Patient Centred Care trial.	17 general hospitals, 1 academic hospital Newly diagnosed patients with localised prostate cancer, with at least 2 treatment options	N = 336 Language: Dutch age overall: 65.3 (SD 5.9), DA 65.3 (5.9), control 66.3 (5.7) p = 0.06. Education (total): Low 112 (34%), medium 82 (25%), high 137 (41%) married/partner (total) 295 (88%)
Diefenbach, MA[176] 2018 RCT USA	Examining the impact of a multimedia intervention on treatment decision making among newly diagnosed prostate cancer patients: results from a nationwide RCT	Cancer Information Services (CIS) Men with localised prostate cancer, who called the CIS for information, who had access to a computer and were English speaking.	N = 349 age 64.73 (SD 8.39) Education: High school or less 18.9%, some college: 26.6%, college graduate/> 54.2% Ethnicity: White 76.2%, African American 16.9%, other 2.6% Income (USD) <30000 21.2%, 30000-59000 23.5%, 60000-79000 17.8%, >/= 80000 30.7% Medical insurance 91.6%
Durand, M-A[177] 2020 RCT USA	What matters most: randomized controlled trial of breast cancer surgery conversation aids across socioeconomic strata	4 NCI-designated cancer centres in urban and rural locations that provided care to a diverse population in terms of socio-economic status (SES), ethnic and racial populations. Participants included English, Spanish and Mandarin-Chinese speaking women (18 years or older) with localised breast cancer.	N = 616 Language: English 535 (86.9%), Spanish 61 (9.9%), other 13 (2%) Age mean: 59.7 (SD 12.5) Education: high school or less 63 (10.2%), high school 125 (20.3%), > high school 421 (68.3%) Race/Ethnicity: Black 96 (15.6%), Hispanic 78 (12.7%), White 394 (64%), other 30 (4.9%) SES: Lower 203 (33.0%), higher 413 (67.1%) Health literacy: low 276 (44.8%), not low 333 (54.1%)
Jibaja-Weiss ML 2011 RCT USA	Entertainment education for breast cancer surgery decisions: A randomized trial among patients with low health literacy cancer	Breast pathology clinics in two public hospitals administered by the Harris County Hospital District.	N = 138 (completed = 76) Age 51. years (SD 10.9) Language: English 89 (65%), Spanish 49 (35%) Ethnicity: White 22 (15%), African American 52 (38%), Hispanic 62 (45%), Asian American 2

	patients early-stage disease.	Women, diagnosed with early-stage breast cancer (I–IIIA), were candidates for breast-conserving surgery. Could speak English or Spanish. Patients did not have medical insurance; Many have a high school education or less.	
Li K.D 2021 Analytical cross-sectional USA	Differences in Implementation Outcomes of a Shared Decision-Making Program for Men with Prostate Cancer between an Academic Medical Center and County Health Care System (LAC-DHS).	Men with newly diagnosed prostate cancer, no evidence of metastatic disease, without prior treatment (including on active surveillance). Ability to read English or Spanish	Age: Total 63 (58, 68), Academic centre 64 (58, 69), LAC-DHS 64 (49, 64) $p < 0.001$ Race/ethnicity: White: total 118 (46%) Academic centre 108 (55%), LAC-DHS 10 (17%) Black: total 27 (11%) Academic centre 18 (9%) LAC-DHS 9 (16%) Asian total 22 (9%) academic centre 17 (9%) LAC-DHS 5 (8%) Hispanic/Latino total 26 (10%) academic centre 2 (1%) LAC-DHS 24 (41%) Other total 61 (26.9%) academic centre 51 (23.3%) LAC-DHS 10 (17.2%)
Wyld L [178] 2021 (Multi-centre cluster RCT). England and Wales	Bridging the age gap in breast cancer: cluster randomized trial of two decision support interventions for older women with operable breast cancer on quality of life, survival, decision quality, and treatment choices.	Women 70 years or older, able to read English, with primary operable breast cancer. Intervention sites offered the DESI to all women regardless of enrolment status.	46 clusters (21 intervention, 25 control) n = 1339 (670 intervention, 669 control) age 77 (IQR 70-96, range 69-102)
Yen RW [100] 2020 RCT USA (high and low SES status)	Text-only and picture conversation aids both supported shared decision making for breast cancer surgery: Analysis from a cluster randomized trial.	Women with localised breast cancer deciding between breast-conserving surgery plus radiation vs mastectomy, recruited from 4 NCI-designated cancer centres.	n = 311 age 60.5 (SD 12.2) Language: English 283 (91.0%), Spanish 24 (7.7%), other 4 (1.3%) Race/ethnicity

			Black, non-Hispanic 35 (11.3%), Hispanic 30 (9.6%), white non-Hispanic 229 (73,5%), other 11 (3.5%) Education: Less than college 201 (64.4%), college or higher 110 (35.4%) Socio-economic status (SES) Low 104 (33.4%), high 207 (66.6%) Health literacy inadequate 141 (45.3%) adequate 168 (54.0%) Insurance private 220 (70.7%), public/uninsured 91 (29.3%)

Table 3.2: Characteristics of qualitative studies of patient experiences

Lead Author, year, country of study	**Title**	**Phenomena of interest**	**Setting**	**Cultural**	**Participants**
Burton, M 2015 UK	The information and decision support needs of older women (>75 yrs.) facing treatment choices for breast cancer: a qualitative study	Information needs and preferences for the older age group (>75 yrs.) of women relating to the choice between surgery and PET	Clinics	Not stated except that these were older women (> 75 yrs.) who had been diagnosed with invasive breast cancer in the preceding 60 months and offered a choice of primary endocrine treatment (PET) or surgery.	33 women with age range of 76-91 years. 22 women received PET. 11 underwent surgery.
Mcvea, KLSP 2001 USA	Low-income women with early-stage breast cancer: Physician and patient decision-making styles	Previously unsuspected factors influencing cancer decision making in real world settings	State of Nebraska indigent patient assistance program.	Mainly white indigent women.	Women (25 in total) with stage 1 or 2 breast cancer. Median age 56 years, 19 rural-dwelling, 22 white, 3 non-white.
Michel, J 2021 USA	Improving Shared Decision Making in Latino Men with Prostate Cancer: A Thematic Analysis	Prostate cancer patients' information gathering, preference for information presentation, technology use and to identify qualities	Metropolitan medical centre urology clinic.	Underinsured low-income Latino population in Los Angeles.	20 men recently diagnosed with prostate cancer age 50 or older (range 52-74). In the process of deciding on a cancer treatment.

		of ideal decision-making treatment.		Participants originally from South America, Central America, and Mexico.	Formal education 8.6 - 11.9 years.
Shaw, J 2015 Australia	Treatment decision making experiences of migrant cancer patients and their families in Australia.	Factors that influence the cancer treatment decision-making experiences of first-generation migrants with cancer from Arabic, Chinese, or Greek backgrounds.	Community-based cancer support groups and three oncology outpatient clinics.	First generation migrant from a Chinese (Cantonese or Mandarin), Greek or Arabic speaking country, and had one of these languages as their first language.	Patients 18 years and over, diagnosed with cancer in the preceding 3 years.
Sheppard, VB 2008 USA	Latina a Latina (SM): developing a breast cancer decision support intervention.	Patients' perceptions and experiences making treatment decisions and survivor advocates' breast cancer stories	Patients from support groups and physicians, patient advocates from a Latino breast cancer resource organisation.	Latin American persons (including islands of the Caribbean) and Latin Americans who speak Portuguese, Quechua, and Guarani.	Women with breast cancer and breast cancer survivors most from Central America and age range 34 - 59.
Sheppard, VB 2010 USA	Development of decision-support intervention for Black women with breast cancer	Factors that influence Black women's' adjuvant therapy decisions	Washington DC metro area.	Black women patients (14) residing in the District of Columbia. Survivor advocates (10), and cancer providers (total 5 Black, 3 White, 2 Asian).	Breast cancer patients in active treatment, survivor advocates who mentored other women, and cancer providers.
Wong, J.J 2011 Canada	What Do Older Patients with Early Breast Cancer Want to Know While Undergoing Adjuvant Radiotherapy?	The experiences of women with breast cancer diagnosis and treatment	Radiation therapy clinic.	Not stated, other than English speaking.	Breast cancer patients, over the age of 70years.

3.4.2. Effectiveness of decision interventions

Most (6) interventions were offered online [160], [161], [162], [163], [166], [179], of which two provided a printout of the decision process for the patients to use at home or in the consultation [160], [161], [162], [165], [179], two included assistances from research or clinic staff [165], [180], and one additionally included paper-based information [179]. One intervention used a video-based information guide [159], and one used computerised interactive edutainment, accessed at the clinic, with the assistance of the case manager who also provided emotional support [165]. Two interventions consisted of a DA used in the consultation with trained surgeons [100], [164], while a third included an in-consultation DA in addition to an online component [179]. Description of the interventions is given in Table 3.3.

Of the five studies which assessed participant knowledge of cancer and treatment [159], [162], [164], [165], [179], three demonstrated a significant increase with DA use [164], [165], [179] (Table 3.3). One study found that while patients subjectively felt more knowledgeable, objectively assessed knowledge was not significantly increased [162]. AlSagheir et al. found that sociodemographic characteristics such as low income and lower level of education did not impact on patients' levels of understanding of cancer and treatments [159]. Durand et al.reported that their Picture Option Grid (POG) DA had more impact amongst disadvantaged patients and reduced disparities in knowledge between patients of lower and higher SES in comparison with usual care (UC) [164]. The POG also improved more outcomes than the Option Grid (OG) DA, possibly, as reported by the investigators, because the DA included pictures.

Table 3.3: Description of interventions with results of studies of effectiveness

Lead Author, Year	**Decision aid description and framework used vs comparator**	**Outcome Instruments**	**Outcomes**
Aeshah I. AlSagheir 2020	A video-based Arabic language DA for chemotherapy decisions for metastatic colorectal cancer patients. The DA lists the 2 treatment options (with or without chemotherapy), with the treatment benefit, response rates, and estimated survival rates. The DA used graphic illustrations and numeric estimates. The was used in addition to usual care. DA development was based on the Ottawa Decision Support Framework (ODSF) Comparator: Usual care alone	Knowledge: Self-developed Arabic questionnaire (score 0-8). (Measured at baseline, 1 month) GAD 7 (general anxiety disorder - 7) (Measured at baseline, 1 month, 6 months)	No significant difference between DA and usual care groups in understanding of cancer and treatment at baseline (p=0.86), and at 1 month (p=0.45). DA and usual care groups had mean reductions in anxiety (at 6 months); 2.27, *p*=0.033 and 1.94, *p*=0.045, respectively. NSD between arms. Sociodemographic factors (> 50% had low income and low education) had no impact on levels of understanding.
Berry, DL 2013	The Personal Patient Profile Prostate (P3P) is a self-administered, web-based intervention that provides personalized coaching and education based on the patient's priorities. Video vignettes based on patient characteristics demonstrate patient-provider communication coaching, Patients could print the information to use to prepare for the consultation. The doctors also received a printout to add to the patient's file. The P3P was accessible in the clinic or at home. The ODSF framework was used in developing the P3P.	Decisional Conflict Scale [O'Connor] (DCS) consists of 5 items (uncertainty, informed, values clarity, support, effective decision). 5-point Likert scale (25 total) - 0 (low conflict) to 100 (high conflict). (Measured at baseline, 1 month and 6 months). Spielberger State-Trait Anxiety Inventory (measured at baseline)	Significantly reduced DC in P3P arm over time for the 2 subscales of **uncertainty,** 3.61 units (95% CI, 7.01 to 0.22) (P = 0.04), and **values clarity**, 3.57 units (95% CI, 5.85 to 1.30) (P = 0.002). Inadequate information (informed subscale) was significantly associated with being older, non-White, and having less income. Lack of values clarity was associated with less income, minimal pre-enrolment use of the Internet and inadequate support. Conflict related to perceived support significantly decreased as men were further from biopsy by number of weeks. The largest decrease between 1 and 2 weeks and associated with non-White race and baseline support scores.

	Control: The usual patient education resources in the clinic. Both groups were offered links to reputable websites for prostate cancer		
Berry, DL 2018	The Personal Patient Profile Prostate (P3P) as described above.	DCS. 10-item, low-literacy version. Score 0 (nil) – 40 (highest conflict).	In multivariable analysis, P3P intervention group reported a 5-unit (95% CI, 0.59–9.40) lower DCS score (p=0.03) at 1-month than the usual care group. In multivariable analysis: higher DCS at 1 month was associated with unemployment, lower income, having only 1 consultation, and high to intermediate risk cancer. Decision conflict varied significantly between sites. (Table 3.1)
Cuypers, M 2018	Patients entered clinical information onto a Web-based DA, with research staff assistance. Information was provided about prostate cancer and the eligible treatments. A values-clarifying exercise was included. An electronic summary was available to be printed and taken home. The DA was developed using an existing evidence-based online Canadian DA and European treatment guidelines, and guided by the IPDAS criteria. Comparator: Usual information and counselling	Prostate cancer (Pca) subjective knowledge level per treatment (e.g., "How well do you think your knowledge about surgery is?") Objective knowledge: 5 multiple-choice test questions from the Pca Decision Quality Instrument DCS (O'Connor) Patient's perceived role during decision making. (Problem-Solving Decision-Making Scale) DA arm additional questions to evaluate the DA (e.g., "Was the online DA format your preferred	Participants using the DA felt more knowledgeable. Mean objective knowledge (test) scores were comparable between trial arms. No difference between groups in patients' perceived role in decision making. No difference in decision conflict: DCS in DA group 23.5 (SD 13.4) vs control group 24.1 (SD 13.0) (p = 0.39). Mean HADS scores: medium or severe HADS scores were more common in participants who would prefer a printed DA (p = 0.03). DA users with HADS scores < 8 reported less decisional conflict. DA users with severe or high HADS scores trended to greater likelihood to prefer treatment advice.

		format?" and "Would you preferred if the DA had provided you with a treatment advice?"). HADS Scores ≥ 8 represented substantial levels of anxiety or depression.	Subgroup analysis: 84% of actual DA users (N = 156) were in favour of the online DA format, 16% (N = 30) would preferred to have received the DA in print. Participants favouring the online DA format were younger (M= 64.6 vs. M= 67.3, p = 0.02) and more often highly educated (50% highly educated vs. 27%, p = 0.04). **Additional information**. Of participants who received but did not access the DA, 56% (N = 15) indicated a DA in print was preferred.
Diefenbach, MA 2018	Online DA "Healing Choices". An online, video-based DA. Participants also received a CD-ROM version of the program. The DA contained information about cancer, treatment options and side effects. Beliefs and expectations about cancer treatments and outcomes were addressed. Normalising statements with stress relieving exercises addressed emotions. Decision coaching included the modelling of decision skills. The DA supported patients making values-based decisions. DA was developed based on the self-regulation theory and social cognitive theory. Comparator: Usual personalised consultation service.	Decisional Conflict Scale (measure at 2 months) Cancer related distress: Intrusion subscale of the Impact of Event Scale (IES). Subscale score of ≥ 20 indicates clinically significant distress. (Measured at baseline and 2 months)	No significant difference in DCS score at 2 months: intervention group: mean 36.0 ± 12.03 vs comparison group mean 37.50 ± 12.60, p = 0.32). Significant effect on levels of perceived decisional support (intervention, M = 34.8, SD = 15.7; comparison, M = 38.3, SD = 16.1; p = 0.05). No significant difference between groups in in cancer-related distress at 2 months (p = 0.93) Race (tested as a two-group variable; White vs. African American) was the only significant moderator of decision support (p = 0.05). African American participants in the DA group reported greater decisional support compared to usual care. Patients with lower education levels benefitted more from the intervention with respect to perceived decisional support (p = 0.05).

Durand, M-A 2020	Paper based in-consultation conversation DAs. 1. The Option grid (OG) was a text-only 1-page DA providing information simply with a table of treatment options 2. The Picture Option Grid (POG) provided the same information in four pages with simpler language and pictures. The surgeons received training in SDM and the use of the tool. Comparator: usual care	Decision quality instrument with 19 items and 3 subscales (knowledge, concordance and decision process) adapted for persons with low socio-economic status (SES) CollaboRATE (a validated patient measure of SDM). Observer OPTION-5 to assess SDM in the consultation, by analysing the T1 audio recordings. Outcomes timeline: Baseline (T0), during the surgical visit (T1), immediately after the visit (T2), 1 week after surgery or within 2 weeks of the first postoperative visit (T3).	The POG and OG resulted in greater knowledge (T2 and T3) in comparison with usual care. NSD between the interventions (POG and OG) for knowledge. The POG resulted in higher self-reported and observed SDM in comparison with usual care. NSD between the interventions (POG vs OG) (estimate, 0.36; 95% CI, 0.09-0.63; P = .01). **Author comments.** The POG reduced disparities in knowledge between patients of lower and higher SES in comparison with usual care. The POG improved more outcomes than the OG and had a positive impact on disadvantaged patients possibly due to inclusion of pictures.
Jibaja-Weiss ML 2011 RCT USA	"A Patchwork of Life: One woman's story for Making Breast Cancer Treatment Decisions" was a computerised, multimedia, interactive patient decision aid (CPtDA) available on line or as a CD-ROM. Information regarding surgical options was provided through interactive 'soap opera' episode. Assistance and emotional support were provided by the case manager. The Ottawa Decision Support Framework was the guiding framework.	Breast cancer and treatment knowledge using an adapted questionnaire with 16 questions. (Measured pre-decision, pre-surgery and 1 year later). DCS (10-item low-literacy version) (Measured pre-decision, pre-surgery and 1 year later). Surgical treatment preference (BCS, modified radical mastectomy, unsure), at pre-surgery visit.	Pre-surgery, significant increase in knowledge for CPtDA group and none in control (p <0.001). Decreased DCS for all scales over the periods of assessment. At pre-surgery assessment, DCS was significantly lower for feeling informed (p=0.007) and marginally for clarity of personal values (p=0.053) in CPtDA group. CPtDA program patients were less likely to prefer breast-conserving surgery (40.5% vs. 50.0%), and more likely to prefer modified radical mastectomy (59.5% vs. 39.5%, P = 0.018), compared to UC patients. No CPtDA patients were unsure about their surgical preference compared to 10.5% of controls.

	The control group received usual care with printed information materials.		
Li 2021	The DA was used in the consultation to provide information ant guide treatment deliberation between the doctor and the patient. Patient stories were included with the use of illustrations and limited writing. Intervention cohort with the use of DA were compared to a baseline cohort without the DA use.	OPTION scale for observed shared decision making. Max score 48 (Greater SDM)	The mean OPTION score increased significantly with the PtDA, (P ≤ .0005). Largest improvement was for: Item 1, “The clinician draws attention to an identified problem as one that requires a decision-making process” (+1.258 points) and item 3, “The clinician assesses the patient's preferred approach to receiving information to assist decision making” (+3.092 points). Item 7, “The clinician explores the patient's concerns (fears) about how problems are to be managed” showed a decrease, (- 0.171).
Wyld L 2021 RCT England and Wales	Decision support interventions (DESI) for older women with breast cancer. The DESI comprised a of an information booklet with values-clarifying exercise, an online algorithm based on demographic and clinical factors to be used in the consultation. The DESI was designed using the Coping in Deliberation (CODE) framework.	Knowledge: 8 item bespoke questionnaire (Score 0 - 8) (Measured before and 6 weeks after decision making). CollaboRATE (3 item SDM measure scored 0 (no effort) - 9 = (every effort to promote SDM)) transformed into a scale of 0 -100 Spielberger Short State-Trait Anxiety Inventory (6 items), measured before treatment, 6 weeks and 6 months after decision making. Treatment choices.	Greater knowledge by patients in the intervention arm (median scores 5/8 versus 3/8; P<0.001) and more participants in the intervention arm stated that they knew the available options (94 % vs 74 %; P 0.003) and associated advantages (91% vs 76%; P-0.054). Patients reported a high quality of shared decision making, with a median score of 100 in both arms (P 0.729). No difference in STAI scores at 6 weeks or 6 months. At intervention sites, 124 of 591 patients (21.0%) with an ER-positive tumour underwent PET, compared with 88 of 570 (15.4%) at usual-care centres (P=0.029). At intervention sites, uptake of adjuvant chemotherapy was lower than at usual-care sites: 69 of 670 (10.3%) versus 99 of 669 (14.8%) (P=0.013).

Yen RW 2020 RCT USA high and low SES status	The Option Grid (OG), and picture option grid (POG) DAs were designed to be used in the consultation between the oncologist and the patient. The DAs were developed using evidence-based tables to compare treatment options for breast cancer based using treatment options for breast cancer. Comparator: Usual care (UC)	Patient-reported SDM using CollaboRATE, Scores above 40 corresponds to at least baseline ability in SDM. Observed SDM from recordings of consultations using observer - OPTION-5 score assessment.	Top scores on CollaboRATE: OG arm (81.6 %), POG (80.0 %), UC (56.4 %), p < 0.001. No significant difference in scores between OG and POG. (p > 0.05). The mean OPTION-5 scores: OG arm - 73.0 (SD = 14.2), POG arm 56.3 (SD = 21.9), UC arm - 41.0 (SD = 27.5), p <0.0001 (ANOVA). Mixed-effects multilevel regression model adjusted for surgeon, clinic, and site clusters: OG was associated with a 32.6 (95 % CI 14.8, 50.4) point increase in OPTION-5 score compared to UC (p < 0.001). POG was associated with a 23.7 (95 % CI 7.4,40.0) point increase in OPTION-5 score (p = 0.004) compared to UC. Crude mean OPTION-5 scores for patients of lower SES were 43.1 and for patients of higher SES were 56.8 (p < 0.0001). Crude mean OPTION-5 scores for patients of inadequate health literacy were 50.9 and for patients of adequate health literacy were 52.9 p = 0.50). There were significant differences in scores when stratifying by arm for SES but not for health literacy.

Five studies reported using the Decision Conflict Scale (DCS) to measure decision conflict (DC) [160], [161], [162], [163], [165]. Three reported a significant decrease in either the total DCS score [161], or some of the subscales [181], [182] compared to the usual care. Berryet al., found that while the DA decreased decision conflict significantly at one-month, higher DC was associated with lower income and clinic site [161]. In an earlier paper, Berry et al. reported no significant decrease in total DC amongst DA users over time (from baseline to 6 months) [160]. Only the scores for the subscales 'uncertainty' and 'values clarity' decreased. The decision conflict related to the five individual subscales (uncertainty, informed, values clarity, support, effective decision) were significantly higher for vulnerable persons. Baseline decision support substantially impacted on total DC as well as the subscales: informed, values clarity, support, and effective decision. For vulnerable participants, those with more trait anxiety, and those with inadequate baseline information and support DC was increased for "feeling uninformed". While Diefenbach et al.also found no impact of the DA on total DC, vulnerable persons reported greater levels of support after using the DA [163].

Four studies reported on effectiveness of the DA in improving SDM [100], [164], [166], [179] of which three showed a positive effect [100], [164], [180]. Durand et al.reported that the picture option gird (POG) DA resulted in greater levels of self-reported and observed SDM compared to UC [164]. Observed SDM scores also increased significantly when using the DA in a study by Li et al.[166]. The greatest increases were for assessing the patient's preferred approach to receiving information to assist decision making, and the clinician informing the patient that a treatment decision is required. Yen et al.found that both the in-consultation POG and the OG improved self-reported and observed SDM [100]. Additionally observed SDM scores were significantly lower for people with low SES but not those with low HL.

Studies that measured anxiety [159],[160],[162],[179] and cancer-related distress [163] after the decision-making consultation found no difference between intervention and control arms. However, anxiety affected outcomes related to decision making. Berry et al.found that trait anxiety was associated with levels of feeling uninformed (DCS subscale) [160]. Cuypers et al. reported that participants who preferred a print version of the DA were more likely to have medium to severe HADS scores [162]. Although not statistically significant, DA treatment advice would have been preferred more often by participants with high or severe HADS scores.

Two studies reported DA effects on treatment choice [165], [179]. Jibaya-Weiss et al. reported unexpectedly finding that women using the DA were less likely to choose breast conserving surgery over a modified radical mastectomy, but that they were more likely than controls, to be sure about their choice [165]. Wyld et al. found that using the DA significantly increased more conservative treatment choices by older women, who may have chosen treatments based on impact on quality of life rather than surviva [179] l.

Four studies reported on the participant preferences for DA formats, interaction with DAs or assessed implementation factors [160], [162], [166], [179]. Berry *et al* found that 69% of participants accessed their online DA from a home computer, with just over 50% submitting responses to questionnaires by email rather than by mail [160]. However, the acceptability and usability of the program overall, were highly rated. Cuypers et al. reported that 16% of online DA users would have preferred a print version. Of those who received the DA but did not access it, 56% would have preferred a print version. Those who did prefer the online version were younger with higher levels of education [162]. Li et al. found that implementation of the DA at intervention sites required substantial changes in usual clinic practice, and that completion rates improved in county hospitals after providing a Spanish translation of the DA [166]. Table 3.4 summarises the outcomes of the effectiveness studies. Green blocks indicate that the intervention significantly improved the measured outcomes, while yellow blocks indicate no significant difference in outcomes between the intervention and control arm.

Table 3.4: Summary of the effectiveness of treatment DAs to improve decision-making outcomes

1st Author, year	Knowledge	Shared decision making	Decision Conflict Scale*	Anxiety/ distress
AlSagheir, AI 2020	NSD			NSD
Berry, DL 2013, 2018			Decreased (2013) Decreased (2018)	NSD (2013)
Cuypers, M 2018	NSD		NSD	NSD
Diefenbach, MA 2018			NSD	NSD
Durand, M-A 2020	Increased	Increased		
Jibaya-Weiss 2011	Increased		NSD	
Li, KD 2021		Increased		
Wyld L 2021	Increased	NSD		NSD
Yen RW 2020		Increased		

3.4.3. Patient experience of treatment decision making

The seven qualitative papers yielded 33 findings. These findings were grouped into 13 categories which were synthesised into four review findings. (Appendix F).

Synthesised finding 1: Patients differed in terms of their information needs, means of accessing information, and desired content.

Patients needed information about their cancer and prognosis, treatments available, and what to do or not do while on chemotherapy. *"The only material they give me is papers with the appointment... But information about what I should do or not do, or how to treat, or what to eat or what not to eat, no. (57-year-old Mexican Spanish speaker, 12 years of education)"* [168] Many patients relied solely on the clinician for information, even when feeling confused during the consultation. Those who sought clarification outside the consultation usually sought in-person information vs paper or internet-based information *"…connected with another cancer survivor, who as she expressed, "explained everything to me and [answered] any questions I had.""* [172]. Concise individualised information with simple, straightforward text and pictures or videos were preferred. Older or less educated patients felt less comfortable with internet-based information. "*I've got it, [internet] but I don't bother about it very much ... No, it would be the last thing I'd do [go to the internet]". (80 yrs.)* [171]

Synthesised finding 2. Decision making is a process that required effort from the patient to consider options under stressful circumstances, making choices that are not always based on clinical information. Preferred format of decision supports varied by patient characteristics.

Patients felt the process was rushed without enough information at the time to make decisions. "*things have to be decided too fast'... 'lack of knowledge' ... 'just didn't feel sure"* [167]. Making decisions required work from the patient for which they needed direction and support. *"the navigator helped her to "get in the habit of writing questions and reviewing them before seeing her doctor.""* [169] Patients did not have the skills to participate in option deliberation in the consultation. Treatment choices were regularly influenced by social and emotional factors rather than by what was clinically most appropriate. "*I'm raising a child that is two years old. I cannot be in and out of the hospital. I said I need all this done now"* [167].

Synthesised Finding 3. Clinician and patient interaction styles impacted on the decision-making consultation and decision roles. Patients may not always adopt roles they would have preferred. Decision support measures enabled more active engagement.

With few exceptions, patients felt unheard with unidirectional communication between the doctor and themselves. "*I think that was the worst part of my whole breast cancer surgery...Nobody was listening to me"* [167]. Some would have preferred more active participation but felt helpless. *"For my case, the specialist never discussed with me, never took my opinion in consideration. . . The doctor won't listen to you. It's not that we didn't want, and it's not that we didn't initiate to know more, I really wanted to know, I felt helpless, felt myself helpless. He ''HOLD'' the ''POWER''." (Mandarin patient, emphasis from* *original paper)* [173]. Very few patients reported an active role in decision making. Many patients reported doctors making decisions for them without further discussion of choices, which some preferred, respecting the doctor's knowledge and expertise and trusting the doctor to know what was best for them "*… it leaves you no room for decision. I just feel that it's not up to me to decide, I am not a professional doctor, so I have to rely on the doctor, whatever he tells me to do" (Cantonese patient)* [173]. Those who actively decided on treatment, may still have sought the doctor's approval of their decision. Patients appreciated having time to talk to their health caregivers, feeling more supported. Being accompanied by family at the consultation promoted interactive discussions. "*I had two of my daughters with me, and they asked a lot of questions. But since I've been going by myself, I [have] really felt neglected"* [170]. Talking to cancer survivors, patient navigators or decision coaches not only helped with information but provided much needed psycho-emotional support. "*I appreciated speaking with her (cancer survivor coach). She made me feel quite at ease in the face of a difficult situation. She gave me hope"* [170].

Synthesised Finding 4. Patients experienced strong emotions following a cancer diagnosis that impacted on their ability to make decisions. Social, cultural and language factors influenced decision making, indicating the need for an enhanced psychosocial approach to decision support.

On receiving the cancer diagnosis, patients experienced shock and overwhelming emotions which reduced their ability to process information and make appropriate treatment decisions. "*The problem was I wasn't deciphering [the information] because I was so afraid"* [167]. Treatment choice was influenced by the patient's family responsibilities. Family roles in decision making varied from not playing any role to being very much involved. Cultural or religious beliefs impacted on treatment discussions, decisions, and adherence. *"I take Chinese herb, I asked my doctor. The doctor didn't agree with me at the beginning. For example, during the chemotherapy, the doctor told me I shouldn't take anything, but I felt it would be better. I took Ling-Zhi and shark bone powder now." (009, Mandarin patient)* [173]. Language barriers may have prevented a patient from participating in the decision-making process, even if they wished to do so. *"Don't know how to communicate. I want to talk about something but don't know how to talk. The Caucasian think that you have nothing to ask, I feel it very hard to communicate my feelings" (Cantonese patient)* [173]. Patients wished for psycho-emotional support from the health care system. “*It would have been helpful to meet with a social worker or psychologist to help them come to terms with “stresses they are going through”*” [172].

3.4.4. Integrating decision aid effectiveness outcomes and patient experiences

Juxtaposing the quantitative and qualitative evidence identified synergies and gaps between DAs tested and patient reported needs and support for decision making (Table 3.5). The four synthesised findings of patient experiences correspond to four of the outcomes tested in the effectiveness studies. These include 1) knowledge of cancer and treatment, 2) decision-making process (decision conflict) and treatment choices, 3) patient-doctor interaction and decision roles (SDM), and 4) emotional responses (anxiety and distress).

All the interventions addressed most information needs reported from papers describing patient experiences; and described language and presentation adjustments for vulnerable populations in their studies. The interventions assessing knowledge of cancer and treatments as an outcome reported mixed results. While most of the DAs were self-administered and offered online, vulnerable persons were less likely to embrace online DA formats, and high levels of distress may impact on their ability to interact with online tools. The studies which included an interaction with a staff member (case manager or doctor) while using the DA resulted in a significant increase in knowledge [164], [165], [179], while those that were self-administered had no significant effect on knowledge of cancer or treatments [159], [162].

Patients felt rushed to make decisions while being inadequately informed or supported to make informed decisions. Most DAs included values clarifying exercises (VCE) for patients to identify their preferred treatment based on personally acceptable pros and cons. Some DAs also provided patient testimonials or vignettes describing the decision-making processes. Despite these interventions, most studies did not report a significant decrease in DC. While baseline decision support impacted on DC levels in general, non-white minority groups and people with lower education were more likely to benefit from the added support of the DESI [183]. As is reported from patient experiences, many would not choose the clinically most appropriate treatment with psychosocial and emotional factors impacting on treatment choice. These important considerations may not be adequately addressed in the VCEs.

Vulnerable populations reported difficulties engaging with doctors during the consultation. Most in-consultation DAs, successfully increased patient reported and observed SDM, with the greatest improvement amongst people with low SES[184], [185]. From one study, clinicians demonstrated improved skills in opening treatment decision conversations, but still struggled with patient centred items such as exploring patient fears about managing problems[186].

Patients consistently mentioned the emotional impact of the cancer diagnosis which affected their ability to make decisions. This is supported by the findings from two studies that anxiety negatively affected patients' feeling informed and their ability to interact with online DAs. While investigators designed DAs to represent and appeal to minority groups, with some including video vignettes to address emotional needs, no DAs reported in-person counselling to address the emotional, social, cultural, and religious influences on decision making.

Table 3.5: Integrated quantitative findings of effectiveness and qualitative findings of decision-making needs

Qualitative Findings	**Quantitative Findings** (NSD – no significant difference)	**Comments**
1. Patients differed in terms of information needs and accessing sources of information, desired content and format. **Information content needs.** About their cancer, prognosis, treatments available, and what to do and not to do while on chemotherapy. **Information gathering.** Tend to rely solely on the clinician for information. Seek information from other people. **Information format and presentation.** Concise individualised information. Simple, straightforward text and pictures or videos preferred. Older or less educated patients less comfortable with internet-based information.	**Effectiveness outcomes** 6 DA intervention studies assessed knowledge. 1 study assessed knowledge using the DCS "informed" subscale. **AlSagheir 2020** NSD in understanding of cancer treatment with no difference by socio-demographic factors (low income, low education) **Berry 2013/2018** • NSD in DCS informed subscale • Lower informed subscale scores associated with older, non-white race, less income, more trait anxiety, baseline measures of inadequate information and support. Preferred format: • P3P intervention initially accessed by home computer by 69%, 58% at 1 month, and 52% at 6 months. **Cuypers 2018** Participants in the DA arm felt more knowledgeable, but the mean objective knowledge (test) scores were comparable between trial arms. Preferred format:	An online self-administered DA may not be the most appropriate delivery of information for person with low education, low SES, or with high anxiety. Vulnerable persons may benefit more with a paper-based or video format DA with an opportunity to discuss information and choices in person with a suitably qualified healthcare provider.

	- Of participants who received but did not access the DA, 56% (N = 15) indicated a DA in print was preferred. - Participants favouring the online DA format were younger and more often highly educated. **Durand 2020** - **POG resulted in greater knowledge** compared to usual care. NSD between the interventions (POG and OG) for knowledge. - **The difference in knowledge between patients of lower SES and those of higher SES was smaller for patients in the POG arm than patients in the UC arm.** **Jibaya-Weiss 2011** - **Higher knowledge scores in DA group** **Li 2021** Preferred format - The completion rate increased after the creation of a Spanish module at the county (in addition to reminder calls to academic centre). **Wyld 2021**	

	• **Greater knowledge scores** and more patients in DA arm reported knowing available options and associated advantages.	
2. Decision making is a process that starts before the treatment decision consultation, requires effort from the patient to consider options under stressful circumstances, often making choices that are not only based on clinical information. **Process and timing.** Patients feel the process was rushed without enough information at the time to make decisions. **Work of decision making.** Making decisions requires work from the patient for which they need direction and support. **Deliberation on Options/Choices** The decision-making process proceeds too quickly for them, and they struggle with the	**Effectiveness outcomes** **Berry 2013/2028** • Significant decrease in DCS at 1 month • DCS for all subscales (uncertainty, informed, values clarity, support, effective decision) significantly higher for vulnerable populations. • Perceived support improved further from biopsy, with the largest decrease between 1 and 2 weeks, also associations with clinical site, non-White race and baseline support scores. • Being an effective decision maker is associated with baseline support scores. • Total decision conflict associated with baseline uncertainty and lack of support. **Cuypers 2018** • NSD in total DCS. • DA group felt less prepared to make a decision.	Vulnerable persons may need more time to absorb information and deliberate on options. They would benefit more with assistance using a DA rather than using an online or self-administered DA. Non-clinical considerations for treatment preferences should be addressed in a DA.

process of deliberating options due to lack of knowledge or lack of self-efficacy. **Reasons for choices.** Treatment choices were heavily influenced by social and emotional factors rather than by what was clinically most appropriate.	• DA users in favour of the online DA format and with HADS scores < 8 reported less decisional conflict and more information satisfaction compared to other DA users. **Diefenbach 2018** • NSD in total DCS score. • Significant positive effect on levels of perceived decisional support • African American participants, and patients with lower levels of education appeared to benefit more from the intervention with respect to perceived decisional support. **Jibaya-Weiss 2011** • NSD in DCS (< 3 days after the decision and at 3 months after the decision) • Patients viewing DA less likely to choose breast conserving surgery and choose modified radical mastectomy. Also, none were unsure of choice compared to UC (10% uncertain). **Stankowski-Drengler 2019** • NSD in perception of treatment information conveyed by surgeon by randomization arm, but surgeon seen was significant predictor in multivariable regression.	

	Wyld 2021 • NSD in the proportion of participants stating that they knew their preferred option or felt ready to make an informed decision. • Lower rates of surgery and chemotherapy at intervention sites	
3. Decision-making consultations are affected by the interaction style of clinician and patient, impacting on decision control, such that patients sometimes adopted roles that they did not prefer. Patients reported a variety of preferred decision supports. **Clinician-patient interaction.** Most vulnerable patients reported minimal discussion with the doctor in the consultation. **Preferred or perceived passive decision role.** Patients felt disempowered to make a decision. **Preferred or perceived active decision role.** Very few reported an active decision role. **Decision support.**	**Effectiveness.** Four studies assessed shared decision making (SDM) **Durand 2020** • The POG resulted in **higher self-reported and observed SDM** compared to UC. NSD between POG and OG. **Jibaya-Weiss 2011** No difference in perceived SDM (< 3 days after decision) **Li 2021** • **Increased observed SDM**: mean OPTION score increased significantly when applying the PtDA. • Largest increase in items 1 and 3 (Drawing attention to the problem needing a decision and assessing preferred approach to receiving information to assist decision making). • Least increase in item 6 (explores patient's expectations about how problems are to be managed)	DAs designed to increase SDM, may be more effective if implemented in a consultation with a doctor with appropriate training on the tool. In view of limited time for the consultation, it may be better to include a decision coach who gives information and can discuss options with the patient before the consultation with the doctor who then uses a simple DA to confirm the patient's choice.

Having support, either through family or a survivor coach, as well as frequent communication with the healthcare providers was appreciated.	**Stankowski-Drengler 2019** • NSD between arms in report of being asked their terms of preference for surgery type but varied by surgeon seen. **Wyld 2021** • Self-reported high levels of SDM in both arms. • Use of the DESIs in women who were offered a choice was lower than anticipated. **Yen 2020** • **Patient reported SDM for POG and OG significantly higher** than UC and NSD between interventions. • Both interventions resulted in **increased observed SDM.** • Crude observed SDM scores were lower for lower SES and inadequate health literacy. When stratifying for arm, only significant for SES.	
4. Patients experienced strong emotions following a cancer diagnosis that impacted on their ability to make decisions. Social, cultural and language factors influenced decision making, indicating the need for an enhanced psychosocial approach to decision support.	**Effectiveness.** Anxiety or depression were more likely to be assessed for any increase due to using a DA. **AlSagheir 2020** • Both groups had reduction in anxiety at 6 months. NSD between groups. **Cuypers 2018** • Mean HADS scores were not statistically significantly different between both format preference groups, however, medium or	When designing an intervention for vulnerable populations, it is important to adequately address their emotional distress and to provide support for them to make decisions taking into account their language

Emotional/Social impact of cancer and treatment decision making. Patients reported significant distress on hearing the diagnosis which affected their ability to make decisions. **Family, social, cultural influences in decision making.** Social, cultural or language differences impacted on their treatment decision making, making which may increase their distress. **Strategies for socio-emotional support.** Patients suggested having counsellors to assist them.	severe HADS scores were more common in participants who would prefer a printed DA (p = 0.03). • A treatment advice from the DA was preferred more often by DA users with severe of high HADS scores, although differences did not reach statistical significance. **Diefenbach 2018** • NSD in cancer-related distress at 2 months between the intervention and the comparison groups.	differences, social and cultural circumstances.

3.5. Discussion

This review provides a narrative synthesis of the effectiveness of cancer treatment DESIs for vulnerable patients integrated with a synthesis of patient reported experiences of cancer treatment decision making. Developers of the DESIs reviewed in this study recognised the need for understandable language, minimal text, with some using audiovisual modes of delivery. Despite this, there were variable effects on patient knowledge of cancer and its treatments, with DAs presented by a staff member being more effective than those that were self-administered. Most DESIs included values clarifying exercises and some utilised patient testimonials or vignettes to aid deliberation over options aimed at reducing decision conflict. Effectiveness of reviewed DESIs in reducing DC varied. For vulnerable people reporting greater baseline DC, the DESIs had a greater impact in reducing some subscales of the DCS. Decision interventions developed to improve SDM specifically, were effective. These visual DAs were utilised in the consultation with the clinician for giving information and deliberating options, which address the need for in-person information and support. Patients using the DAs, did not always choose the clinically most appropriate treatment. This finding is supported by the evidence of the qualitative studies which indicate numerous non-clinical factors, such as socio-economic challenges, impacting on vulnerable patient treatment choices. Patient anxiety impacted on their feeling informed and on their preferred format of a DA reflecting the patients' reports of how anxiety affected their ability to absorb information and make decisions.

Patients in LMICs may share several characteristics with vulnerable people in HICs and face similar challenges to understanding their diagnosis, communicating with doctors and accessing oncology care [62], [105]. While factors common to both populations in HICs and populations in LMICs impact on cancer treatment decisions, the extent of impact of these limitations may be greater in LMICs [1]. Generally, oncology resources in HICs are extensive, however access may be challenging to vulnerable populations who live in rural areas, are underinsured due to socio-economic challenges, or struggle to interact with health services due to ethnicity, cultural or language barriers. In LMICs, oncology resources range from basic in low-income countries, limited in middle income country rural areas to enhanced in urban areas[14]. In addition to possible limited availability of resources, oncology patients in LMICs may face personal and situational difficulties when making informed treatment decisions.

Patients in LMICs have similar information needs to those patients reported in this review, largely due to lower levels of education and health literacy (HL) as well as difficulties with communication [1], [31], [187], [188], [189], [190], [191]. Poorer health literacy is likely to be associated with extremes of age, lower education level and poorer socioeconomic status. Patients with lower HL are likely to receive less appropriate cancer treatment choices and are less likely to achieve their desired outcomes both in HICs and LMICs [43], [192], [193]. Patients in this review considered factors other than clinical outcomes when deciding on treatment. Similarly, patients in LMICs may be limited in treatment choices due to financial constraints, distances to travel to treatment centres and cultural practices [1], [31], [32], [187], [188], [194]. As with patients in this review, patients in LMICs experience strong emotions on being diagnosed with cancer, and fear of cancer, shock and denial compounded by cultural beliefs may impact on their intention to adhere to treatments or lead them to consult traditional healers [188], [194].

As indicated in this review, vulnerable people in HICs are less likely to engage in shared decision making [64], [195]. Similarly, patients in LMICs are less likely to play an active role in decision making, even if they prefer to be actively involved in decision making [196], [197], [198]. Barriers to participation in treatment decision making include patient education and HL impacting on their knowledge of cancer and treatments, lack of knowledge of their right to participate, poor communication complicated by cultural and language barriers, patriarchal cultural norms and traditional paternalistic attitudes of doctors to health decision making [31], [32], [43], [187], [190], [191], [194], [196], [198]

With the many similarities and few differences in decision support needs between vulnerable populations in HICs and patients in LMICs, it may be feasible to translate the successes of some decision support interventions to LMICs. While our search found no documented decision support interventions in LMICs, there are cancer education and patient navigation models which have been tested in LMICs. Cancer patient education strategies include print-based tools such as pamphlets, simple technological interventions (for example, videos) to more sophisticated interactive or application-based interventions or short message service (sms)-based interventions, and in-person patient education [199]. Nurses usually offered the education sessions either one-on-one or in groups. Vulnerable patients making cancer treatment decisions were more likely to report in-person support than print or other materials to support them in the process [190], [191].

Care coordination and patient navigation services in LMICs focus mainly on patient education and support as well as assistance with linkages to follow up services and health-care appointments [200]. These services are usually provided at an individual level with in-person or telephonic contact. Some services included printed materials, mHealth services or showing motivational and education videos on mobile phones. Most navigators were nurses, with a few involving social workers, cancer survivors, volunteers and community health workers. All studies implementing patient navigation services achieved their hypothesised outcomes of improved care-coordination, adherence to treatments, improving health outcomes and reducing social and personal barriers to cancer care [2], [32].

Given our review findings, we recommend that decision supports of varying formats may be adapted for use in LMICs. Printed DAs containing pictures with minimal text using simple language and translated into local languages, may be used to supplement information shared in the consultation. Videos with culturally appropriate patient testimonials or short vignettes will be useful, especially if used in addition to in-person discussions with patient navigators to address any questions. We recommend patient support, coaching and navigation by either a nurse or suitable team member, including trained lay counsellors such as cancer survivors. Additionally, a simple visual decision aid to be used in a consultation with oncologists who receive simple communication strategy training may prompt more active participation in treatment discussions.

Evidence-based and culturally appropriate interventions to improve cancer patient support in LMICs is feasible [2], [32]. However, interventions should be developed using a recognized implementation framework and including all relevant stakeholders to ensure effective decision support based on adequate evidence of local needs, grounded in theory and evaluated using validated methods for effectiveness, acceptability and feasibility.

3.5.1. Limitations

There were some limitations to this review. Only English papers were selected, thereby potentially missing contributing studies from other languages from LMICs. The quantitative studies varied in implementation and outcome measurements, making direct comparisons of outcomes difficult, necessitating a narrative analysis. The strength of our study is that we compared the effectiveness of DAs on decision support outcomes with patient-reported experiences of decision making to identify decision support interventions that are addressing patient-reported needs and the potential gaps still to be addressed.

3.6. Conclusion

Vulnerable patients, including those in LMICs are at high risk of not participating in and making uninformed cancer treatment decisions. Similar to DESIs for vulnerable patients in HICs, any DESI developed for patients in LMICs, in addition to providing adequate information, must address distressing emotions and psychosocial determinants of decision making with counselling, while providing decision coaching and inviting the patient to participate in treatment discussions at their preferred level.

PART 2

CHAPTER 4

"To get better and to raise my grandchildren and also take care of my physically challenged daughter."

(Oncology patient – South Africa)

Chapter 4 . A cross-sectional study of health literacy, information needs, decision control preferences and decisional conflicts of oncology patients in South Africa (Paper in review)

4.1. Introduction

Cancer treatment decision making is influenced by clinical factors, patient-related factors, health care provider (HCP) factors, and available health care resources. Patient health literacy (HL), emotional distress and the patient-clinician interaction during the consultation will affect information processing and the patient's ability to participate fully in decision making. It is important that patients have access to relevant information in an understandable format, feel free to ask questions and express their concerns in a supportive consultation environment [201], [202].

Globally, oncology patients report high information needs while engaging in treatment decision making, some despite having been given adequate information [203], [204]. Common needs include disease information, stage, possibility of cure, treatment options, risks and side-effects and duration of treatment, and alternative treatments [205], [206],[144]. In Africa, patients may not be aware of their rights to information or may be given information in a language or format that is not understandable to them [145],[207], [208]. Many do not feel empowered or equipped to ask questions in the consultation, citing lack of opportunity, fear of doctors and a difference in language or culture as barriers. Patients with low literacy are at greater risk of communication difficulties, with lower information recall and understanding, and feeling less empowered to ask questions [203],[209].

Adequate HL is essential to engage in the process of information exchange, critical appraisal, deliberation and making a treatment decision [210], [211]. Health literacy is a multidimensional concept requiring functional, interactive and critical skills to access, understand and appraise information to improve health decisions and subsequent outcomes [47], [49]. The Integrated Model of Health Literacy (IMHL) identifies personal, situational, and societal/environmental determinants of HL [47], while social support, emotional state, motivation, and self-efficacy, mediate the effects of HL on health outcomes [50], [51]. Patient age, education, socioeconomic status and home language, are common determinants of HL, both in high-income countries (HICs) and low to middle-income countries (LMICs) [57], [58], [59]. Having adequate HL is associated with fewer cancer-related patient needs at diagnosis, improves patients' understanding of the severity of their cancer [212],[39] and increases the likelihood of choosing appropriate treatment [213].

Being diagnosed with a life-threatening illness, facing decisions regarding complex treatments with potentially serious adverse events and uncertainty about expected outcomes, exacerbates patient vulnerability in the medical consultations necessitating high levels of trust in the clinician [214]. Shared decision making where clinicians and patients jointly consider options and decide on the best treatment plan is considered an ideal approach under such circumstances [201]. However, patient preferences for SDM are variable. Patients in HICs are more likely to prefer SDM compared to those in LMICs where more patients may prefer and adopt a passive role, due to cultural beliefs, and expectations of paternalism believing that the doctor is the expert [201],[144], [145].

Elements of effective patient-clinician communication and decision making include the bilateral exchange of information and deliberation within a supportive environment of mutual respect and trust where the patient is empowered to participate in the process of decision making whether shared, active or passive as preferred [215]. A patient-centred approach promotes an environment conducive to informed decision making. Characteristics of patient-centredness include a biopsychosocial approach to illness, seeing the patient as a person beyond the disease, seeking to balance power and responsibility for decisions, developing a therapeutic alliance and the clinician's awareness of the impact of personal biases on the decision-making process [216].

Interventions to improve cancer-related decision making for patients have been mostly developed in HICs where patient demographics, health literacy, access to health information, decision control preference (DCP) and final treatment choices differ from that found in LMICs [217]. There are very few published studies of patient HL, information needs and DCPs in Africa, including South Africa, with none focussing on cancer treatment decisions.

The aim of this study is to describe the factors impacting on South African cancer patient chemotherapy treatment decision making including sociodemographic factors. HL, information needs and DCP. Elements of the therapeutic alliance and decision conflicts of cancer patients making chemotherapy treatment decisions were also assessed. This is the first step toward a greater understanding of the barriers and facilitators to oncology patient informed decision making, which will inform the development and testing of an intervention to enable patients to participate in making informed cancer treatment decisions in South Africa.

4.2. Methods

4.2.1. Setting and Participants

This descriptive quantitative cross-sectional study was conducted at the Oncology clinics at three hospitals in South Africa. Two hosptials (Hospital A and Hospital B) are tertiary level public hospitals in, Gauteng, serving mostly urban-dwelling patients. Hospital C provides tertiary level public health services to a mixed urban/rural population living in KwaZulu Natal (KZN). The population of these 2 provinces accounts for 45% of the country’s 60 million people with IsiZulu being the most commonly spoken language in both provinces (Gauteng 20% and KZN 78%) [218], [219].

The study was conducted between 16 March and 29 November 2021. Using non-probability convenience sampling, we enrolled 124 participants to provide a ratio of at least 10 participants per demographic variable studied [220], [221]. Participants ≥ 18 years old, with a histologically confirmed diagnosis of cancer, fit enough to participate in an interview who had had an oncologist consultation for a chemotherapy treatment decision within the previous 48 hours were eligible to participate. Participants speaking languages in which the interviewers were not fluent were excluded.

4.2.2. Procedures

At the Hospital A Haematology Oncology department, most patients were admitted as in-patients and once diagnosed, the clinical team referred eligible patients to the interviewers. At Hospitals B and C, patients attending oncology clinics were approached by study staff and invited to participate. Eligible, consenting participants were enrolled in the study. All interviewers were fluent in English and the most common local languages, and interviews were conducted in the participant’s preferred language. All interviewers attended a training workshop checking that translations into other languages maintained the intended meaning of the survey questions. De-identified study data collected on paper was captured on the REDCap electronic database hosted at the University of the Witwatersrand [222].

4.2.3. Measures

Demographic and socioeconomic data included: age, gender, education level and employment, home language, English literacy, and ability to use mobile phone/computer to access health information. Participants' wealth index was computed using principal component analysis of the variables: home ownership, access to water and electricity, and possession of common household items. Three categories of wealth index were computed [223]. Clinical data included patient-reported cancer type and stage.

We assessed participant HL using the "Health Literacy Test – Limited Literacy" (HELT-LL) tool, validated for use in South African low literacy populations [57] (Appendix K). The 12-item assessment measures functional, interactive, and critical literacy with a maximum score of 24. A score of 0-10 indicated inadequate HL, 11 -20 marginal HL and 21 – 24 adequate HL. Bilingual isiZulu and English speakers translated the HELT-LL into isiZulu using forward and back-translations. The translated questionnaire was piloted with 10 isiZulu speaking volunteers for clarity and accuracy. No changes were made to the format (Appendix L).

We measured social support using the Perceived Social Support Scale (PSSS), an African adaptation of MOS-SSS (Medical Outcomes Survey Social Support Survey) [224] (Appendix J). The PSSS consists of four questions with yes/no answers, yielding a total possible score of 4. Questions included: (1) "Do you have someone to turn to for suggestions about how to deal with a personal problem?" (2) "Do you have someone to help with daily chores if you were sick?" (3) "Do you have someone to show you love and affection?" (4) "Do you have someone to do something enjoyable with?" The PSSS was validated for use in African adult caregivers of vulnerable children with HIV [225].

To assess the therapeutic alliance, we asked 9 questions from "The Human Connection (THC) scale" [226], with responses, "A lot", "A little" and "not at all". The questions are available in Appendix J. We assessed pre-consultation information needs, by asking: "Are there things about your health or treatments that you do not understand but want to know about?". Participants who answered yes were asked: "What are the things you would like to know more about?"

After their consultation with the oncologist, we asked participants their decision control preference. We used the 15-point version (patient-family-physician triad) [227]. Patients are asked to select one of the 15 options, which was then classified as passive, active or shared preference in decision making (Appendix N).

We explored decision conflict by adapting questions from the 10-item Decision Conflict Scale – Low Literacy [228]. (Appendix O). We asked 7 questions with "yes"/"no" responses. For those who had decided on treatment, we asked the open-ended question: "Can you explain the reason for your choice?" For those who were undecided, we asked: "What would help you to make a choice?".

4.2.4. Analysis of data

We used Pearson's chi-squared test and Fisher's exact test to measure differences in categorical variables between sites. For continuous variables we used the Wilcoxon rank-sum test, or Kruskal-Wallis rank test. An outcome with a p value of 0.05 or less was considered statistically significant. Based on the Integrated Model of Health Literacy determinants of HL, we used a multivariate ordinal logistic regression to examine personal, situational, and environmental factors and knowledge of cancer stage associated with HL level. For the open-ended question regarding information needs, all comments were downloaded onto an excel spreadsheet, and analysed. Information needs were coded and categorised into 1) cancer information, 2) stage, 3) treatment, 4) possibility of cure. The frequency of expression of each category was noted to quantify information needs. Some participants expressed more than one category of need, each of which was counted separately. Analysis of quantitative data was performed using STATA 14[229].

This study received ethics clearance from the Human Research Ethics Committee (Medical) at the University of the Witwatersrand (protocol no. M200986).

4.3. Results

We enrolled 124 patients who completed all the pre-consultation questionnaires. Four could not be traced after the consultation and did not complete the DCP questionnaire and the decision conflict questions. For all participants who completed the questionnaires, we had no missing information. As shown in Table 4.1, the median age of the 124 patients was 49 years, most were women (76.6%), not in a permanent relationship (64.5%), were unemployed (71.8%), with 21.0% having only grade 7 primary education. Most spoke isiZulu

(44.3%) with fewest speaking English as their home language (13.7%). The remaining 52 spoke Sesotho (15), isiXhosa (10), Setswana (9), Afrikaans (7), Sepedi (5), or other South African languages (6). Just under 50% of participants completed the HELT-LL survey in their home language. Only 57.3% of all participants reported to be fully English literate and only 25 participants (20.2%) had adequate HL. Fewer than 20% knew their cancer stage. Most patients preferred an active decision-making role (82.5%), which was significantly more likely amongst those who attended the oncology clinic at Greys Hospital.

Table 4.1: Participant Characteristics (n = 124)

Patient Characteristics	**Total**	**Hospital A**	**Hospital B**	**Hospital C**	**p value**
Age in years (Median, IQR)	49 (40-60)	43 (35-57)	49 (42-62)	56 (47-60)	0.060
Total participants: n (%)	**124 (100)**	**41(33.1)**	**43(34.7)**	**40(32.2)**	
Gender					0.113
Female	95(76.6)	27(65.8)	34(79.1)	34(85.0)	
Relationship Status					0.947
Married/partner	44(35.5)	14(34.1)	15(34.9)	15(37.5)	
Home language					<0.001
English	17(13.7)	5(12.2)	7(16.3)	5(12.5)	
Isizulu	55(44.3)	9(21.9)	13(30.2)	33(82.5)	
Other	52(42.0)	27(65.9)	23(53.5)	2(5.0)	
Education level					0.102
Nil - Grade 7	26(21.0)	5(12.2)	7(16.3)	14(35.0)	
Grade 7 – 12	81(65.3)	31(75.6)	28(65.1)	22(55.0)	
Tertiary	17(13.7)	5(12.2)	8(18.6)	4(10.0)	
Self-reported English literacy					<0.001
Unable to communicate	34(27.4)	8 (19.5)	4(9.3)	22(55.0)	
Able to communicate verbally but not read	19(15.3)	4(9.8)	9(20.9)	6(15.0)	
Able to communicate verbally and read	71(57.3)	29(70.7)	30(69.8)	12(30.0)	
Employed					0.173
Unemployed	89(71.8)	24(58.5)	32(74.4)	33(82.5)	
Wealth Index					0.001

Category 1 (Poorest)	42(33.8)	10(24.4)	8(18.6)	24(60.0)	
Category 2	41(33.1)	14(34.1)	17(39.5)	10(25.0)	
Category 3 (Wealthiest)	41(33.1)	17(41.5)	18(41.9)	6(15.0)	
Social Support Score					0.402
0-2 (Lower)	20(16.1)	5(12.2)	10(23.3)	5(12.5)	
3-4 (Higher)	104(83.9)	36(87.8)	33(76.7)	35(87.5)	
Patient knowledge of cancer stage					0.016
Unknown	100(80.7)	34(82.9)	29(67.4)	37(92.5)	
Health Literacy Categories (Total score 24)					0.28
Inadequate (0-10)	14(11.3)	6(14.6)	6(14.0)	2(5.0)	
Marginal (11-20)	85(68.5)	25(61.0)	32(74.4)	28(70.0)	
Adequate (21-24)	25(20.2)	10(24.4)	5(11.6)	10(25.0)	
HELT-LL completed in home language					<0.001
Yes	57(46.0)	7(17.1)	12(27.9)	38(95.0)	
Need for further information					0.391
Yes	88 (71.0)	26 (63.4)	33 (76.7)	29 (72.5)	
Decision control preference	**n = 120**				0.003
Active	99 (82.5)	31(77.5)	29 (72.5)	39 (97.5)	
Shared	4 (3.3)	1 (2.5)	2 (5.0)	1 (2.5)	
Passive	17 (14.2)	8 (20.0)	9 (22.5)	0 (0.0)	

[a] IQR (Interquartile range), [b] Wealth Index components: Homeownership, indoor running water, electricity, fridge, microwave oven, washing machine, TV, DSTV (satellite TV), computer, mobile phone, Wi-Fi access at home.

Higher education level was associated with higher HL (Compared to primary level, secondary: OR 2.22, 95% CI 0.58 – 8.55, tertiary: OR 14.61, 95% CI 2.2 – 96.61), with the wealthiest people also more likely to have adequate HL (OR 4.05, 95% CI 1.03 – 15.98), however employment was not associated with greater HL (Table 4.2). Patients at Hospital B were least likely to have adequate HL (OR 0.07, 95% CI 0.14 – 0.37). English proficiency was not associated with greater HL, and concordance between home language and the language of the HL survey did not affect HL outcomes. Patients knowing their cancer stage were marginally more likely to have higher HL (OR 3.27. 95% CI 0.96 - 11.07).

Table 4.2: Ordinal logistic regression for inadequate, marginal, and adequate health literacy

Variable	**OR**	**95% CI**
Age	0.87	0.57 – 1.31
Education		
Primary (</= Grade 7)	Referent	
Secondary (Grade 8 – 12)	2.22	0.58 – 8.55
Tertiary	14.61	2.2 – 96.61
English proficiency		
Cannot communicate	referent	
Can communicate	2.87	0.75 - 11.02
Wealth Index		
1 (Poorest)	Referent	
2	2.08	0.62 - 6.93
3 (Wealthiest)	4.05[a]	1.03 - 15.98
Employment Status		
Unemployed	Referent	
Employed	0.76	0.25 - 2.32
Social Support Score		
(0-2) Lowest support	Referent	
(3-4) Highest support	0.71	0.19 - 2.62
Language discordance		
Discordant	Referent	
Concordant	0.69	0.09 – 5.55
Site		
Hospital C	Referent	
Hospital A	0.20	0.04 - 1.01
Hospital B	0.07[b]	0.14 - 0.37

Language		
English	Referent	
IsiZulu	0.37	0.06 - 2.22
Other languages	0.44	0.04 - 4.97
Cancer stage known		
No	Referent	
Yes	3.27	0.96 - 11.07
Pseudo R	0.247	
^{a} p < 0.05, ^{b} p< 0.01		

Participant report of components of a therapeutic alliance was positive, with mutual respect and patient trust in the doctor being reported "a lot" by > 90%, while doctors enquiring about how the patient or family is coping "a lot" was reported by 46% and 18% respectively (Table 4.3).

Table 4.3: Responses to questions assessing patient-doctor therapeutic alliance (n = 124)

Questions	**A lot**	**A little**	**Not at all**
	n (%)		
Do you think doctors see you as a whole person (more than a person with an illness)?	96 (77)	12 (10)	16 (13)
Do you think the doctors here treat you with respect?	115 (93)	7 (6)	2 (1)
Do you respect the doctors here?	123 (99)	0 (0)	1 (1)
Do you understand most of what the doctors explain to you?	95 (77)	26 (21)	3 (2)
Are you comfortable asking the doctors questions about your health?	100 (81)	20 (16)	4 (3)
Are you comfortable asking the doctors questions about your care or treatment?	101 (82)	17 (13)	6 (5)
Do you trust the doctors treating you?	115 (93)	6 (5)	3 (2)
How often do the doctors ask you how you are coping with your illness?	57 (46)	45 (36)	22 (18)
How often do the doctors ask how your family members are coping with your illness?	22 (18)	35 (28)	67 (54)

While 77% reported understanding what the doctors explained ‘a lot’ and just over 80% reported being comfortable with asking questions ‘a lot’, 88 (71%) participants reported having information needs prior to the consultation (Tables 1 & 3). Most common questions were about treatment (56%) followed by information about cancer, and possibility of cure (14% each), stage of cancer (10%), and symptoms being experienced (6%) (Table 4.4).

Table 4.4: Information needs prior to the chemotherapy consultation

Information Need	**Frequency of expressed need (102)**	**Examples from interviews**
Treatment related	57 (56%)	What harm can XRT do to me should I happen to be given it instead of Chemo? About the chemotherapy - how will the procedure work? Will chemotherapy make me better or will I have to get my breast removed? What happens when I come late for treatment? How is chemotherapy going to work since I am HIV positive? What is bone marrow transplant and how many chemo cycles do I have to receive?
About cancer/diagnosis	15 (14%)	What is breast cancer and what causes it? What is leukaemia, what is it doing to my body, what is the cause? How did I get the illness, is there a way to prevent it in the future should I get cured and what are some of the things I should avoid eating? What exactly causes cancer, and can it really be cured?
Prognosis/ possibility of cure	14 (14%)	How long do people in my situation live? Can cancer be cured and if not, can they remove the breast? Now that I have had surgery, will Cancer be completely gone after chemo? How long will it take for me to be cured?
Stage of cancer	10 (10%)	What stage is my cancer, is it treatable? What does stage 1 cancer mean? How will I know if cancer has spread in my body?

Symptoms of cancer	7 (6%)	What caused the lower abdominal pains and swelling of the lower abdomen after walking a long distance? How will it (cancer) treat my body? Is it normal to have poor appetite for food, and my system rejecting food when you have my kind of illness?

Most of the patients interviewed after their consultation with the oncologist, decided to have chemotherapy (98%). Of these, 92.5% were sure about their choice, 97.5% were satisfied with their choice while 14.2% reported choosing with some pressure from others (Table 4.5). Eight of the 118 who chose chemotherapy, reported not knowing the side-effects. Of these, three had inadequate HL, 5 had an active DCP, and 4 had additional information needs prior to the consultation. (Appendix P).

Table 4.5: Decision conflict regarding choice of chemotherapy

Patients who chose chemotherapy (n=118)[1]	Yes	No
Do you think you are sure about what to choose?	111 (92.5)	9 (7.5)
Have you had enough advice or information to make a choice?	111 (92.5)	9 (7.5)
Have you been given enough support from doctors to make a choice?	113 (94.2)	7 (5.8)
Have you been given enough support from family to make a choice?	97 (80.8)	23 (19.2)
Have you been given enough support from friends/others to make a choice?	80 (66.7)	40 (33.3)
Are you choosing without pressure from others?	103 (85.8)	17 (14.2)
Are you satisfied with your choice?	117 (97.5)	3 (2.5)
[1] One patient was undecided, one patient chose not to have chemotherapy		

4.4. Discussion

This study aimed to describe factors related to cancer treatment decision making amongst patients at the oncology clinics at 3 public-sector hospitals in South Africa (SA). We found that few patients attending the clinics had inadequate HL, with most having a marginal HL. Most patients did not know their cancer stage and information need was high, despite most reporting being comfortable asking questions about their illness or treatments. Most patients preferred an active decision role and most reported feeling supported in their decision to have chemotherapy.

As with most studies in HICs and in Africa, we found that higher levels of HL were associated with higher education level [58], [59], [60],[230]. A recent South African study found that any education greater than grade 7 significantly increased HL [57]. Wealthier people in our study were more likely to have higher HL, as is found in other studies [57], [58], [59], [60]. Overall, wealthier people tend to have a higher education, with 79% of all poor people in South Africa having no formal education [231]. While studies in HICs and in Africa found unemployment to be associated with inadequate HL, our study found no association, probably because 48% of unemployed people in SA have a grade 12 or higher level of education [232]. Patients at hospital B had significantly lower HL than patients at hospital C, even though patients at hospital B were wealthier, were more likely to know their cancer stage and have fewer information needs. Because of the greater diversity of language spoken at hospital B, fewer patients completed the HL survey in their home language. It is not clear how much impact this would have had on the score.

Just under 60% of participants reported being fully fluent in English with 12.9% having no understanding of English at all. English as a home language and English literacy did not contribute significantly to HL levels in our study. This is an important finding as oncologists may be inclined to assume that English literacy implies greater health literacy and understanding of medical information.

Although most patients had marginal or adequate HL, about 70% of our patients had additional information needs, despite a large majority declaring good understanding of their doctor's explanations and being comfortable asking questions about their illness or treatment. The most common information needs in our group related to treatment, diagnosis, and possibility of cure, similar to findings of in Uganda, and studies from Germany and Japan [205],[210]. Similar to our findings, German patients had high information needs, despite satisfaction with information given [205]. Sepucha et al. reported that there is little relationship between feeling extremely well informed, and actual knowledge which was associated with lower education and income, and complete trust in the doctor [233]. In Africa, patients may also report being satisfied with the information they have received out of respect for the doctor as expert [144],[208]. In Uganda, only 50% of breast cancer patients reported receiving enough information from doctors [144]. It is also possible that patients may answer research questions positively, because they do not want to seem critical of their doctors on whom they rely for their treatment.

Most of the patients (82.5%) in our study preferred an active decision role. This result differs from findings in other LMICs, where patients often prefer a passive role, and from HICs where patients are more likely to prefer a shared decision role [144], [145],[234], [235], [236], [237], [238]. Our findings regarding DCP are similar to those of a multi-national study of cancer patients receiving palliative care where, in South Africa, 69.7% had an active DCP. Furthermore, a study of patients with chronic disease in South African family practice clinics reported 46% with an active DCP,[239], [240]. Some South African patients making cancer treatment decisions speak of resenting the directive manner of communication and felt excluded from decision making, representing a desire for a more active role [207]. While for high risk interventions with high certainty of the outcome, a directive communication style may be necessary (such as an emergency surgery for trauma, treatmens with clinical equipoise require a less directive approach (Whitney, 2004).

Most of our patients reported high levels of mutual respect and of trust in the doctor. However, fewer reported being seen as a whole person ‘a lot’, with less than half reporting ‘a lot’, that doctors asked them how they or their family are coping. Components of a therapeutic alliance between patient and clinician include, the clinician engaging with the patient, that the patient understands the information shared with them, mutual respect and patient trust in the clinician so that they work well together to make effective decisions [226]. While in this study some aspects of the therapeutic alliance were positively reported by most, others such as seeing the patient as a whole person and enquiring about how they and their families are coping are not. These aspects may represent the unequal exchange of information and the lack of adequate engagement with the patient to understand the impact of the disease not only on the patient holistically, but also their families who may be providing support at home.

Most of our patients chose chemotherapy, with only 1 declining and 1 undecided. Patients arriving at oncology clinics have already been considered eligible for chemotherapy. The options presented are to do chemotherapy or not. In the absence of any alternatives, patients usually opt for chemotherapy given their hope for a cure. Patients may also agree to chemotherapy, even if they are undecided, out of respect for the doctors. Most reported knowing the side effects, having sufficient information and support to decide on treatment, felt sure about, and were satisfied with their choice, although some felt that they were choosing with some pressure from others. Eight patients chose chemotherapy despite not knowing the side effects. Three had inadequate HL, with 5 having an active DCP. One patient who had marginal HL, and needed information about chemotherapy, made a choice without gaining any further knowledge, was not sure about, nor satisfied with the decision which was made with some pressure from others. A second patient with inadequate HL, but an active DCP was not satisfied with, nor sure about their decision, reporting that they were not given a choice.

This small group may not be representative of a wider population of patients with similar characteristics; however, they offer a glimpse of what patients may be experiencing through the complex process of cancer treatment decision making with inadequate skills or opportunity to participate as preferred.

The strength of this study is that it was conducted at 3 sites in 2 provinces of SA, with differing patient demographics and socioeconomics. We also used a locally validated HL tool translated into IsiZulu, the most spoken language, and all other tools were reviewed by interviewers who were multi-lingual and knowledgeable in most of the diverse cultural aspects of health care. A survey of psychological distress would have been an added strength, as receiving a cancer diagnosis and deciding on treatment is very stressful which would impact on patients’ ability to understand medical information and may have affected the outcomes of the surveys. A limitation is that despite the multi-site study, the findings may not be generalisable to other parts of the country due to the high diversity of our population as well as unequal access to health resources.

4.5. Conclusion and recommendations

This study contributes to current evidence in South Africa and potentially Africa, showing that few patients accessing public health facilities have adequate HL. Additional information includes patient reported information needs, decision control preferences and decision conflicts. Assessing information need, DCP and patient resources during the consultation will permit a more tailored patient-centred approach to the discussion, deliberation, and informed decision on treatment. Treatment decisions are not a single event for the patient, but a process of information gathering, deliberation with the doctor and family, to then to come to a decision. The following may improve patient and clinician understanding and therapeutic bond to make a mutually informed decision:

1. Begin the treatment decision conversation by asking the patient their understanding of their illness.
2. Address any misunderstanding and questions that may arise and give information about their cancer and treatment in layman’s terms checking that they understand what is being explained.
3. Explain that a decision needs to be made, propose what is an acceptable timeframe, and ask whether they need to think about it, discuss it with family members, or want to make the decision themselves; bearing in mind that they may prefer for the doctor to make the decision, after being fully informed.

PART 2

CHAPTER 5

"What would you like the doctor to understand about you and maybe your circumstances when talking about starting your treatment?"

Participant

"Maybe ask me that how I feel, my feeling and my thoughts yes, my views yes."

(SA Oncology Patient)

Chapter 5 Oncology patient and staff experiences of cancer treatment decision making

This chapter reports on the qualitative study findings to gain a deeper understanding of the experiences of patients and oncology teams of cancer treatment decision making, and of the factors which impact on patient informed treatment decisions. I have initially provided full results of the analysis of seven domains in Tables 5.2a – 5.4c and Tables 5.6a -5.8. I then focussed initially on the similarities and differences between patients' and staff's experiences and perceptions, and then narrowed my focus to the communication in the consultation as a potential starting point for an intervention. A manuscript for publication will be drafted focusing on the patient-provider interactions in the consultation.

5.1. Introduction

Cancer treatment decision making occurs on a continuum from the patient noticing and acting on concerning symptoms, followed by agreeing to diagnostic procedures to making a treatment decision at the oncology clinic and adhering to the treatment plan. The first signs of cancer may be missed or ignored by patients, due to lack of knowledge, misconceptions or fear. Health system inadequacies may result in a late diagnosis and once diagnosed, patients may not be adequately informed about their cancer and potential treatments [6], [241]. Upon reaching a tertiary oncology clinic, several patient, provider and health system factors will impact on informed treatment decision making [9], [13]. The foundation of cancer treatment decision support should be clinical counselling by a registered practitioner [9]. Adding patient DAs and non-directive decision coaching by a suitably trained health professional may provide additional support for a patient to make an informed, value-based treatment decision [9].

My systematic review of the effectiveness of decision support interventions to improve cancer treatment decision making (see Chapter 3) showed that the decision support interventions (DESIs) reviewed have variable effectiveness on improving knowledge, reducing decision conflict and increasing shared decision making. For vulnerable people, who may have low literacy and communication challenges, DAs with simple language and pictures were preferred. Self-administered internet-based DAs were less effective in improving knowledge than DAs administered by a suitably qualified staff member. The review also showed that while some DAs were tailored for vulnerable populations, none utilised in-person counselling which was preferred by vulnerable persons. This is a potential gap in the design of DESIs to adequately address patients' decision support needs.

My empirical survey study of determinants and adequacy of cancer patient HL, decision control preferences (DCP) and decisional needs (chapter 4) found that most patients had low to marginal health literacy. English literacy varied, and few patients could access online information about their cancer. Although patients preferred active participation in decision making, they reported high cancer information needs despite stating that they understood most of what their doctors explained and felt very comfortable asking questions in the consultation. *(manuscript in review).* These contradictory findings required further exploration to better understand the experiences of cancer patients making treatment decisions in our South African tertiary level oncology clinic setting [1]. This qualitative study aimed to explore patient and provider experiences of cancer treatment decision making and identify facilitators and barriers to effective patient-informed treatment decision making.

5.2. Methodology

The qualitative study was framed within a phenomenological methodological paradigm which was appropriate to understand the essence of the experience, or the underlying meanings and interpretations that individuals assign to their experiences [242]. I used an exploratory qualitative research design to provide insight into the experiences of cancer patients and oncologists in making treatment decisions as well as the facilitators and barriers to informed decision making by the patient. The study data collection comprised of two components, i) in-depth interviews with patients attending the oncology clinics for chemotherapy and ii) focus group discussions (FGDs) with the doctors and with nurses working in the clinics. The purpose was to deepen my understanding of the patient factors impacting on treatment decision making as well as their experiences of the therapeutic relationship depicted conceptual framework in Figure 1.2 (see Chapter 1). In addition, I aimed to explore the treatment decision-making consultation from the perspective of the oncologists, to understand their identified barriers and facilitators to patient informed decision making. Focus groups with the nurses served to further inform and triangulate my understanding of the reported experiences of the patients and the oncologists through the lens of the nurses' observations and experiences.

5.2.1. Patient interviews

The interviews with the patients were semi-structured and sought to explore patients' understanding of cancer and its treatments, their experiences and perceptions of barriers to, and facilitators of informed decision making. Being cognisant of the potential language barriers, and social and professional power gradients in the interviews, had I conducted them myself, I selected interviewers who spoke most of the official South African languages and with whom, patients would potentially feel more comfortable with to truthfully discuss their experiences. Two interviewers were female retired professional nurses who had worked in palliative care teams within public healthcare system, one additionally providing spiritual counselling to patients with cancer. Both nurses were also experienced in research. Neither nurse was a staff member of the clinics where the interviews took place, and had no prior relationship with the participants, and neither wore any uniform throughout the study period. The third interviewer was a female social worker who was also experienced in research, working in the public healthcare system. She was already conducting research-related interviews in the clinic and provided counselling services to patients referred from the oncology team. She therefore may have been familiar to some of the participants, however she clarified with participants that the interview was for research purposes only when going through the consenting process.

5.2.2. Focus group discussions

The FGDs were conducted after the patient interviews were completed at each site. The facilitator guide was developed similarly to the patient interview guide, informed by the results of the mixed methods systematic review and the quantitative study. I personally facilitated all the FGDs, which were all conducted in English. I have a broad experience of working at all levels of the healthcare system (From primary care clinics to tertiary level hospitals). I was aware that my qualification and experience as a palliative care doctor would impact differently on my interactions with the oncologists and the nurses. Being a qualified doctor would provide some professional affinity with the Oncologists, however being a palliative care practitioner would mean that my experiences with patients would be different to that of the oncologists, and that this could potentially influence my interactions with my oncology colleagues. I knew some of the oncologists through a professional relationship, which I was aware could potentially result in an imbalance in my interaction with the participants in the FGD. I was cognisant of the potential professional barriers between myself as a doctor, and the oncology nurses when conducting the FGDs with them. However, having worked very closely with professional palliative care nurses as colleagues in multi-disciplinary teams, I hoped that I would be able to establish a rapport with the oncology nurses and gain their trust to discuss what may be potentially difficult topics. While analysing the data, I was conscious of my potential biases, keeping an open mind and making notes of my responses as I listened to the recordings and while reading the transcripts.

5.2.3. Sites and participants

Thirty patients (ten at each site) diagnosed with cancer who had recently initiated chemotherapy treatment at the oncology clinics at three tertiary level hospitals, two serving a largely urban, multi-lingual, and multi-cultural population in Gauteng, and one serving a largely rural, Zulu-speaking population in KZN, were invited to participate in in-depth interviews. Patient participants were purposefully selected to ensure representation of patients with different cancers, education levels, languages, and across the usual age range seen in the clinics. Given the narrow focus of the study on cancer patients's experiences of treatment decision-making and the purposive sampling strategy, a sample of 10 participants per site was selected to allow for adequate data to be collected to reach data saturation[243]. Doctors and nurses working in the clinics were invited to participate in FGDs with the researcher. A total of 53 oncology staff participated in eight discussions, including 25 doctors, 27 nurses and one patient navigator.

5.2.4. Data collection instruments

I developed interview guides for the semi-structured interviews (Appendix U), as well as a FGD guide for the discussions with the oncology staff (Appendix V). The findings of my systematic review and quantitative study informed the open-ended questions. After reviewing the interview and FGD guides with my supervisors and the interviewers, I refined the questions and prompts to be used in the final instruments.

5.2.5. Data collection

For the patient interviews, the interviewers approached patients in the clinics while waiting for their blood results before seeing the oncologist and invited them to participate in the study. Interested patients were taken to a private room in or near the clinic and the study was explained to them in further detail. After consenting an in-depth interview was conducted with the participant in their language of choice. . The interviews took place from

April 2023 to June 2023 and lasted between 20 mins and 1 hour. No participant experienced significant distress requiring suspension of the interview or additional counselling services. Participants were re-imbursed for travel costs for each interview.

For the focus group discussions, the interviewer approached the head of each unit to discuss the study, give feedback on the results of the quantitative study and arrange for a convenient time and location for the oncologists and nurses to participate. At the time of the focus group discussion, I introduced myself to the group and explained the purpose of the study and that participation was voluntary. Focus group discussions with consenting participants were conducted at each site between May 2023 and October 2023. The discussions ranged from 45 minutes to 1 hour and 20 minutes each. At each clinic nurses and doctors were invited to participate in separate groups to maximise participation by members of each professional group. Focus group participants were offered a small gift as a token of appreciation for their time. I was aware that there may still be a power dynamic between senior members and junior members of each group, and I explained the group discussion rules at the outset and tried to engage all participants in the discussion. All the FGDs were conducted in English by me (PhD candidate).

All the interviews and discussion groups were audio-recorded, and transcribed. Patient interviews conducted in languages other than English were translated by translators fluent in both English and the language of the interview. Transcripts of the patient interviews were sent to the interviewers for checking for accuracy. Transcriptions of the FGDs were checked by me.

5.2.6. Data Analysis

To gain insight into the experiences of treatment decision making of cancer patients and oncology clinic staff, a deductive thematic analysis based on the research questions for this qualitative study was conducted following the steps of Braun and Clarke, 2006 [244]. While the process recommended by ‘Braun and Clarke’ is usually associated with an inductive approach to a thematic analysis, it may also be applied to a theory driven deductive approach. The deductive approach allowed for qualitative findings which could confirm or refute the findings of the previous two studies (my systematic review and quantitative study) and elucidate any new themes to add to the conceptual model chosen for this thesis.

The transcripts of the interviews and FGDs were analysed separately. Two researchers read the translated transcripts of the in-depth interviews and the FGDs several times to familiarise themselves with the data. The audio-recordings of the FGDs were replayed while reading the transcripts initially. Listening to the audio-recordings while reading the transcripts allowed for the researchers to pick up any missed phrases or incorrectly transcribed words, as well as to facilitate audio immersion into the context of the discussions. Initial notes were made during this process of immersion consisting of initial impressions, reflections and questions arising from the data. Once familiar with the data, initial coding was commenced. The patient interview transcripts were coded based on i) the research question related to patient cancer knowledge, and their sources of knowledge, and ii) the research question related to the patient’s cancer decision-making experience, including their perceptions of facilitators and barriers to informed treatment decision making. The FGD transcripts were coded based on i) the staff's perceptions of the patients' knowledge and sources of information, ii) their perceptions and experiences of treatment decision-making consultations as well as iii) the barriers and facilitators to patients' informed treatment decision making. Weekly meetings between the two coders were held to discuss the code applications and the coders' impressions of the experiences of the participants. Once the transcripts had been coded, the codes were grouped into initial themes which were checked against the coded extracts. The themes were refined, based on constant checking until final themes were agreed on and were then checked for clarity, with a third researcher not involved in the data collection or coding process[245]. While coding the transcripts, no new codes emerged from the last transcripts of the patient interviews nor of the focus group discussions. Once the separate analyses of the patient interviews and the staff FGDs were completed, the themes were compared for similarities and differences to identify mutual themes between the patients and staff. Barriers to patient informed treatment decision making and potential facilitators were identified, which may be addressed with a future intervention.

5.3. Results

From the patient interviews and the FGDs with the oncology staff, it emerged that multiple patient-related, family-related, provider and health system-related factors impacted on patient informed decision making. Themes from the patient interviews included: 1) patient reported knowledge and understanding of cancer, information needs, and sources of information, 2) patients' experiences of the treatment decision consultation and 3) facilitators and barriers to patient informed treatment decision making, Themes from the FGDs with the providers included: 1) factors impacting on cancer treatment decision making, 2) consultation level factors that impacted on informed patient treatment decision making, 3) facilitators of patient informed decision making, and 4) strategies to improve patient informed treatment decision making. Figure 5.1 illustrates the factors which impacted on the cancer patients' informed treatment decision making, superimposed on the conceptual model for this thesis.

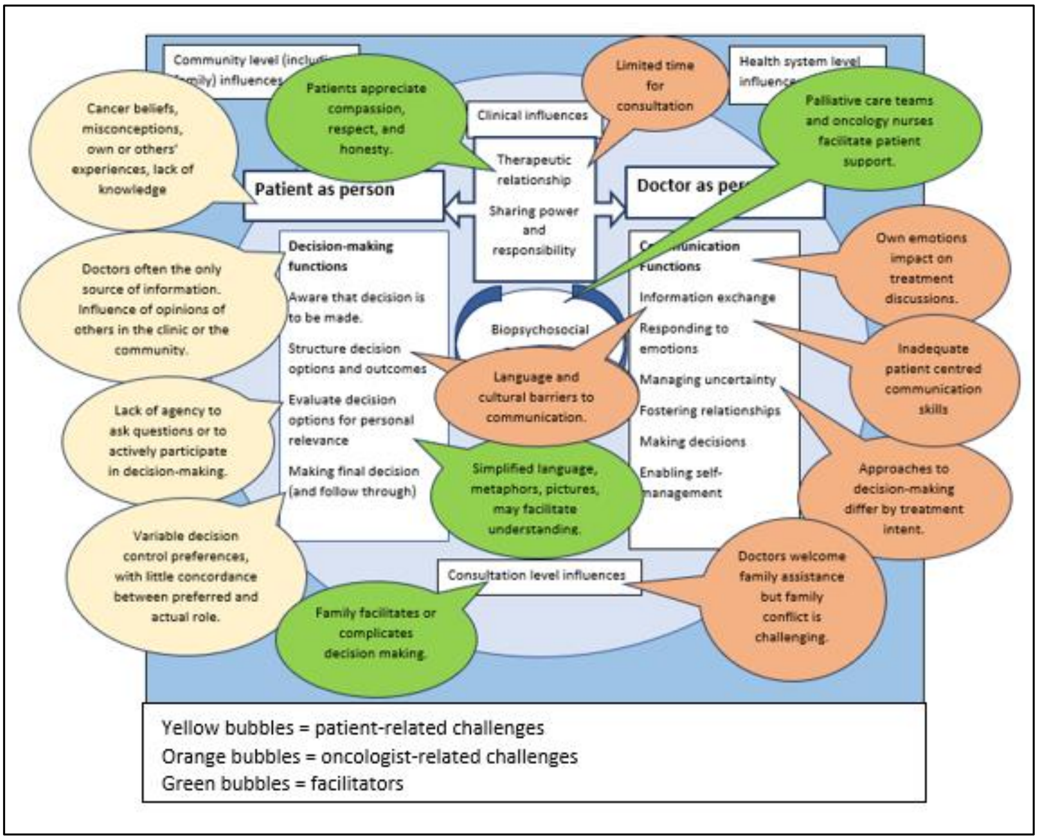


Figure 5.1: Barriers and facilitators of patient informed treatment decision making

5.3.1. Patient in-depth interviews

The average age of the patient participants was 49 years (range 19 – 74) (Table 5.1). Men and women were equally represented at 50% each. Most participants were married (53%) and lived with their children and partner/spouse (47%). IsiZulu was the most commonly spoken home language (43%), followed by English (23%). Most patients (77%) reported being fully literate in English, with 37% of patients having attained grade 12 at school and a further 37% holding a tertiary qualification. Smartphone ownership was at 77%, and 55% used a mobile phone to access information on the internet.

Table 5.1: Patient sociodemographic and clinical data

Variables	
	mean (range)
Age (years)	49 (19-74)
	n (%)
Gender	
Male	15 (50)
Female	15 (50)
Relationship	
Single	9 (30.0)
Married/Partner	16 (53.4)
Widowed/divorced	25 (16.6)
Home language	
isiZulu	13 (43.3)

English	7 (23.3)
Tswana	7 (23.3)
Sesotho	2 (6.8)
Afrikaans	1 (3.3)
Education	
≤Grade 7	4 (13.3)
Grade 8 - 11	4 (13.3)
Grade 12	11 (36.7)
Tertiary level	11 (36.7)
English literacy	
Verbal understanding only	4 (13.3)
Verbal understanding and can speak	3 (10.0)
Verbal understanding, can speak and read	23 (76.7)
Phone type	
No phone	2 (6.7)
Mobile phone but not a smart phone	5 (16.7)
Smart phone	23 (76.7)
Use of phone/computer for information online	
Computer and mobile phone	9 (27.6)
Mobile phone only	8 (27.6)
Computer only	4 (13.8)
Neither	9 (31.0)
Cancer site	
Haematological	7 (23.3)
Breast	8 (27.6)
Colon	4 (13.8)
Other	10 (33.3)
Did not know	1 (3,3)
Time since diagnosis	
Median (IQR)	4.5 (3,6)
108 months (outlier)	1
Did not know	1
Previous cancer treatment (Some patients had more than one treatment modality previously)	
None	21 (70.0)
Surgery	7 (23.3)
Radiation	1 (0.03)
Chemotherapy	4 (0.1)

Interview findings

The interview findings were synthesised into 3 main themes: 1) patients’ knowledge and understanding of cancer, their information needs and sources of information, 2) patients’ experiences of the treatment decision consultation and 3) facilitators and barriers to patient informed treatment decision making.

Theme 1. Patient reported knowledge and understanding of cancer, information needs, and sources of information

Sub-theme1.1. Patient perceptions, beliefs and misconceptions about cancer

Patients almost universally associated cancer with death. Many believed that only old people or white people could be diagnosed with cancer and some expressed fear that it was contagious, being caused by a virus: "*Me in my body I think that there is this virus and uh, it's dangerous on the other hand it's not, but you just need to take treatment to get better yes" (B04)*. Patients commonly believed that not choosing chemotherapy was not an option because they would otherwise die of their cancer. While some perceived chemotherapy to be a poison, "*What I understood is that it is poisoned "cause" I get the carbo-platinum, and, uh, I did not really "understood" what the poison will do to you" (B01)* others believed that experiencing the side effects was an indication that the chemotherapy was treating the cancer, "*I think the chemo is working when I come from chemotherapy, it's working because-because my hair, do you see how my hair is". (A08)*.

Sub-theme 1.2. Knowledge and understanding of the cancer diagnosis and treatments; and personal responses to cancer symptoms

Knowledge of cancer, its causes and treatments varied from having no knowledge: "*Eh, in my mind, anyway it was something that I am experiencing for the first time, which I didn't know how it was acquired, where it was from, so, I do not- I just accepted the situation when they explained it to me*". *(C07)* to sophisticated understanding. Some could not name their cancer, while others gave detailed information about cancer, and some understood that some cancers are hereditary. Some patients waited until a lump became painful before attending a clinic, while others responded to abnormal symptoms much sooner to seek medical attention. Staging of cancer was poorly understood, some confusing it with cycles of chemotherapy, *"I was told there are stages, stage 4. They say I am in stage 4. I must have completed the cycle, which is stage 6. I did not know that. When is Stage 6 coming?" (A08)* and not realising the seriousness of stage 4. Diagnostic tests were less difficult to comprehend, with some understanding that tests were needed to measure response to treatment. Similarly, knowledge and understanding of treatments ranged from no idea about treatment to understanding that different treatments for cancer existed and that patients responded differently to the same treatment, "*We might take the same illness. But with chemotherapy, I can react differently to you. I can- I can see results differently to you*" (A06). Some understood the concepts of cancer progression and remission *"cancer is not curable but suppressed and, in the body, it hides itself then I mustn't say that that because I am taking treatment and tell myself that I am ok and its finished but not". (B05)*.

Sub-theme 1.3. Variable cancer information needs

While patients reported various levels of knowledge or understanding of cancer, many still had information needs. (Table 5.4) Further information requested included the cause of cancer, information about their stage or progression of cancer, mechanism of action, "*'Cause chemo breaks down everything, (.) and I would like to know why, why does it have to breakdown everything and not just a cancer?" (C09),* side effects of treatments, and monitoring for response to treatment. Often, despite reporting feeling knowledgeable, patients would ask questions at the end of the interview, indicating an inconsistency between patients reporting feeling informed but still having further information needs. Information on navigating the healthcare system with numerous appointments and clinic procedures "*What do I do with that treatment do I separate them or do I alternate go to Joburg and them come here, that's all I want to know now that I am confused." (B02),* were also an unexpected information need. Patients who were in denial or who were fatalistic about their cancer preferred less information, while others felt better prepared to deal with the cancer if they had more information, with some feeling that doctors were withholding information "*It's almost like the doctors are withholding information, they were too scared to tell me everything…You know, unless you ask them directly" (A10)*.

Sub-theme 1.4. Limited sources of Information

Patients varied in efforts to gather information. Very few accessed information on the internet, a few relying on family assistance. Few accessed paper-based information. Most spoke to other people within their family or community or with other patients "*I got information from another girl whom we attend the treatment together" (B05)*. For many patients, the doctor was the only source of information, "*There is no other way besides hearing it from the doctors". (B09)* and some reported that doctors explained about their cancer and treatments well. Patients did not always feel empowered to ask questions in the consultation "I. *Didn't you ask the doctor what that is when he told you that you have cancer? didn't you ask the doctor? P: No, I never asked them..." (A01)* and consulted other healthcare providers including alternative practitioners. In the oncology clinic, patients often asked the nurses to explain what the doctors had told them "*They didn't explain anything to me as yet. Because what I find out about-from a nurse when I came for my last chemo". (C04)*. Knowing someone who had cancer or having had previous experiences with cancer usually improved understanding "*so I was in that picture, to say I wonder if I will be able to survive. 'Cause I saw what it did to my family". (C01)*, but others' or their own negative experiences could perpetuate misconceptions.

Theme 2. Patients' experiences of the treatment decision consultation

Sub-theme 2.1. Variable decision control

Patients' preferred decision control varied from wanting to actively participate and make their own treatment decisions "*Me…me cause it concerns me…maybe the advice yes but the decision I would love to take it for myself". (B04)*and less frequently to share the decision with their family or to leave the decision to the doctor "*Then I listened to the doctors, what they said to me, and I did as they wanted me to do". (A08)*. None spoke of a shared decision role with the doctor. From patient accounts of the decision-making process, it was clear that consenting to treatment was considered an active decision role, indicating a possible misunderstanding of the concept of active participation in decision making.

Sub-theme 2.2. Differing levels of agency

The patients exhibited differing levels of agency from taking responsibility for their treatments and actively seeking information or engaging with the doctors, while others passively relied on their doctors to make the best decisions for them: *"I fully give, um, that* *over to the doctors. I believe they, in the doctors, I believe they know more than me. They know what to do". (B01)*

Sub-theme 2.3. Patients feeling pressured to make decisions

Some felt time pressure to start treatment urgently, while others felt pressured by family or doctors to agree to treatments *"I was told that no this chemo is very expensive please don't uh…what is called this don't default so I had to go or I had to abide by what was told to me". (B07)*.

Theme 3. Facilitators/barriers of patient treatment understanding and decision making

Sub-theme 3.1. Patient related barriers or facilitators of decision making

From the patient accounts of their experiences, it was possible to identify facilitators and barriers to effectively achieving patient informed decision making. Receiving the diagnosis had a significant impact on the patients cognitively, "*Even when they were telling me that I need to start taking chemo, I was afraid since even as I was walking on the street, I didn't know if I was walking on earth or what"(C01),* many struggling to comprehend information or participate in discussions. Information recall was variable, however some, despite poor recall, reported being satisfied with the doctor's explanations *"P: You know, I don't understand that much as such, they explained a lot to me. I: They explained a lot to you? P: Hha, a lot. I: Okay, so are you satisfied with what the doctors explained to you? P: Mm" (A02)*. The patients experienced a mix of emotions impacting on their ability to engage in discussions about treatment, while for some patients, past family experiences affected their treatment deliberation. When asked what would assist them to decide, many could not easily identify specific facilitators. Some patients appreciated having family present at the consultation, however family attendance was not always possible and occasionally not welcomed *"Ehh, eish… I think they would make me feel uncomfortable, they would make me feel uncomfortable plus I was admitted in hospital" (B08)*.

Sub-theme 3.2. The impact of the patient-doctor relationship on patients' decision making

Patients appreciated compassion and respect from the doctor *"they should not just say it as if you have perhaps had a fracture and you have come to put a bandage with concrete and that you will be okay. Cancer is something else, it's not- it's not easy" (C01)*. Some patients reported doctors mitigating the seriousness of their condition, which could impact on their decision making, "*Then I saw the scan and the doctor told me that there is something they found, and they told me not to worry, it is small. So, when the results came, the doctor told me that no, it shows that the cancer has spread to the bone eh it is at the sternum… I told the doctor that you shouldn't have told me that it was something small... Tell me, you obviously read the results, you know very well what they are talking about, so now you decided to tell me after" (A05),* while those actively involved in decision making preferred honesty or full disclosure .

Sub-theme 3.3. Health system barriers to or facilitators of patient informed decision making

The patients received very little information from the referral clinic or hospital, *"No, he didn't explain anything to me. The doctor, remember isn't it I see him, he is just it's a medical doctor, he does not work strictly with the breast" (A05)*. At the oncology clinic, limited time with doctors resulted in insufficient explanations, and a perception of having no opportunity to ask questions. Some felt that decisions about their treatment had already been made, without them having had any real choice, *"The way that they explained it to me it seemed as if they had already taken the decision and they were just telling me that I am going to take treatment" (B08)*. They appreciated counselling for emotional distress as well as an opportunity to ask questions about their treatment *"Ja the counselling yes, I think most of us we need it because like…counselling yes but the video and the recordings no because I will not be able to ask questions like I won't get the answers ready same time" (B04).*

5.3.2. Focus group discussions with oncology staff

Twenty-five doctors and 28 nurses participated in the FGDs. Only 17% of all participants reported receiving any communication or counselling training outside of their undergraduate studies (Table 5.10).

Table 5.2 Characteristics of oncology staff

Characteristics (Focus groups = 8)	N = 53
Age (mean, SD)	40.10 (11.25)
	N (%)
Gender	
Female	35 (66.0)
Male	15 (28.3)
Did not report (DNR)	3 (5.7)
Profession (self-reported)	
Doctor group N= 28	
Doctor/medical officer (general practitioner)	14 (26.4)
Registrar (resident)	3 (5.7)
Fellow	1 (1.9)
Consultant (specialist)	7 (13.2)
Nurse and allied support group N =28	
Student Nurse	2 (3.8)
Nurse	8 (15.1)
Enrolled Nursing Auxiliary (ENA)	4 (7.5)
Enrolled Nurse (EN)	3 (5.7)
Professional/Registered Nurse (PN/RN)	8 (15.1)
Operational Manager	1 (1.9)
Patient navigator	1 (1.9)
Did not report	1 (1.9)
Professional experience	

0 - 10 years	32 (60.4)
11 - 20 years	11 (20.7)
>20 years	9 (17.0)
Did not report (DNR)	1 (1.9)
Oncology experience	
0 - 10 years	42 (79.2)
11 - 20 years	6 (11.3)
>20 years	4 (7.4)
Did not report (DNR)	1 (1.9)
Years in clinic	
0 - 10 years	46 (86.8)
11 - 15 years	4 (7.5)
>20 years	1 (1.9)
Did not report (DNR)	1 (1.9)
Extra-curricular training in counselling/communication	
Yes	9 (17.0)
No	43 (81.1)
Did not report (DNR)	1 (1.9)

Focus group findings

Four themes emerged from the FGDs: 1) Provider reported factors impacting on cancer treatment decision making, 2) Consultation level factors that impact on informed patient treatment decision making, 3) Facilitators of patient informed decision making, and 4) strategies to improve patient informed treatment decision making.

Theme 1. Provider reported factors impacting on cancer treatment decision making

This theme is composed of seven sub-themes identifying factors such as patients' knowledge, personal factors, situational factors and healthcare provider and health system factors impacting on patient informed treatment decision making.

Sub-theme 1.1.. Impact ofpatient beliefs, knowledge and sources of information

Providers reported that patients often have preconceived notions that cancer kills, which leads to a fatalistic attitude. Furthermore, the reported that some patients believe that the treatment will kill them, based on hearsay; *"they compare it to somebody who died or "somebody said, I must not take this treatment because it is going to kill me" (*Doctor C02). They also indicated that patients have very limited knowledge of cancer or the reason for their referral, and lack understanding of the meaning of stages, implications for treatment and the treatment plan, *"when we read a referral letter and we say to you, "do you know why you are here?', they say "no, I just came to the clinic because I had a problem with my anatomy and the doctor said I must come here" (*Nurse C04).

They perceived that patients either actively seek information or are exposed to information in the clinic waiting room or in their communities where they are vulnerable to misinformation, *"there's waiting room, the place they pick up information or disinformation. …. It sounds really far-fetched, but ja, I mean, it's just all hearsay, but it can have a huge influence on the patient" (*Doctor A03).

Sub-theme 1.2. Provider perspectives on patient related personal factors impacting on informed decision making

Patient age, education, literacy and socioeconomic circumstances were reported to impact on patient understanding and absorbing of information. It was appreciated by providers that being diagnosed with cancer impacts cognitive function, which affects their ability to understand and recall all the information they are given. Cultural beliefs were also perceived to impact on the interactions between staff and patients, requiring a knowledge of cultural values to engage with patients effectively, *"Your black elderly males. … They don't want to look like they are weak of some sort and it's not about anyone being weak or anything but it's just a matter of you interacting with your doctor. And get to know what's really going on with you" (Nurse B03)*. The impact of the historical Apartheid policy was also perceived to impact on patients' agency, with patients tending to be passive, not participating much or asking questions in the consultation. It was also appreciated that patients present to providers experiencing several emotions in reaction to their cancer diagnosis ranging from shock and denial to depression, anger and anxiety. They are perceived to be fearful of the unknown, the treatment and of dying, "*A lot of patients are scared to die, and you know, and they're scared if they don't listen to us, they're going to get sicker or they're going to die" (*Doctor A03). And yet hope that the treatment will prevent death, will often be the overriding reason to choose treatment, even when it is futile (Table 5.12).

Sub-theme 1.3. Provider perspectives on family related factors impacting on informed treatment decision making

From a provider perspective, family support for patients emerged as a very strong influence on patient treatment decision making. However, while some family support positively impacts decision making, family misconceptions and lack of knowledge may impact negatively on decision making: "*So, I think whether it's palliation or it's adjuvant or neo-adjuvant kind of cancers, patient's family involvement is very important, because they make decisions while they are at home for the patient who is nursed by us here" (*Nurse B02).

Sub-theme 1.4. Provider perspectives on situational factors impacting on informed treatment decision making

Providers reported that for patients who have a good chance of cure, oncologists may be more directive in treatment decision making as opposed to in palliative-intent situations, where they favour giving patients more choice options, having considered the risk-benefits profiles of treatments. They perceive that highly anxious patients feel an urgency to act immediately to remove the cancer. Even when treatment is futile in incurable cancer, providers reported that some patients may want to continue, while others may refuse palliative treatments, when they feel that quality of life means more than extra time. Some treatment decisions are difficult for doctors when faced with patient psychological distress, even if treatment is known to be futile, *"Sometimes yes, we leave it to the patient's choice. Sometimes they request that they want to continue. And we know in the background and biochemically and evidently like it's not responding but we tell them, we inform them, sometimes they do accept, but psychologically its, you know…" (*Doctor C02).

Providers also reported socioeconomic and cultural factors were important considerations for patients faced with cancer treatment decisions. These include a number of factors that all may negatively impact on patients accessing treatment: *"it literally takes him three days to travel to get his chemo, three days to go back. Transport is an issue, is this medication going to cost me anything, what's this going to cost my family, … I think those are the type of things that a doctor can talk about with the patient" (*Doctor A02). They reported that some patients had family responsibilities with no support to complete their treatment, while cultural and religious beliefs were also perceived to impact on patient treatment decisions, often delaying initiation of cancer treatments. "*he was reluctant to make the decision and he needed to go consult the traditional healers and his family and ehh community and ehh delayed the treatment" (*Doctor C03).

Sub-theme 1.5. Provider perspectives of nurse factors impacting on informed treatment decision making

Nurses reported that they often educate patients who do not understand or recall the information from the consultation with the doctor, and often provide emotional and social support for them. They perceived that patients feel more comfortable speaking to nurses, whom they respect, and that nurses play a role in advocating for their patients' treatment, "*usually I think with them, since most of them are blacks, they believe strongly in our opinion. So the doctor would have told them one, two, three, and they would come out and want to confirm it with you. "Ehh, can I do this? Is this going to help? Ehh, is this the real side effect of chemo and everything?" So when you have reassured them as a- as a professional nurse, then they get to calm down" (*Nurse B03). However, nurses also reported on the strain they experience supporting patients in the clinic, "*We were all crying. Because it also puts that emotional strain on us. You know, so we also need like something, I don't know what it is, that will, you know, also help us to deal with the things that we really see here" (*Nurse C06).

Sub-theme 1.6. Provider perspectives of clinician factors impacting on informed decision making

Professionally, doctors perceive themselves to be respected as experts by the patients, "*they are relying on our expertise, expertise to tell them what kind of you know to assist them in the decision making" (Doctor B17),* but that their experience and maturity also impact on decision making. Doctors described how they explicitly explain the choices available however, "*a lot of the patients if I could just tell them sign, they would have signed it because they- they've been told next thing is chemo by whoever" (*Doctor B03). Dealing with bad news is difficult for clinicians, especially with known patients who relapse necessitating treatment plans to be revisited Doctors understood that honesty in the consultation is important, but *"you want to get the news across without intimidating the patient or making them scared which was wrong, because we're supposed to be honest" (Doctor C03).* Besides being professionals, they reported that oncologists are human beings who must deal with their own emotions "*now I have a scan here that says we can't take you to surgery, and oh, those patients, because they're also going to break your heart… I won't be able to look, continue seeing other patients with the same- you'll be down literally for the day" (*Doctor B01), impacting on their patient interactions.Doctors not only deal with the fear of potentially worsening outcomes following treatment decisions, but are also concerned about the potential threat of litigation, *"So, we were checking, how is he doing? Oh, no, ... They gave him chemo and killed him (family reported). Besides you having said- I mean, that's- we always, ehh and sometimes we forget to make people sign. But we must always make them sign" (Doctor B02).*

Sub-theme 1.7. Clinician perspectives on health system factors impacting on informed treatment decision making

Doctors lamented the general lack of resources, from referring clinics, or within the tertiary oncology clinic itself which are obstacles to adequately informing patients about their cancer and supporting them to make a treatment decision. Staff shortages, lack of space, and overwhelming patient numbers limit time available to support patients making treatment decisions, *"when they say they are scared to ask, maybe there was a rush between the doctor and the patient, because of the doctor wants to call the next patient" (*Nurse A04). They further reported distressing health system failures leading to delays in treatment, which too often limits options available to patients, "*and so, if there is something that needs to be worked on, they will be last on the list (of surgeries). Sometimes you don't even say. Because if they can't swallow and you are saying, by rights, you should be getting something to help you- it's- you are traumatizing them" (*Doctor C04). As a consequence, they reported that patients often arrive at the oncology clinics with very little knowledge,, "*some patients came here without knowing that there is a cancer. They told them, come here the doctor of XXX; they will tell you" (*Nurse C05), did not understand when they were told, or there was a long delay between diagnosis and arriving at the clinic.

Theme 2. Consultation level factors that impact on informed patient treatment decision making

This theme consists of three subthemes describing the assessment of patient needs, communication between the doctor and the patient and the decision-making process.

Sub-theme 2.1. Provider assessment of patient decisional needs

The Oncology staff reported assessing not only patients' knowledge and their ability to understand the information they were providing, but also identifying those who required support in coping with the diagnosis and making a decision. Assessments included asking questions directly, or gauging how patients answered questions, or relying on an intuitive sense that patients were unable to understand the information *"And I think it's very often, I know it sounds wrong but body language when they walk into the room. The patient that is very unsure of themselves and kind of avoiding eye contact doesn't actually know why they are here" (*Doctor B03).

Sub-theme 2.2. Factors impacting on communication between provider and patients

Several communication barriers were identified by the doctors, including language barriers, and the challenges of explaining difficult concepts in ways understandable to patients. Some patients' passivity complicated communication with the oncology staff. Doctors believed that their patients trust them, "*I think we should never underestimate the level of trust that patients have in us" (*Doctor A01), however, "*also patients don't feel comfortable talking to* *us as they would with a social worker or a nurse" (Doctor B05).* Other challenges included the difficulty of breaking bad news with patients and managing confidentiality with others in the consultation, especially with stigmatising co-morbidities, "*So, I'm like "okay and HIV", she (the patient) kicked me - under the table, like ja, do not" (*Doctor B02). Oncology staff recognised that communication is a different but necessary skill set to clinical skills, "s*o, we, we always hyped up about the sophisticated scientific stuff. But it's equally important to learn how to communicate with your patient. And, and basics you know" (*Doctor B110). While family presence in the consultation could provide support for the patient, doctors found that navigating family and patient dynamics in the consultation process was challenging, "*because there's always the very good supportive ones, and then you have the extremes … They are the decision makers, they force, I mean you want to say don't take chemo and they are like "no, take it" (Doctor B02),* some doctors reporting that it was easy to ignore the patient, "*I guess we always then tend to forget about the patient" (Doctor B02),* and directing communication to their family members, who were perceived to be less vulnerable.

Sub-theme 2.3. Clinician perspectives on doctor-patient decision-making processes

Clinicians reported varying patient decision roles, "*You go to the one extreme where it's bombarding with questions and then you get to the other patients who are like,… yes, yes, yes. And we say, what do you want to do? We've got these options, it's like 'whatever you tell us, it's fine'" (*Doctor A01). There was very little report of shared decision roles except for palliative treatment decisions, when patients were expected to share in the decision for treatment or not. Many patients lacked personal agency to engage in treatment discussions, which the staff attributed to historical or cultural reasons, "*Unfortunately, the way apartheid was, it made our community more submissive … because we are in this part of the world where people for many years of their life, someone had to make decisions for them" (Doctor B02)*. Decision conflict was perceived to be more prevalent when there was a decision to stop futile oncology treatments, either between the patient and the oncologist, the family and the oncologist, or between members of the oncology team. The patients refusing curative treatment for cultural or religious reasons resulted in doctors feeling very conflicted about the patient's choice, "*So, he said, 'I didn't want the surgery', even though it might have been curative up front, because of that. So … like he's educated and he knows his stuff … he made an uneducated decision. Yes, poor stigma decision" (*Doctor B03). Sometimes patients indirectly declined treatments, "*Mm even though they had agreed to start. Yes, they've got chemo scripts and everything, then patients just don't pitch" (*Nurse B02).

Theme 3. Provider perceptions of facilitators of patient informed decision making

The first two themes focussed on decision-making factors and many of the challenges faced by patients and oncology teams making treatment decisions. This theme comprises the identified facilitators of informed patient decisions, either as they arose in the conversation or in response to direct questions posed to the groups. The oncology staff spoke of how informed patient decision making is not only facilitated by providing understandable information, but also by providing support to enable patients to make decisions, "*Counsellors can speak to them and have sort of a pamphlet for each illness or each cancer"*

(Doctor A02). Nursing staff coaching patients to ask questions in the consultation was considered helpful, with support from palliative teams, social workers and spiritual counsellors proving invaluable to assisting with decision making. "*so they (palliative team) help, because holistically, they're looking after our patients, you know…. They are like gold in the department" (*Nurse A04). All staff mentioned how having the patient's family attend the consultations provided support for the patient and aided patients' understanding of information, "*That's the one thing that's often crucial, to get the family participation, not only the decision at the heart of things, but in the information as well" (*Doctor A01).

The staff highlighted the importance of providing timely information, ideally before patients arrive at the clinic. Doctors confirming patient comprehension using a teach-back methods were also suggested to be helpful, "*and I'll be like listen when you walk out this door, you must be able to tell your family exactly what's going on. And then I ask them to cite what they've said"(*Doctor B01). To overcome language barriers, in the absence of formal interpreters, the presence of a nurse in the consultation was critically important to assist with the translation of information.

Theme 4. Provider suggestions of strategies to improve patients' understanding

The oncology staff suggested that information needs to be presented using simple words, in a patient's home language with examples that they could relate to "*Ja, like in Sesotho, it's mofetse. ... So, if you talk about cancer, they'll be blank. But if you say, mofetse wa letswele, they know that you are talking about breast cancer" (*Nurse B03). There were conflicting opinions about the usefulness of written materials, "*I think the most durable, cost effective ehh method is a booklet that they can take home" (Doctor C02) vs "even if you go there and you give them pamphlets to read, they don't read, they throw it down there" (*Nurse A04), reflecting the diversity of expected preferences and literacy skills of their patients. Providing pictures or using images on smartphones as well as using Google appropriately in the consultation were all suggested strategies that have been used to assist patients with understanding information about their cancer and treatments. Videos were helpful, especially because patients could both see and hear the information, "*I think some of our videos here, and, you know, in the clinic, while explaining that, we can show them videos, … Yes, because they could probably be trying to explain to their families what they have seen here " (Doctor C03).*

5.4. Discussion

This qualitative study explored at a deeper level with oncology patients and providers, the factors that impact on patients' informed treatment decision making. The patient-reported experiences were frequently identified and confirmed by the oncologists and nurses in the FGDs. However, there were discernible differences based on their unique perspectives of the informed treatment decision-making process. Table 5.23 provides a comparative summary of the findings from the interviews and FGDs.

Table 5.3 Comparison of themes from the patient interview analysis and the focus group discussion analysis

Patient interview results	Focus group discussion results
Patient reported knowledge and understanding of cancer, information needs, and sources of information.	**Patient knowledge and sources of information**
• Several patient-held perceptions, beliefs and misconceptions about cancer. • Variable knowledge and understanding of cancer, diagnosis and treatments. • Numerous cancer information needs • Sources of information include doctor, nurses, other patients, family and friends.	• Similar reports of patient-held beliefs and perceptions impacting on cancer-related decisions. • Poor patient knowledge and understanding, related to literacy level. • Other patients, charlatans and "Google" as sources of information and misinformation.
Patient's decision making experience	**Treatment decision-making consultation**
• Most preferring active decision control and believed that they played an active role. • Some deferring treatment decision to doctors due to faith/trust in doctors or fatalism (giving up). • Varying levels of agency for information seeking to facilitate decision making. • Patient-perceived pressure or urgency to make a decision.	***Decision making process.*** • Patients played a mostly passive decision role. • Patients lack agency to ask questions. • Family presence can aid understanding but may also negatively impact on decisions. • Irrational decisions based on stigma and cultural norms. • Non-adherence to treatment due to family influence or visiting traditional healers. • Difficulty managing family in consultations related to confidentiality and conflict.
Patient doctor interactions facilitating or impeding decision making. • Patients appreciate compassion/empathy and respect for themselves. • Patients value honesty, but some experienced premature reassurance and minimising of severity of situation.	***Assessment of patient needs*** ***Communication*** • Language barriers and cultural communication barriers complicated consultation discussions. • Patients trust oncologist but are more likely to ask questions with nurses or social workers. • Oncologists are adversely affected by difficult conversations about prognosis and illness progression. • Inadequate communication skills and training for doctors and nurses.

Facilitators/barriers of understanding & decision making.	Factors impacting on informed decision making - staff perceptions
Patient related facilitators or barriers to understanding and decision making. • Cognitive impact of diagnosis and confusion impact on information recall and processing. • Emotions impact on ability to make decisions. • Family/social factors affecting decision choices. • Family presence in the consultation. • Impact of previous personal or vicarious experiences on treatment choices. • Religious beliefs and faith in healing. ***Decision for treatment associated with expectation of cure even if incurable.***	***Patient factors*** • Patient demographics and socioeconomic status. • Emotional and cognitive responses to the diagnosis. ***Family factors*** • Family knowledge and understanding of cancer and treatments. • Family support • Family interfering with the decision making. ***Situational factors*** • Clinical factors impacting on choices. • Patient perceived urgency to start treatment. • Socioeconomic factors impacting on choices. • Cultural/religious factors impacting on choices.
Health care provider/health system barriers to decision making • Poor communication in prior diagnostic consultations. • Limited time with doctor in consultation. • No consistent relationship with a doctor • No explanation from doctor. • No perceived opportunity to ask doctor. • No choice given over treatment options. ***Counselling (to relieve stress and foster information clarification)*** • Counselling is beneficial for managing emotions and gathering information. • Written materials and videos may be helpful but may need someone to answer questions.	***Nurse factors*** • Nurses have a good relationship with patients. • Nurses try to inform the patients, although feel that patients should be asking the doctors. • Nurses provide emotional support. • Supporting severely ill patients impacts negatively on nurses' capacity for compassion, especially when unsupported by management. ***Clinician factors*** • Professional factors such as skills and experience impact on discussions about possible treatments. • Personal communication styles and emotions. ***Health system factors*** • Lack of adequate treatment options or delays in access to treatment and lack of resources for giving adequate information. • Inadequate communication of Information at referring clinics • Constrained oncology clinic resources.

	Facilitators of informed decision making - Providing adequate understandable information - Providing emotional/social/spiritual support - Palliative care teams are invaluable resources. - Family attending consultation to aid understanding and for support. ***Strategies to improve understanding and recall***. - Adjusting information to suitable literacy level. - Using simplified language, examples and metaphors. - Using written information, images, pictures, photos, videos/YouTube.

5.4.1. Summary synthesis of emergent themes impacting on patient informed cancer treatment decision making

Patient Beliefs

Patients held several beliefs and perceptions of cancer which were shaped by their culture, community norms, their faith, hope and fatalism. Oncology staffs' perceptions from their interactions with the patients matched the reports of the patients. The staff also emphasised how these beliefs could negatively impact on treatment decisions, while for some patients' faith and religious beliefs helped them to cope. The patients' knowledge of cancer and treatments varied widely, which oncology staff considered to be related to the patients' levels of education or employment, and a lack of suitable translatable terms in a local language. Similar findings of patient-held beliefs and information gaps were reported from a study of cancer patient needs in the Eastern Cape province of South Africa [190].

Emotional responses and impacts

Nurses described how emotional, uninformed patients arrived at the clinic, and considered how highly emotional patients would struggle to assimilate and process information. Patients themselves reported how shock and emotional distress caused confusion and they appreciated compassion, yet valued honesty from the doctors. Doctors acknowledged the role of the patients'' emotions on cognitive abilities to process information, also reporting the difficulty they had in sharing bad news with patients, not wanting them to lose hope. Doctors were also aware of the high regard patients had for their expertise and younger doctors reflected on their own limitations compared to their more experienced colleagues.

Information sources and needs

While patients mostly relied solely on the doctors for information, and reported not receiving sufficient information or explanations, doctors spoke of their struggle to explain cancer-related terms in simple language complicated by the difficulties of translation of some words. Patients, feeling uninformed, would rely on conversations with other patients in the clinic for information and support. Oncology staff were aware of the informal information-sharing and were concerned about the level of non-personalised misinformation received. While doctors and nurses spoke of their fears of this misinformation, nurses also recognised the importance of the support patients shared in the clinic. A South African study of gynaecological cancer patients' experiences also identified a lack of sufficient information given to patients who gleaned more information from other patients in the clinic rather than from the staff. Many patients in that study were also passive participants, not taking control of their information needs or treatment decision making and trusted their doctor to decide the amount of information they needed [245].

The amount of information desired varied based on the patients' emotions, illness severity and individual patient activation to participate in the decision-making process. Most patients rarely asked questions in the consultation, which contrasts with the results of the previous quantitative survey in which patients reported high levels of comfort asking questions. Patients felt more comfortable to ask nurses to explain after the consultation which the busy nurses found distressing; however, they would assist with information and support as much as they could. Family attending the consultation would be welcomed by staff who appreciated their facilitating of patient understanding of cancer and treatments. However, family presence in the consultation could also result in conflicts arising around confidentiality issues and disagreements about treatment decisions, adding to the burden of patient-centred communication.

Family, nurse and palliative care supportive factors

Family support was identified as a strong facilitator of decision making, but the family could also negatively impact on decision making as was found in other studies in LMICs [1]. Patients usually preferred an active decision role confirming the results of the quantitative surveys, yet staff observed a more passive role with patients deferring to family, especially elderly or very ill patients; or to the doctor, in whom patients had faith that they would be healed. Some patients would report having been actively involved in decision making, yet really consenting to what the oncologist or family decided.

While the patients generally did not specifically suggest facilitators of informed decision making, they mentioned the importance of family support in the consultation and the supportive relationship with the nurses. The oncology staff recommended counselling for emotional and social support, and decision coaching to improve patient agency in the consultation. The palliative care team involvement was considered a valuable asset in the clinic.

Communication and time constraints

The oncology staff all emphasized the lack of communication skills training which was viewed at educational institutions as separate to clinical skills training. A similar lack of adequate communication skills to manage patient emotions and psychosocial issues has been reported in the previously mentioned Eastern Cape study [190]. The oncology staff in this study highlighted the universal challenge of limited time available in the consultation, due to high patient loads and other responsibilities. Patients themselves spoke of the lack of opportunity to ask questions due to insufficient time available. Other health system barriers to informed decision making included delays to receiving some oncology treatments, impacting on the deliberation of available choices and the oncologist's decisions about how much information to share with patients. The limited availability of easily understood information resources to share with patients and families, was also a barrier to adequately informing patients. These multiple patient-related, family-related, provider and health system-related factors impacting on patient informed decision making are summarised in Figure 5.1.

Implications for practice and intervention development

The patients' lack of knowledge and beliefs about cancer and treatment should be addressed through adequate culturally sensitive communication with the patients, presenting understandable information in an acceptable language. Family presence may facilitate patient understanding or contribute to decisional conflict. Patients usually prefer an active decision control preference, however, often are passive role players, due to lack of agency to contribute to the deliberation of treatment options. Oncologists experience challenges with language and cultural barriers to communication and their personal difficulty discussing bad news. This is compounded by limited consultation time and additional factors including the presence of family. Patients need to be encouraged to participate actively in their treatment discussions, exchanging information with the oncologist to make the most appropriate informed decision even if the patient prefers for the oncologist or family to make the final decision.

My findings highlight the influence of family support on patient decision making, the important role of nurses in informing and counselling patients in the oncology clinic, and the vital multidisciplinary support of the palliative care team which have emerged as previously unacknowledged facilitators of informed cancer treatment decision making in South Africa. The additional support of these facilitating contributions to patient informed decision making should be leveraged in the process of intervention development. The authors of an Eastern Cape study in 2014 made similar recommendations regarding communication training for oncology staff members and decision support for patients[190], while a review of interventions to assist ethnic minorities in HICs making cancer related decisions identified support for effective communication between patients and oncologists as the foundation of most of the interventions analysed [99]. Developing a feasible effective intervention to improve the patient-oncologist interaction to share information and deliberate on treatment options would be an important pragmatic first step in the process of improving patient informed decision making.

A strength of this study is the exploratory qualitative design which elicits the unique experiences of cancer patients and staff in making cancer treatment decisions in this setting. Obtaining information from patients and oncology doctors and nurses provides a broader view of the problem of patient informed decision making from different, yet complementary perspectives. A limitation of the study was that family members and other staff members may have been interviewed to understand their roles and needs in supporting the cancer patient’s decision making, but this was beyond the scope of this study. Interviews with these role-players should be conducted in the future to fill this potential gap in the evidence. While this study was conducted at clinics in two provinces with different population demographics, locally variable contexts may prevent generalisability of these findings to other sites in South Africa or to other LMICs. The interviews were conducted in the patients’ preferred language by interviewers familiar with the patient's culture which is another strength of the study. However, while we captured the experiences of patients in the clinic who had decided on chemotherapy, we did not interview patients who had decided not to take chemotherapy, which may have provided more insight into other treatment decision-making challenges. This is another gap that needs to be addressed in future research.

5.5. Conclusion

The results of this qualitative study indicate that no single intervention will address the patients’ various information and support needs to make informed decisions. There are significant factors within the consultation, the clinic, patients’ circles of influence and within the health system which impact on cancer treatment decisions. While factors beyond the clinic are uncontrollable, it is feasible to develop a decision support intervention, with nurses or palliative staff participating in delivering DAs as a component of the intervention suite. An intervention focussed on the consultation should address the patient-oncologist communication challenges using a patient-centred communication approach.

PART 3

CHAPTER 6

"So, we need to learn basics. So, we're always hyped up about the sophisticated scientific stuff. But it's equally important to learn how to communicate with your patient. And, and basics you know."

(SA Oncologist)

Chapter 6 Integrated discussion and conclusion

This chapter integrates the findings of the studies conducted to assess cancer patient decision support needs and to identify potential intervention strategies to adequately address the need for informed cancer treatment decision making. Firstly, the key findings are summarised, after which the emerging methodological and empirical themes are discussed. The conceptual model for this thesis is re-visited based on the findings of the three studies. Implications of these findings are explored with recommendations for improving patient informed decision making. Following the first four steps of the Intervention Mapping (IM) framework, a potential intervention is developed as a solution, and the proposed steps 5 and 6 are discussed. Thereafter, the limitations of this thesis are addressed, followed by the conclusion.

6.1. Key findings

This thesis aimed to develop an intervention to support cancer patient informed treatment decision making, using the IM framework. The first step is the needs assessment required to identify the goals of the intervention, based on the decision-making problems to be addressed. Prior to assessing local decision support needs, a mixed methods systematic review was undertaken to understand the effectiveness of existing DAs in supporting patient reported decision needs. The two studies undertaken in the selected oncology clinics narrowed the focus to the needs of cancer patients within our local context. The quantitative and qualitative studies showed that patients had high information needs and wanted to be actively involved in decision making yet did not ask questions in the consultation. They reported being satisfied with their decision despite not being fully informed, while usually passively agreeing to decisions made by their doctor or family. The findings of the systematic review indicated that vulnerable persons would benefit from in-person decision-making support. Considering the time constraints in oncology consultations, other clinic staff may assist facilitating patient informed decision making.

These findings together with the findings of the review were used to develop the logic model of the problem to inform the next steps of the intervention development. Table 6.1 summarises the key findings related to the research questions and the stated hypotheses, which were either accepted or rejected.

Table 6.1: Consolidated study findings

Research Question and Hypothesis	Key Findings	Conclusion
Research question 1. • How effective are current treatment decision support interventions to assist cancer patients to make informed, values-based treatment decisions? ○ What are the reported experiences of patients making cancer treatment decisions? ○ How effectively are decision support interventions addressing the cancer patient decisional needs? **Hypothesis** Decision support interventions will improve vulnerable patient informed decision making (improved knowledge and understanding of cancer and treatments) and address patient reported decision needs.	• The search did not identify any studies from LMICs (January 2000 – September 2021) investigating the effectiveness of decision support interventions to support cancer treatment decision making. • Vulnerable persons in HICs making cancer treatment decisions expressed several decision support needs including needs for information, decision coaching and counselling. • Decisions about treatment were impacted by psychosocial needs and influenced by cultural and religious beliefs. Family, when involved, usually provided decision-making support. • Vulnerable persons preferred simple, concise DAs with in-person discussions about their treatment options. • For vulnerable persons, DAs were more effective in increasing knowledge about cancer and treatment if used with a team member, and DAs designed to be used in a consultation with a doctor were effective in increasing patient participation in decision making.	**Based on the findings the hypothesis that interventions improve vulnerable patient informed treatment decision making is accepted, however interventions are more effective if used with in-person support.** • Decision support for vulnerable persons may include concise, simple paper-based DAs. Additionally, in-person support will be required to clarify understanding and to provide decision coaching and counselling. • Developing a cancer treatment DA for vulnerable persons requires consultation with clinical and social science experts and must include participation by the end-users of the DA, being the oncology staff and patients.

Research question 2. • What is the health literacy of the patients attending the oncology clinics at three academic hospitals in South Africa, and what are the sociodemographic factors associated with adequate health literacy? • What is the oncology patient reported information needs, decision control preferences, and levels of therapeutic alliance? **Hypotheses**. Patients attending the oncology clinics will have low health literacy, will have unmet information needs, will prefer a shared or passive decision-making role, and report high levels of respect for and trust in doctors.	• Most patients attending the oncology clinics had marginal health literacy, which was only associated with education and wealth, and not age, employment, language spoken or clinic site. • Patients preferred an active decision role, yet had high information needs regarding their diagnosis, stage, treatment and outcomes. • Patients' high information need did not correlate with their reported levels of understanding information doctors shared and comfort asking questions in the consultation. They reported high levels of trust in and respect for the doctors. • Despite their high information needs, patients reported satisfaction with their decision.	**Based on the findings the hypothesis that South African cancer patients have low HL is rejected, however their HL is marginal. The hypothesis that patients have high information needs and have high levels of trust in and respect for doctors is accepted, however the hypothesis that patients prefer passive or shared decision roles is rejected.** • Further investigation is required to understand the gap between patient reported information needs and their reported understanding of information and comfort asking questions in the consultation. • Decision support interventions which provide information in understandable formats for patients with marginal HL and which enhance communication skills of both patients and doctors and may improve informed decision making.
Research question 3.	• Patients have variable knowledge or understanding of cancer and treatments, rarely ask questions in the	**The hypothesis regarding patient cancer and treatment knowledge and discussion with**

• What is the patient reported knowledge of cancer and treatments, and what are the patients’ experiences of making treatment decisions, including barriers and facilitators to making informed decisions? • What are the perceptions of oncology doctors and nurses of cancer patient decision-making experiences, including barriers to and facilitators of patient informed cancer treatment decision making? **Hypothesis.** Patients will have little knowledge or understanding of cancer and treatments and have little discussion with the doctors about their cancer and treatments.	consultation and do not routinely search for information, but rely on family, community and other patients for information and support. • Besides patient related factors and their emotional turmoil, several situational factors such as family responsibility, social circumstances, cultural, religious or community beliefs impact on patient treatment decisions. • Families can be supportive in decision making and assist understanding in consultations, however if inadequately informed, may contribute to decision conflict. • Nurses play a vital role in providing information and supporting patients with counselling and decision coaching. • Palliative care teams make invaluable contributions to patient supported treatment decision making. • Availability of health system resources at all levels, but most significantly in the oncology clinics, impact on support accessible for patients to make informed treatment decisions.	**doctors; and oncology staff reported barriers to informed decision making is accepted.** • An intervention to support informed decision making needs to be flexible enough to address different needs of different people in different situations. • Improving interactive decision-making skills of the patient and the oncology teams will positively impact treatment decisions based on clinical, patient-related and situational factors. • With limited consultation time for doctor-patient discussion, an intervention should consider utilising other staff members to support patients’ decision making.

6.2. Emerging themes

6.2.1. Methodological themes

Given the complex nature of cancer treatment decisions and the potentially multiple factors impacting on informed decision making, it was decided that a mixed methods approach would provide the necessary breadth and depth of information to understand the unique challenges faced by South African patients making cancer treatment decisions. The strengths and challenges of the methods from my experience and learning are summarised in Table 6.2.

Table 6.2: Summary of strengths and challenges associated with the methods used in this study

	Mixed methods systematic review	**Quantitative study**	**Qualitative study**
Strengths	• The mixed methods review was valuable to assess not only effectiveness of DESIs but also to understand if and how they addressed patient-reported decision needs. • Because of limited publications from LMICs, focussing on the needs of vulnerable populations, allowed for a potentially closer alignment with the needs of patients in our SA context. • The findings of the mixed methods review contributed to my overall understanding of the problem and contributed to the development of the questionnaires for the qualitative studies.	• The quantitative study allowed for the objective measurement of patient HL, DCP and the therapeutic relationship elements in a broader sample of patients. • With the larger sample sizes, the findings are more generalisable to the population within that context. • Quantitative data may be analysed statistically for associations of independent variables with outcome variables to determine with accuracy whether the hypotheses are true for the population sampled.	• Qualitative studies are useful to explore the depth of experiences of participants and allow for understanding of their attributed meaning to these experiences. • Qualitative studies enable one to explore the context, environment and culture influencing their attributed meaning to their experiences. • It was also a flexible methodology to allow for an exploration of unexpected phenomena emerging from the interview in more detail, and to adjust the line of enquiry in response to the participant answers. • The qualitative data complemented the quantitative data by confirming expected findings and elaborating on the controversial findings in more detail and generate new ideas or theory.

Challenges	• The review process was time-consuming and labour-intensive, requiring meticulous attention to detail, and took longer than was naively anticipated. • The review generated large amounts of data which required a lengthy process to assess, categorise and effectively integrate into a common synthesis. • No publications of studies from LMICs were found, although due to logistical reasons, only English language papers were included, meaning that some papers have been missed. This contributed to re-focussing the review on vulnerable populations in HICs.	• Quantitative studies do not allow for deeper understanding of phenomena of interest because of the limited responses to survey questions. • There is a risk of bias if patients respond in a way to please the interviewer, or misunderstanding the questions resulting in unexpected results, due to the limited responses to survey questions. • Even though surveys may be validated for the population, there is a risk of local misinterpretations which require prior understandability and reliability testing.	• Research data collection may be impacted by researcher/interviewer bias which requires self-reflection and awareness to minimise the risk. • Data analysis is time consuming, especially with large amounts of data. • Qualitative data analysis requires at least 2 people to interpret the findings to ensure credibility. • Qualitative research findings may be specific to the context in which the study was conducted limiting transferability to different contexts.

6.2.2. Empirical themes

A key learning of this set of studies was that patients were challenged through numerous decision support needs when making treatment decisions, and that this process was compounded by two critical components:

i. Patient language and cultural communication discordance with oncologists coupled with lack of agency to engage in a discussion about their cancer and treatment options.
ii. Providers not having the skills and time to effectively engage with patients to encourage their participation in treatment decision making.

The findings of the three studies for this thesis ascertained that cultural beliefs and practices influenced South African patients' and vulnerable HIC-setting patients' treatment decisions and patient adherence to an agreed upon treatment. Additionally, from the qualitative study it emerged that cultural beliefs influenced communication norms for some patients adding a layer of complexity to known challenges of language barriers between patient and oncologist. This challenge of cultural communication norms was also a finding of some qualitative studies included in the systematic review. South African studies and a UK study amongst ethnic minority men have reported cultural factors influencing patients' treatment decision-making experiences [6], [91], [246]. However, cultural communication norms were not discussed in these studies, possibly because the focus of the South African study was a broad overview of cancer-related challenges, and the UK study was conducted amongst men who may have been more acculturated in terms of communication norms in the UK. The authors of both studies recommended culturally sensitive, person-centred communication to support decision making. To support a patient's informed treatment decision, besides knowing the patients personal and social circumstances the oncologist needs to be aware of cultural or religious beliefs that impact on the decision-making process [247].

From the qualitative study, while patients did not specifically raise the issue of language barriers in communication, their reported challenges understanding information may be related to such barriers. However, oncology staff reported both language and cultural communication barriers in the consultation. South African doctors and nurses also identified a lack of communication training as an obstacle to meaningful patient engagement, especially when having difficult conversations with patients and family or managing conflict arising in the consultations. Communication difficulties have been found to impede oncology SDM practice [248], while a lack of communication skills impacts on effective discussions with low HL patients in Europe [45]. **Communication skills training for healthcare providers were found to be the most likely intervention to improve patient participation in healthcare decisions in non-Western countries** [101]**.**

Oncologists in our studies also identified the lack of time in the consultation as a significant barrier to effective patient-centred communication to ensure informed treatment decisions. Patients' families attending the consultation could facilitate communication or add to the time burden through family conflict with the patient and/or the doctor. The lack of time as a barrier is echoed in a mixed methods study of patient informed consent in KZN, South Africa [4], [89]. Limited resources and understaffing at health facilities exacerbates this problem [6].

A locally relevant intervention for the South African oncology context should include patient centred communication training for oncologists. Besides generic components of communication as indicated in the conceptual framework, South African oncologists should be trained to be aware of cultural differences in communication and treatment preferences, recognise when an interpreter is needed and acquire organisational skills to effectively manage the time available in the consultation to support a patient to make an informed treatment decision. Implications of these empirical themes are discussed further in section 6.4 (Implications of findings).

6.3. Conceptual framework additions based on review and empirical study findings

The patient and doctor elements of the conceptual framework proposed in chapter 1 is validated by the evidence from the thesis studies. The evidence confirms that **patient** personal and demographic factors and the **doctor's** personal and professional factors influenced the communication in the consultation. The doctor's assessment of the patient's cancer stage, co-morbidities and suitable treatments impacted on available treatment options discussed, while the patient's illness severity impacted on their participation in decision making. Outside the consultation**, social, cultural, religious and environmental factors** were confirmed to affect patient choices, while **health system factors** at each level ranging from the national to the oncology clinic level impacted on informed decision making.

However, **for the South African limited resource setting, my thesis findings do suggest a need for family and additional provider augmentations to the conceptual framework to inform future interventions to enable optimum patient involvement in their treatment decision making**. I discuss these below before integrating the additions in an augmented framework provided in Fig 1. With respect to the patient-doctor consultation, patient health literacy and agency undoubtedly affected their participation in the decision-making process while inadequate patient-centred communication by the doctor exacerbated the limited information exchange and mutual deliberation of choices. The evidence from the mixed methods systematic review indicated that DAs administered in the consultation were more likely to increase the level of vulnerable patient participation (SDM). This was achieved by impacting on both patient decision-making functions and oncologists' communication functions to stimulate information exchange and deliberation of options available. Engaged patients may feel more empowered to take responsibility for deliberating choices, even if they finally prefer the doctor to decide. However, many DAs did not include the social determinants of health which influence vulnerable cancer patient decisions and adherence to treatments. Furthermore, most DAs do not address the **patient's roles and responsibilities in the family and community,** the socio-economic challenges impacting on adherence to treatment, nor the family role in treatment decision making. These were important considerations for both vulnerable patients in HICs and South African patients making treatment decisions and should be included in a treatment DA.

Additional influential factors on decision making have emerged from the qualitative study, which are not represented in the original framework. For South African cancer patients, personal factors such as education and wealth impact on health literacy which is essential for patients to understand their illness and treatments and to critically appraise the risks and benefits of treatment, to make an informed decision. Despite reporting high levels of comfort asking questions in the consultation, patients still had high information needs. These incongruent results raise the question of whether the patients did ask questions, whether they were given sufficient information in a format that they understood, or whether they had poor recall of the details of the discussions. It also became clear that **family played a vital role in either supporting** or interfering with patient decision making. South African patients expressed the wish to play **an active role** in their treatment decision making. Even for those who prefer a passive role, being informed is an ethical and moral imperative, which places a lot of responsibility on the oncologist's communication skills, to provide such information in an accessible way to patients, and to find the available consultation time within the context of limited available resources.

From discussions with the oncology providers and support staff, health system resources and consultation time availability were confirmed to negatively impacted on treatment decision discussions with patients. This constraint was mitigated by nurses and palliative care teams playing a significant supporting role in informing patients on treatment options as well as providing them with emotional support.

These thesis findings of additional family, nurse and palliative care provider information and psychosocial and spiritual support factors impacting on treatment decision making are included in a revised conceptual framework (Figure 6.1). In developing a decision intervention to improve patient informed decision making, the roles of family and nurses should be considered in addition to those of the patient and oncologist.

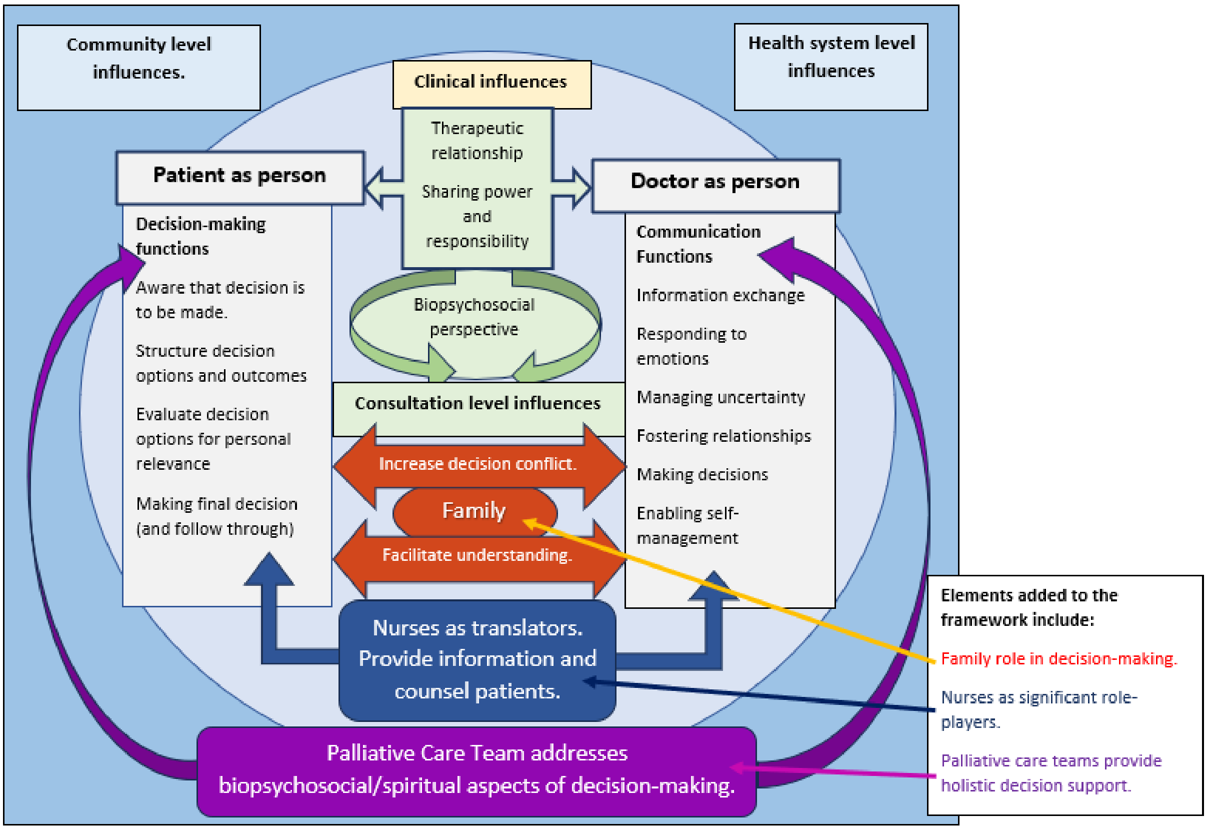


Figure 6.1: Updated conceptual framework of informed cancer treatment decision making

6.4. Implications of findings

The implications of the evidence from the three studies are considered from international and national department of health perspectives, to provincial, district and oncology clinic perspectives and to the patient and family level ofninfluence, with recommendations to ensure the successful development and implementation of a decision support intervention.

- At an international level, this thesis has drawn attention to the lack of publications of the development and implementation of decision support interventions in LMICs, where constrained resources impact on the timely diagnosis, treatment of cancers and communication with patients. Treatment choices may have significant impact on the patient and family's quality of life, not only physically but also emotionally, socially spiritually and economically. Under such circumstances, it would be important that a truly informed decision is made, to prevent unnecessary suffering. Further research to develop locally relevant decision support interventions based on the Implementation Mapping framework (whose rationale for use is provided in chapter 2) is required to assist patients to make informed decisions.
- Nationally, the gaps in addressing cancer patients' information and decisional needs indicate the need for an intervention to fulfil at the very least the requirements for patient's informed consent outlined in the South African National Health Act and expanded on in the HPCSA ethical guidelines [106], [107]. Yet there are additional barriers to patients making informed decisions involving the moral obligation to provide patients a choice of how they wish to make decisions, and inevitably what decisions they wish to make about their cancer treatment [249]. The inclusion of national department of health stakeholders in the process of development of a decision support intervention is essential to ensure their co-development and support for the widespread implementation of the decision support interventions at relevant cancer health facilities.
- From a provincial and district perspective, the reports of patients not knowing their diagnosis, or with very little cancer information on arrival at the oncology clinic indicates a failure of effective communication at the referral facilities or clinics. Given that cancer treatment decision making requires timely information from the time of diagnosis to the treatment consultation, an intervention to improve communication

at referral sites is required. This may include communication skills training, improved interaction and co-ordination of care between referring health facilities and the oncology clinic, and the use of visual aids to improve patient knowledge and understanding of their cancer. Engagement with relevant provincial, district and facility-level department of health stakeholders is required to identify opportunities to implement an intervention at referring centres to improve cancer communication with patients and to improve communication with oncologists at tertiary hospitals..

- At the tertiary hospital level, resource constraints at oncology clinics impact on the provision of adequate understandable information and support for patients to make informed treatment decisions. To meet the NHA minimum requirements of informed decision making, it is essential to engage all relevant management, clinical and social services staff to co-create an intervention which will provide the necessary consultation time with perhaps task shifting to support staff providers to support patient informed treatment decision making.
- For individual patients, health literacy should be considered an asset which may be incrementally improved though each interaction with health care providers. Besides improving patients' understanding of health information, decision coaching with appropriate decision aids in a consultation engagement with provider representatives should enable patients to critically appraise information and engage with healthcare teams to make the best decisions for their care. With limited consultation time for clinician information sharing and counselling, a palliative care team may support patients with decision coaching and counselling, to maximise the time available in the consultation to focus on the informed decision itself.
- Families are an important source of information and support for most patients. With patient consent, families should be included in the process of information sharing and decision making to ensure continuing support for adherence to treatment.
- In summary, to ensure an effective decision support intervention which is feasible, acceptable and likely to be implemented, it is important to include all relevant stakeholders in the development process. However, it is vital to include patients and patient advocates as members of the development team.

6.5. Developing a decision support intervention

This section, informed by study findings, describes the first four steps of the IM process for developing the decision support intervention (Figure 6.2). The first step is to produce a logic model of the problem and needs to be addressed and identify the program goals. Step 2 produces matrices of change objectives to address the determinants of behaviour change and achieve the program goals. Step 3 requires identifying behaviour change strategies, supported by relevant theoretical models. Step 4 is the development of the program to achieve the aim of patient informed treatment decision making.

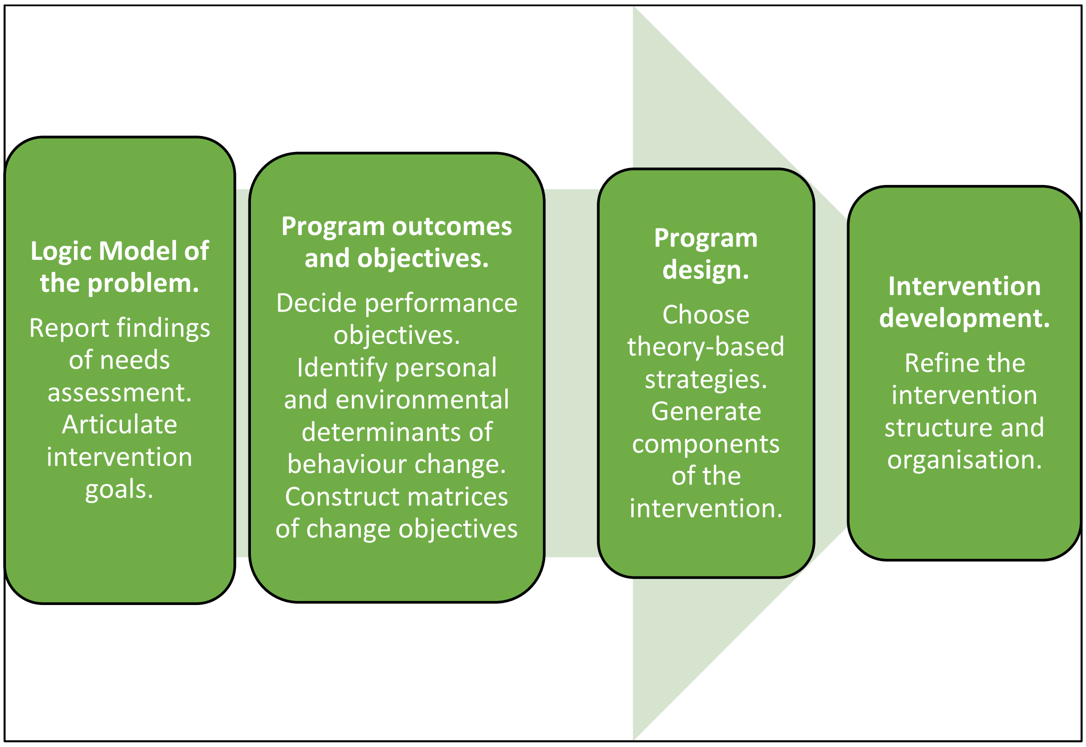


Figure 6.2: Flow diagram indicating the first four steps of the IM process

6.5.1 Step 1. Logic model of the problem and program goals

The integrated evidence from the mixed methods systematic review, the quantitative and qualitative studies as summarised in Figure 6.3 was used to construct a logic model of the informed decision-making problem (Figure 6.4).

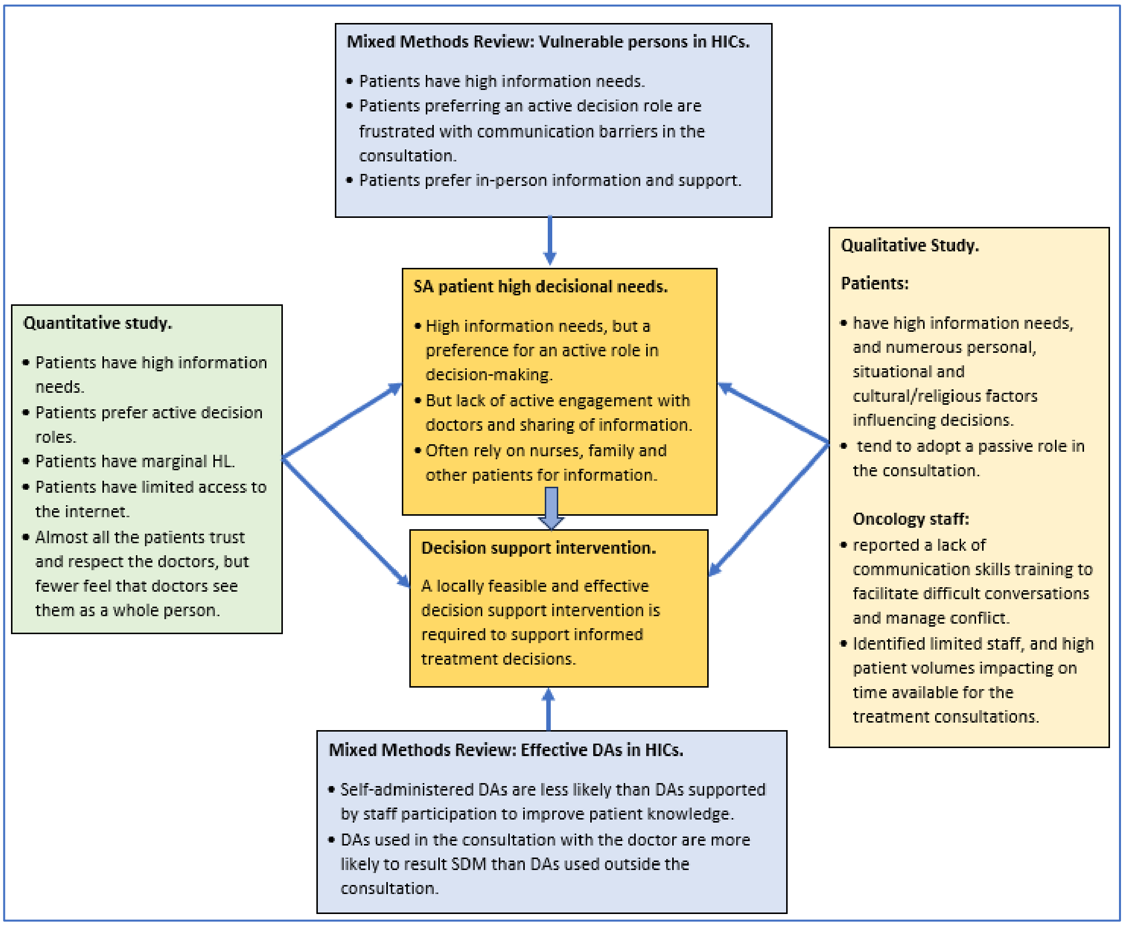


Figure 6.3: Integration of themes based on the empirical findings

Taking into account the empirical findings in this model, the behaviour objectives of the intervention were determined as follows:

1. **Improve the patient’s cancer and treatment understanding.**
2. **Improve the patients’ active role in decision making and articulation of treatment preferences.**
3. **Improve the oncologist’s communication skills.**
4. **Provide an environment to improve the patient’s understanding and communication of their disease and treatment options.**

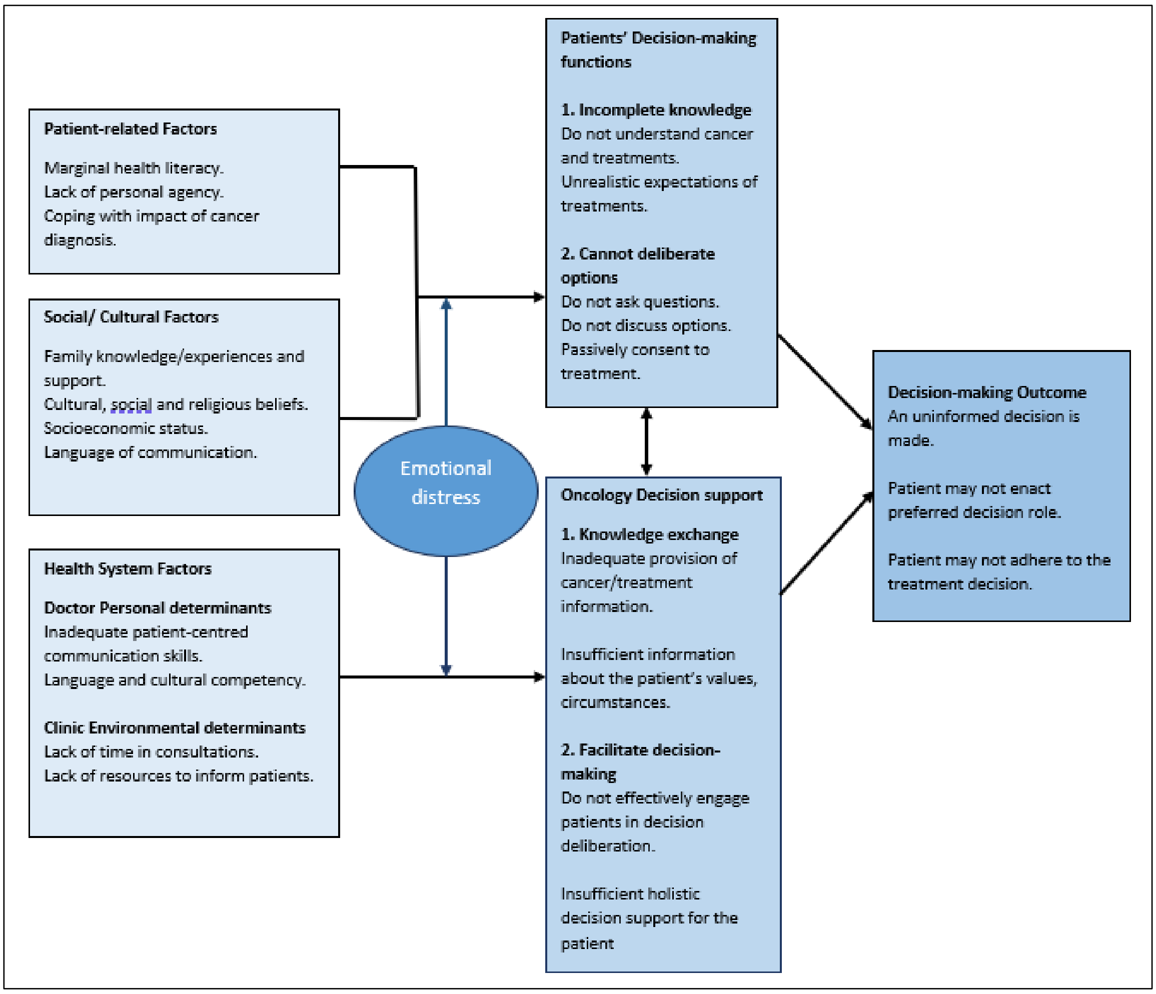


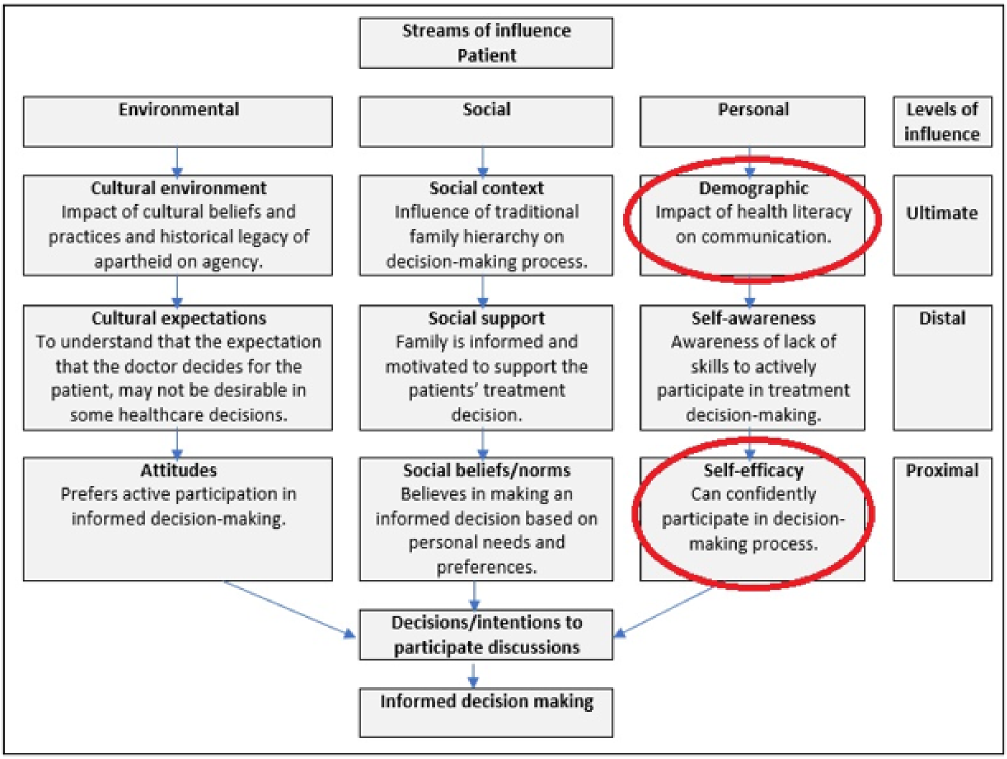
Figure 6.4: Logic model of the problem of patient informed decision making

6.5.2 Step 2. Matrices of change objectives

Personal determinants of behaviour change are potentially modifiable psychological variables which are causal antecedents to behaviour, while external social, cultural and environmental factors influence behaviour at different levels. The Theory of Triadic Influence (TTI) is an integrated meta-theoretical framework incorporating proximal, distal and ultimately exogenous levels of psychological, sociological and environmental influences on personal decisions to engage in health-related behaviour (HRB) [250]. The theory suggests that behaviour change interventions should focus not only the highly predictive proximal predictors of behaviour but also on the more distal less immediate causes, and ultimate exogenous influences on HRB.

The TTI was adapted to map the personal, social and environmental influences on patient informed treatment decision-making behaviours (Figure 6.5).

For this thesis, the focus of the intervention was on the influence of the patient's health literacy and self-efficacy on making informed treatment decisions (Highlighted in red in Figure 6.5). Because the patient's decision-making functions are dependent on their relationship with the oncologist, the intervention will include behaviour changes for the oncologist to support the patient to improve their HL and self-efficacy to make an informed treatment decision.



(This thesis focusses on the determinants that are highlighted in red)

Figure 6.5: Patient related behaviour change determinants, adapted from the TTI

[250]

The personal determinants of behaviour change to be addressed for the patient's (health literacy and self-efficacy) and the oncologist's performance objectives are provided in Tables 6.3, 6.4 and 6.5 respectively. The environmental determinants of change (resources and services) within the oncology clinic which are applicable for both patient and provider groups are provided in Table 6. The key performance objectives for patients were: i) Knows about their cancer and treatment intent, ii) Knows about risks and benefits of treatment options, iii) Knows their decision role preference and iv) Articulates their treatment preference. For the oncologists the performance objectives were: i) Can explain cancer and treatment information effectively, and ii) Can manage conflict and time constraints. The environmental performance objectives for both patients and providers are: i) Patient understands disease, treatments and treatment options and ii) Doctors convey understandable information efficiently and manage conflict.

The first two behavioural objectives are linked to patient behaviour changes required (Tables 6.3 and 6.4), and the third behavioural objective is linked to the oncologist's behaviour change required (Table 6.5) to facilitate patient's informed treatment decision making. The final behavioural objective is linked to the changes required in the clinic environment to facilitate both the patient and oncologist's behaviour changes (Table 6.6).

Table 6.3: Behavioural objective – Improve the patient's cancer and treatment understanding

Personal determinants - Patient		
Performance objectives.	**Determinant: Health Literacy**	**Determinant: Self-efficacy**
Knows about their cancer and treatment intent.	Understands the importance of knowing their cancer and its prognosis.	Can access and understand reliable cancer information.
Knows about risks and benefits of treatment options.	Understands the importance of knowing the treatment options, risks and benefits.	Can access and understand information about the treatment options and side-effects.

Table 6.4: Behavioural objective – Improve patient's role in decision making and articulation of treatment preferences

Personal determinants - patient		
Performance objective	**Determinant: Health Literacy**	**Determinant: Self-efficacy**
Knows their decision role preference.	Understands that they have a choice of decision role.	Can articulate their preferred decision role.
Articulates their treatment preference.	Understands the treatment options.	Can articulate their preferred option.

Table 6.5: Behavioural objective – Improve oncologist's communication skills

Personal determinants - oncologist		
Performance objective	**Communication Literacy**	**Self-efficacy**
Can explain cancer and treatment information effectively	Understands the need to communicate understandable cancer and treatment information.	Oncologists can communicate understandable cancer and treatment information.
Can manage conflict and time constraints	Understand the need for efficient time management. Understands the need to recognise and manage conflict.	Oncologists can convey understandable information timeously. Can recognise and efficiently manage conflict.

Table 6.6: Behavioural objective – Improve understanding of and communication of disease and treatment options

External determinants – patient and oncologist	
Performance objective	**Resources and services**
Patient understands disease, treatments and treatment options	Availability of decision aids and support staff to the patient.
Doctors convey understandable information efficiently and manage conflict	Availability of communication materials and support staff.

6.5.3 Step 3. Selecting theory-based strategies to achieve the program objectives

The next step in the IM process is to develop theory-based strategies to achieve the behavioural and environmental change objectives. For this program, intervention functions of the theoretical domains framework (TDF) [251], [252], [253], and behaviour change techniques (BCTs) from the Taxonomy of BCTs [254], [255] were selected to provide the evidence-based strategies for the implementation of the program. Figure 6.6 shows the TDF domains, Intervention functions and examples of BCTs important for this intervention. The broadly categorised intervention functions are the strategies through which an intervention can change behaviour and the BCTs are the active implementable components of each function.

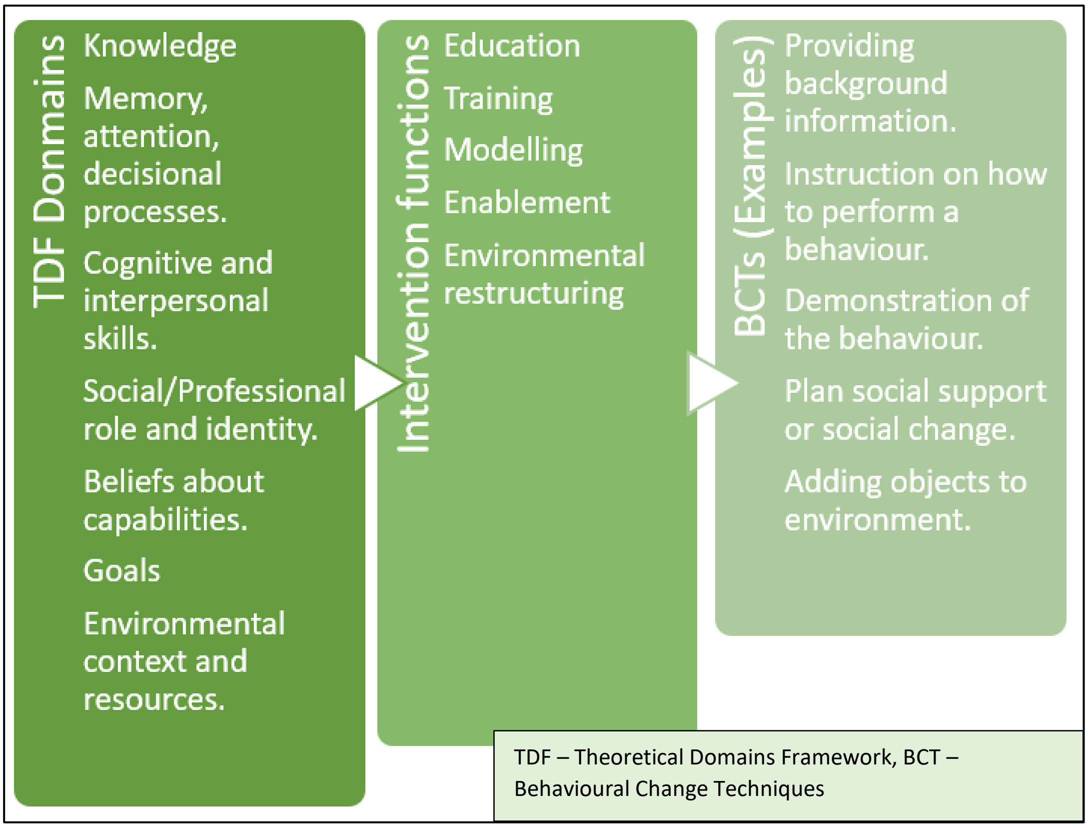


Figure 6.6: Links between TDF domains, intervention functions and BCTs

A secondary analysis of a 2018 Cochrane review of interventions to improve SDM (across several clinical domains, not restricted to cancer) by health professionals identified intervention functions and BCTs most associated with positive effects of the intervention on the intended outcomes [256]. The most effective combination of intervention functions identified included **Education + Training + Modelling (i.e., providing an example for people to aspire to or imitate) + Enablement.** The most effective identified BCTs appropriate for this intervention included:

- Instruction on how to perform the behaviour.
- Demonstration of the behaviour.
- Feedback on behaviour.

The authors recommended four additional BCTs unique to interventions intended to improve SDM [256]. These included 1) **providing background information** (about the diagnosis and treatment), 2) **tailoring information to the individual**, 3) **mental preparation**

for the decision making such as values clarifying exercises for treatment options, and 4) **experience sharing and learning** from others' experiences.

The intervention functions and BCTs related to the change objectives for this thesis intervention are provided in Table 6.7.

Table 6.7: Intervention functions and BCTs to achieve the change objectives

	Intervention Function	**Behaviour change technique**
Patient		
Health Literacy	Education	• Providing background information (about the diagnosis and treatment) • Tailoring to patient demographics. • Experience sharing and learning from others' experiences. • Provide information about consequences (TPB).
Self-efficacy	Training Enablement Modelling	• Instruction on how to perform a behaviour. (SCT) • Demonstration of the behaviour. (SCT) • Mental preparation for the decision making
Oncologist		
Communication Literacy	Education	• Information about social and environmental consequences (TPB)
Self-efficacy	Training Enablement Modelling	• Instruction on how to perform a behaviour. (SCT) • Demonstration of the behaviour. (SCT) • Feedback on behaviour. • Self-monitoring of behaviour.
Environment	Environmental restructuring	• Plan social support or social change. (Social support theories) • Adding objects to environment.

Acronyms: TPB = Theory of Planned behaviour, SCT = Social cognitive theory.

6.5.4. Step 4. Program Development

Step 4 of the process is to refine the intervention structure and organisation. Figure 6.7 displays the interaction of the intervention components to achieve patient activation and informed treatment decision making.

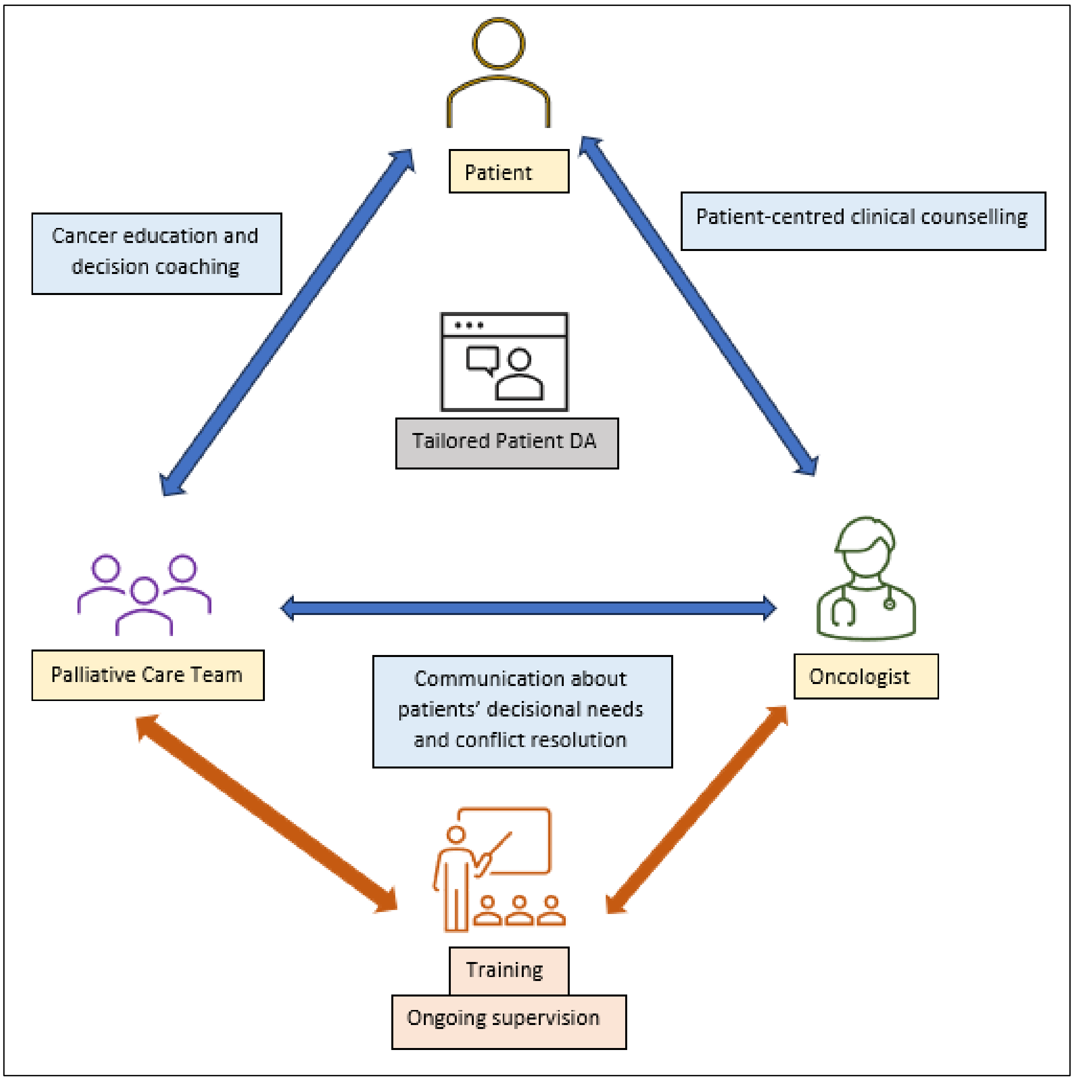


Figure 6.7: Interaction of the intervention components to achieve patient informed treatment decision making

Evidence to support the intervention structure.

The Ottawa Decision Support Framework (ODSF) identifies three intervention modalities [257].

- Clinical counselling provided by a suitably qualified staff member to inform patients of their diagnosis, and treatment options, provide counselling as required, and to guide decision making.
- A PtDA is a tool to provide information about cancer and treatments and may guide clarification of patient values impacting on decisions and to aid their treatment decision making. PtDA formats are variable: online, paper-based, video or audio. A PtDA does not replace clinical counselling.
- Decision coaching is provided by a suitably trained team member to foster a patient’s decision-making skills.

It is clear from the needs assessment that doctors have limited time to spend with patients and that nurses, social workers and palliative care teams already assist with counselling and coaching of patients. While the doctor remains responsible for sharing of the diagnosis and making the decision with the patient, it is possible that palliative care teams with language and culture-concordant, multidisciplinary skills could be trained to assist with decision support using a tailored PtDA to prepare for the decision consultation with the doctor. The doctor may use the same PtDA with patient-centred communication to support an informed treatment decision. Because of the possibility that team members may not always agree on treatment recommendations for patients, regular team meetings to discuss patient decision needs and treatment protocols are vital to ensure that patients do not receive conflicting information when making treatment decisions.

The components of the intervention will include:

i. Training of oncologists in patient-centred communication, conflict management and time management (including clinic restructuring to improve efficiency).
ii. Training of palliative care teams in cancer and treatments and coaching techniques.
iii. Development and testing of a tailored patient decision aid.
iv. Ongoing supervision support for palliative care teams and doctors.

Stakeholder workshop

To complete the creation of the patient informed decision-making intervention, a meeting with stakeholders from the Department of Health, hospital management, oncology clinic staff, palliative care staff, social services and most importantly patient representatives, cancer survivors and cancer NGOs will be convened to discuss the findings of the needs analysis, the theories underpinning the change objectives, and to refine the intervention components and tools, based on their input. The intervention protocols, tools and materials will be developed by a smaller committee selected from the stakeholder group and will provide feedback to the larger group on the final intervention package for review.

6.5.5. Steps 5 and 6. Feasibility study and effectiveness trial.

Once the intervention protocol and implementation materials and tools have been developed, a feasibility study **(Step 5)** will be conducted to test the feasibility and acceptability of implementation processes and materials. Using focus group discussions and in-depth interviews, patient and healthcare provider perceptions and experiences of each stage of the intervention will be explored, with suggestions for addressing any challenges to implementation. These outcomes will be discussed with the development committee to revise components to mitigate any challenges identified.

Once the intervention has been refined and feasibility and acceptability issues have been addressed, a pilot trial protocol will be developed to evaluate the efficacy of the intervention **(Step 6).** The trial will be implemented at two study sites (one intervention site and one control site). Training of staff according to the intervention package will be conducted. Patients with cancer attending the oncology clinic for their first visit will be invited to participate. Patients at the control site will be offered usual standard of care. Patients at the intervention site will be offered the intervention (Figure 6.8).

The primary outcome will be 1) Making an informed decision using a validated patient knowledge assessment (Baseline, immediately post-decision-making consultation and at 6 weeks).

Secondary outcome measuring the decision-making process include:

1. Decision role preference (baseline)
2. Actual decision role (post-consultation)
3. Therapeutic alliance (post-consultation) decision-making role (post consultation)
4. Satisfaction with decision-making process post-consultation and at 6 weeks)
5. Adherence to treatment (at 6 weeks and 12 weeks)

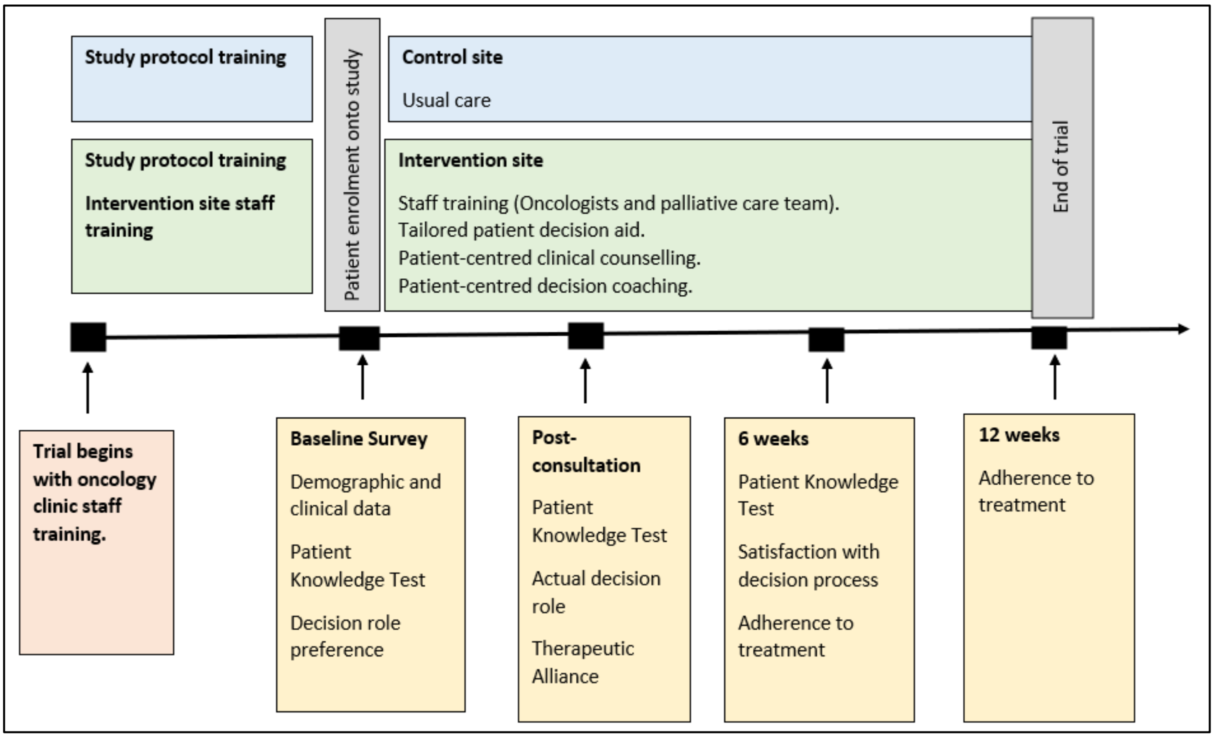


Figure 6.8: Proposed effectiveness trial design

6.6 Limitations of the thesis

This section reflects on limitations of the PhD as a whole. While the studies examined the challenges patients (and providers) faced making informed treatment decisions and explored facilitators of informed decisions, the data was collected from patients who had agreed to chemotherapy and who were later actively receiving treatment. Logistical considerations precluded interviewing patients who had decided against chemotherapy, to understand their experiences and the reasons for their choice. This would be an important component to capture in terms of reasons patients declined treatment or chose to discontinue treatment. While the studies were conducted in three separate oncology clinics, in two provinces in South Africa, inter-provincial and regional differences in factors impacting on treatment decision making may differ and findings of these studies may not be transferable to other oncology clinics. The scope of the thesis did not allow for testing and reporting the intervention package, which will be the next steps.

6.7. Conclusion

Using the intervention mapping approach, it is possible to develop a decision support intervention based on local evidence and sound theoretical frameworks. This thesis is unique in that it proposes a combination of behaviour change techniques (based on empirical evidence) and a patient DA development framework to provide a holistic approach to decision support for patient cancer treatment decision making. This thesis has demonstrated the impact of the siloed approach to healthcare that impedes patient-centred treatment. The foundation of a high-quality healthcare decision is the combination of the best clinical evidence and a patient-centred approach. In South Africa, it is vital to fully integrate culturally sensitive patient-centred communication training into the clinical curricula of all healthcare disciplines. Within the healthcare system, culturally appropriate psychosocial care must be integrated with clinical care, to achieve equitable quality healthcare delivery.

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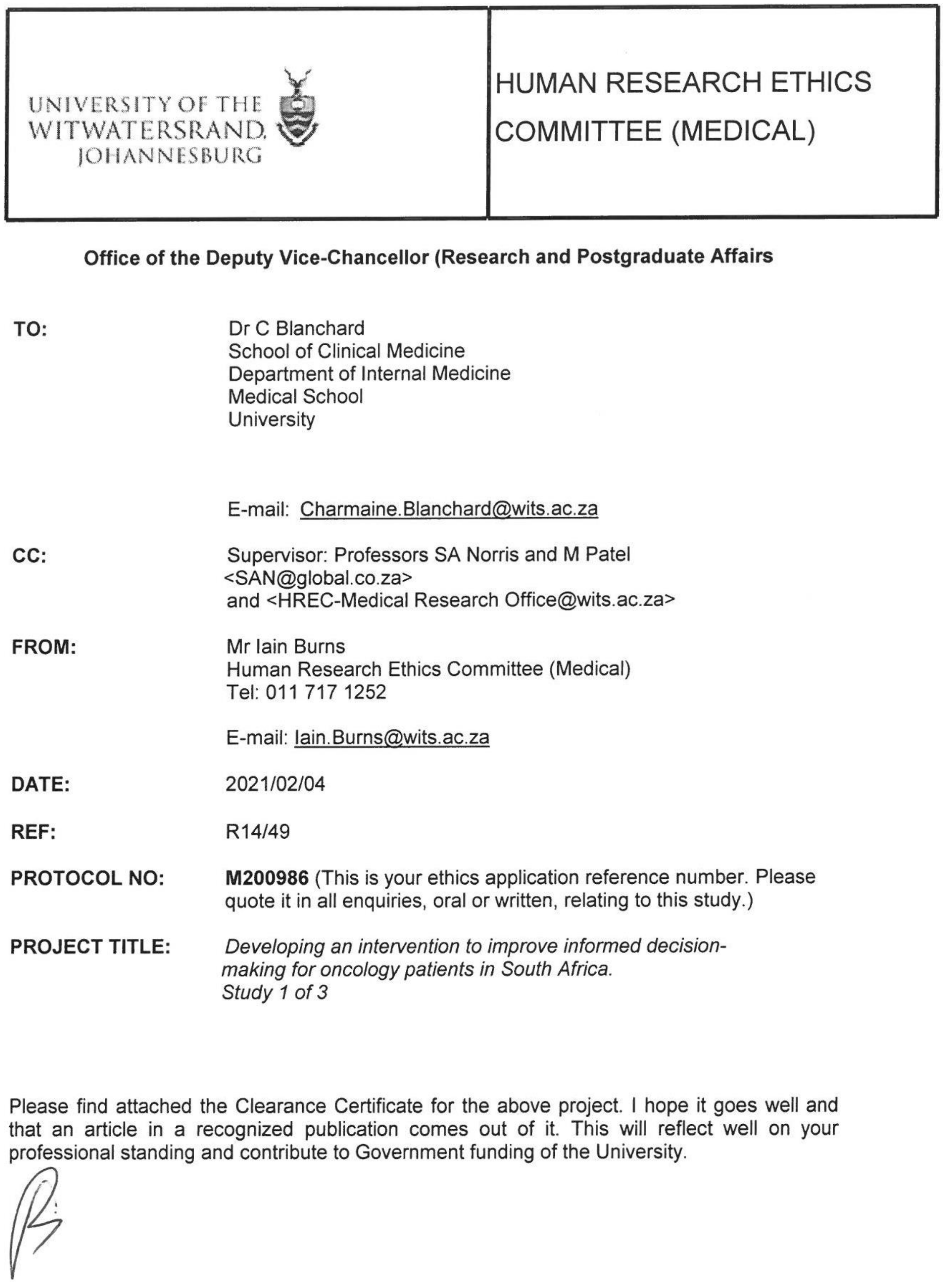
Appendices

APPENDIX A: HREC Clearance Certificate M200986



UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

HUMAN RESEARCH ETHICS
COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research and Postgraduate Affairs

TO:	Dr C Blanchard School of Clinical Medicine Department of Internal Medicine Medical School University E-mail: Charmaine.Blanchard@wits.ac.za
CC:	Supervisor: Professors SA Norris and M Patel <SAN@global.co.za> and <HREC-Medical Research Office@wits.ac.za>
FROM:	Mr Iain Burns Human Research Ethics Committee (Medical) Tel: 011 717 1252 E-mail: Iain.Burns@wits.ac.za
DATE:	2021/02/04
REF:	R14/49
PROTOCOL NO:	**M200986** (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)
PROJECT TITLE:	*Developing an intervention to improve informed decision-making for oncology patients in South Africa.* *Study 1 of 3*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

R49 Dr C Blanchard

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200986

NAME: **(Principal Investigator)**	Dr C Blanchard
DEPARTMENT:	School of Clinical Medicine Department of Internal Medicine Medical School University
PROJECT TITLE:	*Developing an intervention to improve informed decision-making for oncology patients in South Africa.* *Study 1 of 3*
DATE CONSIDERED:	2020/10/02
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professors SA Norris and M Patel
APPROVED BY:	CBPenny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2021/02/04

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

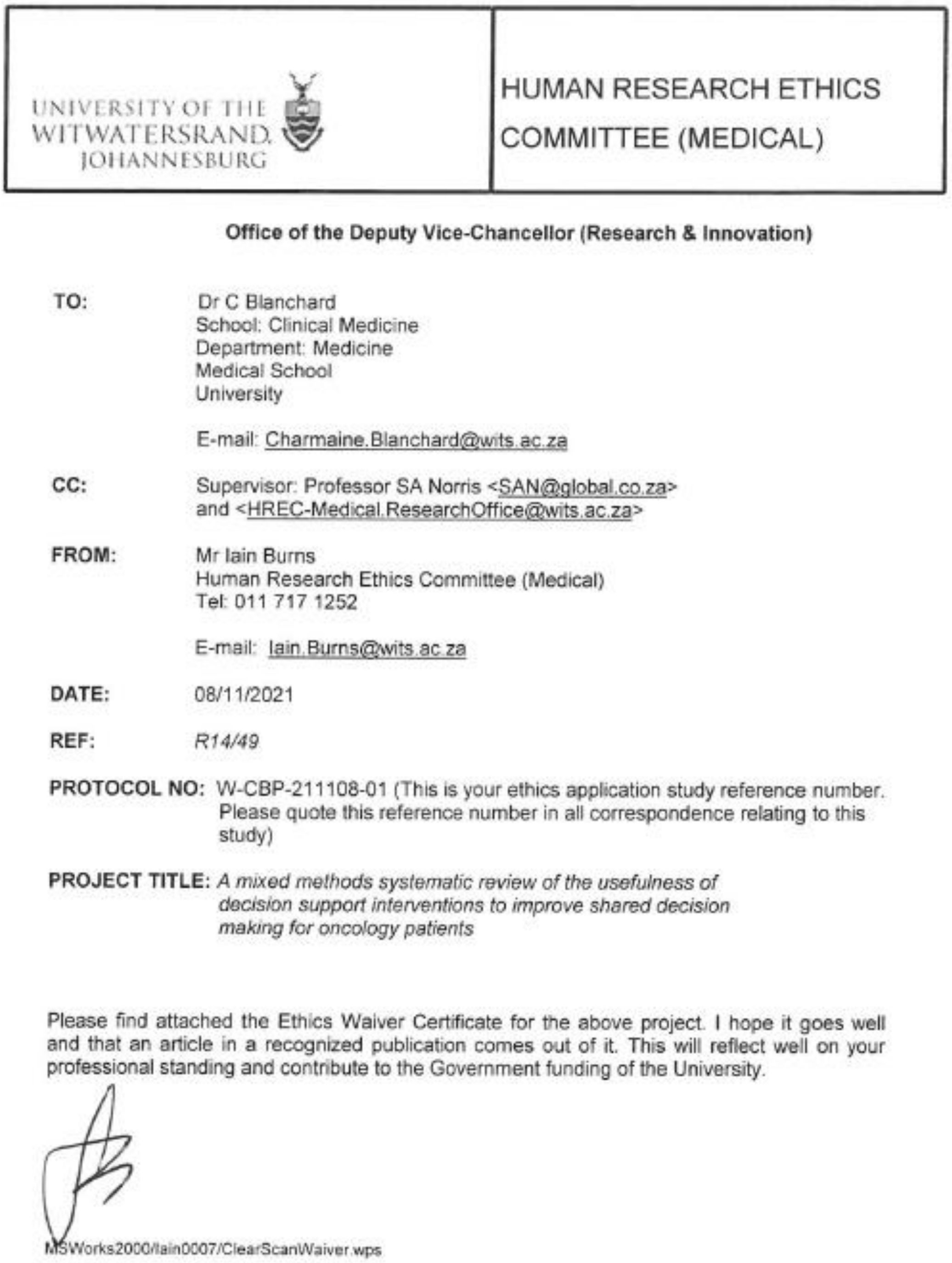
To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **«Missing mail merge field»** and therefore reports and re-certification will be due in the month of **«Missing mail merge field»** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

Date

APPENDIX B: Ethics waiver W-CBP-211108-01



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HUMAN RESEARCH ETHICS
COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research & Innovation)

TO: Dr C Blanchard
School: Clinical Medicine
Department: Medicine
Medical School
University

E-mail: Charmaine.Blanchard@wits.ac.za

CC: Supervisor: Professor SA Norris <SAN@global.co.za>
and <HREC-Medical.ResearchOffice@wits.ac.za>

FROM: Mr Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 08/11/2021

REF: *R14/49*

PROTOCOL NO: W-CBP-211108-01 (This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)

PROJECT TITLE: *A mixed methods systematic review of the usefulness of decision support interventions to improve shared decision making for oncology patients*

Please find attached the Ethics Waiver Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

MSWorks2000/Iain0007/ClearScanWaiver.wps

APPENDIX C: Paper 1. Critical Appraisal Results: Randomised Control Studies

Study ID	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Q11**	**Q12**	**Q13**	**Score**	**Percent**
AlSagheir 2020	Yes	Yes	Yes	No	No	Unsure	Unsure	Yes	Yes	Yes	Unsure	Yes	Yes	8	62%
Berry 2013	Yes	Yes	Yes	No	Yes	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11	85%
Berry 2018	Yes	Yes	Yes	No	Unsure	No	Yes	Yes	Unsure	Yes	Yes	Yes	Yes	9	69%
Cuypers 2018	Unclear	Unsure	Unsure	Unsure	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	7	54%
Diefenbach 2018	Unclear	No	Yes	No	No	Yes	Yes	Yes	Unsure	Yes	Yes	Yes	Yes	8	62%
Durand 2020	Yes	Unsure	Unsure	Yes	Unsure	Unsure	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	8	62%
Jibaja-Weiss 2011	Yes	Unsure	Yes	Unsure	Unsure	Unsure	Yes	Yes	Unsure	Yes	Unsure	No	Yes	6	46%
Wyld 2021	Yes	Unsure	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Unsure	Yes	Yes	10	77%
Yen 2020	Yes	No	Unsure	Unsure	No	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	62%

Q 1: Was true randomization used for assignment of participants to treatment groups

Q 2: Was allocation to treatment groups concealed? (Those allocating groups were blinded)

Q 3: Were treatment groups similar at the baseline? (Note for continuous variables examine means, not only p values)

Q 4: Were participants blind to treatment assignment?

Q 5: Were those delivering treatment blind to treatment assignment? (Doctors treating patients)

Q 6: Were outcomes assessors blind to treatment assignment? (Interviewers administering questionnaires)

Q 7: Were treatment groups treated identically other than the intervention of interest? (Check if other exposures may have had an effect)

Q 8: Was follow up complete and if not, were differences between groups in terms of their follow-up adequately described and analysed? (Not only numbers and proportions, also reasons and if different between groups, was it analysed?)

Q 9: Were participants analysed in the groups to which they were randomized? (Intention to treat analysis, analysed based on group and not whether intervention was used or not)

Q 10: Were outcomes measured in the same way for treatment groups? (Same instruments, timing, procedures and instructions?)

Q 11: Were outcomes measured in a reliable way? (Number of raters, training, inter-rater reliability (reported in the study itself), not validity of instruments.

Q 12: Was appropriate statistical analysis used? (Appropriate statistical tests, power analysis, effect sizes and assumptions of tests respected)

Q 13: Was the trial design appropriate (e.g., parallel, crossover, cluster, step-wedged) and any deviations from the standard RCT design accounted for in the conduct and in an analysis of the trial?

APPENDIX D: Paper 1. Critical Appraisal Results: Analytical Cross-sectional Studies

Study ID	Q 1	Q 2	Q 3	Q4	Q 5	Q 6	Q 7	Q 8	Total	percentage
Li 2021	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	7	88%

Q 1: Were the criteria for inclusion in the sample clearly defined?
Q2: Were the study subjects and the setting described in detail?
Q 3: Was the exposure measured in a valid and reliable way?
Q 4: Were objective standard criteria used for measurement of the condition?
Q 5: Were confounding factors identified?
Q 6: Were strategies to deal with the confounding factors stated?
Q 7: Were outcomes measured in a reliable way?
Q 8: Was appropriate statistical analysis used?

APPENDIX E: Paper 1. Critical Appraisal Results: Qualitative studies and qualitative results of two mixed method studies

Study ID	Q 1	Q 2	Q 3	Q 4	Q 5	Q 6	Q 7	Q 8	Q 9	Q 10	Score	percentage
Burton 2015	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	8	80%
McVea 2001	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Unsure	Yes	7	70%
Michel 2021	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	9	90%
Sheppard 2008	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	8	80%
Sheppard 2010	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	8	80%
Wong 2011	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	Yes	7	70%
Shaw, 2015	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	7	70%

* Mixed method study

Q 1. Is there congruity between the stated philosophical perspective and the research methodology?
Q 2. Is there congruity between the research methodology and the research question or objectives?
Q 3. Is there congruity between the research methodology and the methods used to collect data?
Q 4. Is there congruity between the research methodology and the representation and analysis of data?
Q 5. Is there congruity between the research methodology and the interpretation of results?
Q 6. Is there a statement locating the researcher culturally or theoretically?
Q 7. Is the influence of the researcher on the research and vice versa addressed?
Q 8. Are participants and their voices adequately represented?
Q 9. Is the research ethical according to current criteria or, for recent studies, is there evidence of ethical approval by an appropriate body?
Q 10. Do the conclusions drawn in the research report flow from the analysis or interpretation of the data?

APPENDIX F: Paper 1. Synthesised findings, categories and original study findings

Synthesised finding 1. Patients differed in terms of information needs and accessing sources of information, desired content and format.	
Categories	**Study findings (Quotes from papers)**
1. Information content needs	The only material they give me is papers with the appointment. . .. But information about what I should do or not do, or how to treat, or what to eat or what not to eat, no. (57-year-old Mexican Spanish speaker, 12 years of education) *Michel 2021* ‘I did not have much information about cancer. That word scares you and is synonym of death. So obviously if you don’t have information, you don’t know what treatments there are.’ *Sheppard 2008* she wanted to know “what it is and what your options are in a very straightforward way. I don’t think you should be kept wondering.” *Wong 2011* “I asked him (doctor) how long I will live. . .. The doctor won’t answer me. He said, ‘you keep on taking the medication’.” (Cantonese patient) *Shaw 2015* “When I had to do chemotherapy, I did it. The doctor said it and I did it. . .No (I did not consider another treatment) because I did not know if others existed.” (Greek patient) *Shaw 2015* “I feel more secure . . . he (doctor) explain it very clearly, very detailed. So, I will be well prepared. “(Cantonese patient) *Shaw 2015*. “I was so shocked, and he gave me all this information! (laughs). . . I don’t want to hear, prefer to be in the dark and someone else understands for me and that’s it, . . . the patient really doesn’t need to know, for me when he told me I was shocked and scared and left him (doctors surgery) straight away. . .. I would prefer it if the doctor did not discuss this.” (Arabic patient) Shaw *2015*
2. Information gathering	No [I did not search for information] because he [urologist] had already sent me from here with the information that it was positive. I no longer doubted it. (63-year-old Mexican Spanish speaker, 6 years of education) *Michel 2021* “…connected with another cancer survivor, who as she expressed, “explained everything to me and [answered] any questions I had.” *Wong 2011* “well, I try to ask some doctors in my country back home, through my brothers there” (Arabic patient,) *Shaw 2015* “I made calls. . . I wanted to find one who spoke Chinese, it’s better for communication. Then I found Dr XXX speaks Chinese and his receptionist also spoke Chinese, then we could communicate.” (Cantonese patient) *Shaw 2015* “I can read English, but I don’t understand the meaning of the words I have to take out the dictionary every time I come from the doctor’s. I just sit there and say yes, yes but I leave his consultation and I didn’t understand most things. I find it hard” (Arabic patient). *Shaw 2015*
3. Information format and presentation	when you’ve read about six pages you put it down ... .and as you get older them six pages you never get past because you keep reading the same ones. By the next day you’ve forgotten what it’s saying. Yeah, that’s good that because it gives you all your questions?’ (94 yrs) *Burton 2015*

	‘I didn’t want to go and talk about somebody else’s operation or care because that wasn’t mine. I wanted to know about myself’ (87 yrs) *Burton 2015* ‘I’ve got it, [internet] but I don’t bother about it very much….’No, it would be the last thing I’d do [go to the internet]. (80 yrs) *Burton 2015* her surgeon was helpful because he had explained “exactly what he was going to do and drew a simplified diagram.” *Wong 2011* I do not use any computer of any sort. I only use the phone and actually I do not know how to use it that well. . .. I do not know how to operate a smartphone. (57-year-old Mexican Spanish speaker, 6 years of education) *Michel 2021* I use [cell phone] to get into the web, to look for information within YouTube, that’s how I do my research like for cancer for my prostate. (55-year-old Mexican English speaker, 12 years of education) *Michel 2021* It would be better to have it written or a DVD....It is better for me.... I do not have an education.... I do not have internet. (70-year-old Mexican Spanish speaker, 6 years of education) *Michel 2021* I imagine that the internet is less complicated. Easier to access from your phone. So, I can use it to see what the doctor sends me. (58-year-old Mexican Spanish speaker, 6 years of education) *Michel 2021* A website is much better for many reasons . . . now the phones have become so accessible that. . . even in your own work you can get on a website and check things that interest you. (62-year-old Guatemalan Spanish speaker, 16 years of education) *Michel2021* I’m a very visual guy. . .. I think a website with pictures or a video with simple language would work best for me. I don’t mind reading things online. (65-year-old Mexican English speaker, 12 years of education) *Michel2021* If they had [coaches] right in there at the hospital would be great...a lot of people are going to get a lot of information from them and maybe they’re not going to leave the hospital. . . with a lot of doubts. That creates anxiety because of the uncertainties. (57-year-old Mexican Spanish speaker, 12 years of education) *Michel 2021* making sure the text is “concise” and in “relatively straightforward terms.” *Wong 2011*
Synthesised finding 2. Decision making is a process that starts before the treatment decision consultation, requires effort from the patient to consider options under stressful circumstances, often making choices that are not only based on clinical information.	
Categories	**Study findings (Quotes from papers)**
4. Process and timing	‘things have to be decided too fast’.... ‘lack of knowledge’ ... ‘just didn’t feel sure’ *Mcvea 2001* Negative: ‘The problem is that you just don’t get the right information at the right time.’ *Sheppard 2010* ‘when the doctor gets you by surprise you believe in that doctor and you don’t have a chance to check with another doctor. At the time you’re so tense with the news they gave you that you don’t see another escape and the only one is that one. That’s the only one. So, you do what the doctor tells you. You don’t get a chance to think about it. Once you get the news you have cancer, you get confused and don’t know what to do.’ *Sheppard 2008*
5. Deliberation on Options/Choices	Existential: ‘You know, they always ask if I have anything to say, and I never have anything to say so it’s mostly my fault.’ *Sheppard 2010*

6. Work of decision making	“the navigator helped her to ‘get in the habit of writing questions and reviewing them before seeing her doctor.’” *Sheppard 2008*
7. Reasons for choices	I decided the years I’ve got left… I’m not messing about going into hospital…’ (95 yrs) *Burton 2015* ‘I’m raising a child that is two years old. I cannot be in and out of the hospital. I said I need all this done now’ *Mcvea 2001* ‘Let’s get it over with and out of the way and go about your life’. *Mcvea 2001* ‘I was just going to have to leave it [the cancer] go’. (had no insurance) *Mcvea 2001* ‘It wouldn’t have been handy, but I could have done it’. (far distance to radiation centre) *Mcvea 2001* ‘The decision to get chemotherapy was like either you do it, or you do it. They don’t give you a chance whether you want to do it or not. But I think this decision is whether you want to live or not. It’s survival’. *Sheppard 2008* Negative: ‘I know what [chemotherapy] did to my husband. It took all of his hair out.’ *Sheppard 2010*
Synthesised finding 3. Decision making consultations are affected by the interaction style of clinician and patient, impacting on decision control, such that patients sometimes adopted roles that they did not prefer. Patients reported a variety of preferred decision supports.	
Categories	**Study findings (Quotes from papers)**
8. Clinician-patient interaction	‘He didn’t tell me which [treatment] he thought I should do. He was perfectly objective'. *Mcvea 2001* ‘I didn’t really discuss very much of it. Dr P. would tell me what he thought I should have done’. *Mcvea 2001* ‘I think that was the worst part of my whole breast cancer surgery...Nobody was listening to me’. *Mcvea 2001* “Hi. How are you? Can I see your breast?” because they seemed more interested in her breast than her *Wong 2011* “medical people talk to us as if we know exactly what they are talking about...long explanations...they expect you to know.” *Wong 2011* It was everything they wanted me to know, nothing that I needed to know. But I didn’t know this. I couldn’t ask these questions because I didn’t know what to ask until after it was over' *Mcvea 2001* When they gave me give the diagnostic that I had prostate cancer, there they gave me three options . . . the doctor told me I must get surgery and he booked for the surgery. (74-year-old Venezuelan Spanish speaker, 4 years of education) *Michel 2021* He said, ‘I am going to get you all the test you need and see if I can add you for surgery soon . . . the doctor was a little bit rough with the news. (66-year-old Mexican English speaker, 11 years of education) *Michel 2021* I did not talk much, [the doctor] only told me to manage my food intake. . .. She only said to eat less. . .. She scolded me because I eat fried foods. . .. I could change clinics, but I am doing well with her. I have to respect the rules. (70-year-old Mexican Spanish speaker, 6 years of education) *Michel 2021* “For my case, the specialist never discussed with me, never took my opinion in consideration. . . The doctor won’t listen to you. It’s not that we didn’t want, and it’s not that we didn’t initiate to know more, I really wanted to know, I felt helpless, felt myself helpless. He ‘‘HOLD’’ the ‘‘POWER’’.” (Mandarin patient) *Shaw 2015*

9. Preferred or perceived passive decision role	‘you’re a bit gobsmacked [when they give you a choice] you don’t know what….’ well obviously, he deals with that all day and every day, so I just said, ‘Well what do you advise?’ ...I mean what do you see these people for if not to take their advice?’ (81 yrs) *Burton 2015* ‘‘I don’t have funds to pay for anything. And he said, well, whatever I could pay, pay. I just sort of put myself in their hands and said, ‘Here I am. Whatever you want me to do, I’ll do’’’. *Mcvea 2001* ‘I just don’t fight the doctor.’ *Mcvea 2001* “It’s up to the doctor from the very beginning to the end, whatever the doctor says we just follow. . . It leaves you no room for decision. I just feel that it’s not up to me to decide, I am not a professional doctor, so I have to rely on the doctor, whatever he tells me to do” (Cantonese patient) *Shaw 2015* ‘A couple other doctors came up from Omaha to see someone else, but they had a discussion on my case. And then they got together and decided...they made the decision’ He said we can fix your problem with surgery or chemotherapy. Then he told me he could do my surgery soon and told what to expect from surgery. (68-year-old Salvadoran Spanish speaker, #10, 4 years of education, T2 disease) *Michel 2021*
10. Preferred or perceived active decision role	Right, I said, ‘let’s get rid of it, at my age,’ so I went for a full (mastectomy]. But if I [h]adn’t have had a [mastectomy] I’d have to have had radiotherapy...’ (75 yrs, Mx) *Burton 2015* ‘He [Surgeon] seemed pleased with my decision.’ (76 yrs, Mx) *Burton 2015* “. . .I feel that patients in Australia usually have right of choice. . . So, I think sometimes the doctor can give you choice. . . It means you have choice of treatment.” (003, Cantonese patient)
11. Decision support	‘having a person (breast cancer survivor patient navigator) that went through the same thing transmitted a sense of confidence and hope'. *Sheppard 2008* Positive: 'I have excellent communication with [providers]. They explain things. They take time with me. They always call me back. They’ve been very open about the prognosis.' *Sheppard 2010* Existential: ‘I had two of my daughters with me, and they asked a lot of questions. But since I’ve been going by myself, I [have] really felt neglected.’ *Sheppard 2010* Negative: ‘What would have made it better [is] if any of [the physicians] had talked about what you would feel. They always talk about the statistics, the numbers, the medicines, the side- effects.’ *Sheppard 2010* ‘I appreciated speaking with her (cancer survivor coach). She made me feel quite at ease in the face of a difficult situation. She gave me hope.’ *Sheppard 2008* Positive: ‘I talked to people who had gone through [breast cancer]. I asked for their opinions.’ *Sheppard 2010*

Synthesised finding 4. Patients experienced strong emotions following a cancer diagnosis that impacted on their ability to make decisions. Social, cultural and language factors influenced decision making, indicating the need for an enhanced psychosocial approach to decision support.

Categories	**Study findings (Quotes from papers)**

12. Emotional/Social impact of cancer and treatment decision making	I just kept saying, ‘Do what you’ve got to do, do what you’ve got to do’. We lost a daughter-in-law with breast cancer, she was only 26, and that’s 30 years ago ... she would have still been alive if they’d have taken it off. (84yrs) *Burton 2015* ‘I just thought I have cancer and I wasn’t bothered about it because let sleeping dogs lie. The less you know the less you bother about it.’ (90 yrs) *Burton 2015* ‘[I]was kind of foggy for a while, just figuring what to do next...It took me until February to get it together’. (avoidant) *Mcvea 2001* ‘Total panic and get rid of it as fast as possible’. *Mcvea 2001* ‘He’s not talking about my body; he’s talking about somebody else’s body’. *Mcvea 2001* ‘What do you do, make a decision under complete fear?’ *McVea 2001* ‘The problem was I wasn’t deciphering [the information] because I was so afraid’. *Mcvea 2001*
13. Family, social, cultural influences in decision making	[Wife] sometimes ask questions that I do not make about my diet . . . the talk is very cordial between my wife and the doctor. (62-year-old Mexican Spanish speaker, #12, 12 years of education, and T1c disease) *Michel 2021* I do have family, but they don’t say much. They do not give me much information. . .. My family knows about the problem, but they only say for me to take care. Nothing else. (70-year-old Mexican Spanish speaker, 6 years of education) *Michel 2021* I did not want people to know about it, only my wife. [regarding the decision-making process], I think I will do it alone. (57-year-old Mexican Spanish speaker, 6 years of education) *Michel 2021* ‘My biggest worry was to be able to endure the chemo and continue taking care of my kids. I want to be with my family, which is the most important thing in my life, more than my life. If you get cured, you want to do it for your kids’ *Sheppard 2008* ‘Us as mothers we worry about everybody, our kids, our husbands, our work and the last one we think of are we. We have to be conscious that we are the heads of the family, and we have to take care of ourselves’. *Sheppard 2008* “Don’t know how to communicate. I want to talk about something but don’t know how to talk. The Caucasian think that you have nothing to ask, I feel it very hard to communicate my feelings” (Cantonese patient) *Shaw 2015* “I don’t understand English and everything they gave me was in English. No Greek person has spoken to me. Yes, I have difficulties; I didn’t understand him in everything he said.” (Greek patient) *Shaw 2015* “For us it is difficult. As Chinese in overseas, when we have a problem, we can’t express our symptoms, so we find an interpreter. There are so many interpreters, they phone in. They don’t say it right [the meaning of what is being said]. So often our message is not correctly delivered. The doctor doesn’t understand us” (Cantonese patient) *Shaw 2015* “I take Chinese herb, I asked my doctor. The doctor didn’t agree with me at the beginning. for example during the chemotherapy, the doctor told me I shouldn’t take anything, but I felt it would be better. I took Ling-Zhi and shark bone powder now.” (Mandarin patient) *Shaw 2015* “The doctor tells me to do something, you shouldn’t say ‘no, I won’t do it’, this is in His [Gods] name, whatever they say, we do.” (Arabic patient) *Shaw 2015*

	“The doctor told me, if you are worried you can take out the uterus. . .This kind of explanation for Chinese is a forbidden, we don’t talk about from a religious point of view, because when made human they give you in whole piece, they won’t let you get rid of any organs easily. . . This might be to do with the Eastern and Western culture [difference]” (Mandarin patient) *Shaw 2015* “I told him (doctor) . . . ‘don’t open your mouth, talk with my husband, talk with my children, and have a meeting with all of them. . . Don’t inform me, I don’t want to know, I am happy this way. “(Arabic patient) *Shaw 2015*
14. Strategies for socio-emotional support	It would have been helpful to meet with a social worker or psychologist to help them come to terms with “stresses they are going through.” *Wong 2011* ‘Having a person that went through the same thing transmitted a sense of confidence and hope'. *Sheppard 2008* ‘I appreciated speaking with her. She made me feel quite at ease in the face of a difficult situation. She gave me hope.’ *Sheppard 2010*

APPENDIX G: Paper 2. Screening form for enrolment

Interviewer Name		
Date of Screening		
Site *(circle site)*	CHBAH CMJAH Greys	
Eligibility Questions:	**Yes**	**No**
Is the patient 18 years or older?		
Does the patient have a histologically confirmed diagnosis of cancer?		
Has the patient had a consultation with a doctor regarding chemotherapy treatment?		
Is the patient fit to complete the interview?		
Is the patient willing to consent to participate in the study?		
If yes to all questions, the patient is eligible and may be enrolled with consent		

APPENDIX H: Paper 2. Study Information sheet for patients (Quantitative)

Protocol Title: **Developing an intervention to improve informed decision-making for oncology patients in South Africa**

Principal Investigator: Dr Charmaine Blanchard

STUDY INFORMATION SHEET

Introduction

Good day, my name is: Name _____________ Surname _________________ and I am a research assistant at the CMJAH Oncology clinic ☐, CHBAH Haematology Oncology Clinic ☐, Greys Hospital Oncology Clinic ☐. (*Select relevant hospital clinic*).

I would like to invite you to consider taking part in a research study called "**Developing an intervention to improve informed decision-making for oncology patients in South Africa.**" because you are a cancer patient in this clinic.

Before agreeing to take part, it is important that you read and understand the following explanation of the purpose of the study, study procedures, any possible or minor risks and your right to withdraw from the study at any time. This information sheet is to help you decide if you would like to take part in the study, it may contain words that you do not understand. You need to understand what is involved before you agree to take part in this study, so please ask the study staff to explain any words or information that you do not clearly understand.

The study will be performed at the oncology clinics of Charlotte Maxeke Johannesburg Academic Hospital, Chris Hani Baragwanath Academic Hospital and Greys Hospital (in KZN). Should you agree to participate, you will be asked some questions about yourself, your health and your healthcare preferences. This will take approximately 30 minutes of your time.

Purpose of study

We are doing this study to find out more about how oncology patients make decisions about their treatments. We want to find out what are the challenges to you better understanding your illness and treatments and to making informed decisions about your treatment. We would like to know what can be done to make the decision process easier for you.

The information we receive from those who participate will help us to develop tools that will help healthcare providers to communicate a patient's diagnosis and treatment in a way that is easier to understand and to help patients make informed decisions about their treatment.

Study Procedures

Once you have agreed to take part in this study, you will first be asked questions to see if you qualify for the study. If you qualify, we will ask you to sign a consent form before proceeding with the interview and questionnaires.

The interview will include a few questions about your personal circumstances, your medical history, and your healthcare preferences. We will ask you to fill in three questionnaires. The first one is to measure how well you understand medical information, the second is to ask about your preferences when making medical decisions and the third is to ask about how much you understand about what the doctor has told you about your treatment options and how you made your decision about your treatment. You will be taken to a private room for the interview, and we will ensure that you are not delayed in the queue if you agree to participate.

All information obtained during this study will be kept strictly confidential. Your identity will always be kept confidential and at all times only the study team will have access to the information you provide. All of your personal and study information will be identified by a study number. This information (it is called anonymized because your name is not shown anywhere on the information) will be used for analysis by the study team. We plan to present the results at research meetings and use the results to write articles in medical journals. Only anonymized data will be presented, and your confidentiality will be maintained at all times.

There won't be costs involved for you to take part in the study.

If you have any questions, please do not hesitate to ask me. You should not agree to take part unless you are satisfied with all the procedures involved.

Your participation in this study is entirely voluntary and you can decline to take part, or stop at any time, without giving any reason. Your withdrawal will not affect your access to medical care in any way.

If you have any questions, please feel free to contact the study doctor, Dr Charmaine Blanchard 082 880 1608.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg. A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

If you decide to take part in this study, you will be asked to sign the consent document to confirm that you understand the study, what will be needed from you and agree to participate.

Participant questions raised: ____

____
____
____
____
____
____

APPENDIX I: Paper 2. Informed consent – all participants, both studies

INFORMED CONSENT FOR PARTICIPATION IN THE STUDY ENTITLED**: Developing an intervention to improve informed decision-making for oncology patients in South Africa**

I, **Name** __________________ **Surname** _____________________, hereby confirm that I have been informed by the study interviewer about the nature, conduct, benefits and risks of the study.

- I have received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into any research reports.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the study team.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I am aware that the results of the study, including my personal details and diagnosis will be kept confidential.
- I may, at any stage, without prejudice to myself and my future medical treatment, withdraw my consent to participate in this study. I have had sufficient opportunity to ask questions and hereby accept to participate in the study.
- I agree to all of the procedures and restrictions included in this Information Sheet.

PARTICIPANT

____

Printed name Signature/ thumbprint Date

INTERVIEWER

I herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

____

Printed Name Signature Date

WITNESS STATEMENT (if required):

As an impartial third party, I witnessed the entire consent discussion and the participant's signature on the form. I attest that this entire form was read to the participant named above. This person had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

____

Printed Name Signature Date

Participant received IC copy*: Signature* ___________________________ *Date* ____________

APPENDIX J: Paper 2. Patient Interview questions for quantitative data collection

Interviewer Name	
Date of Interview	
Site	CHBAH CMJAH Greys
Participant study no. *(insert no.)*	CHB HL CMJ HL GH HL
Age	
Gender	• Male • Female
Relationship status	• Single • Married/Partner • Divorced • Widowed
Shared Living Space	• Your children • Spouse/partner • Parents • Relatives • Friends • Employer • Other
First Language	• English • Afrikaans • Zulu • Sotho • Tswana • Pedi • Ndebele • Xhosa • Tsonga • Venda • Other
Language of interview	• English • Zulu • Sotho • Tswana • Afrikaans • Other
Education *(Last Grade completed)*	• Grade 1-4 • Grade 5-7 • Grade 8-10 • Grade 11-12 • Tertiary, College
Self-reported English literacy	• No understanding • Verbal understanding but unable to respond. • Verbal understanding and able to respond. • Verbal understanding, able to respond and read
Employed	• Yes

	• No
If yes:	• Salaried • Self-employed • Occasional “piecework”
If no:	• Retired • Unable to find work. • Disabled
If employed, type of employment:	• Predominantly manual • Predominantly non-manual
Recipient of social grant	• Yes • No
Household Income	• < R2000 • R2001—R5000 • R5001-R10 000 • >R10 000 • Declined to answer
Number living in the house.	• 1–4 • 5–8 • > 8
Home ownership status?	• You/spouse own your home. • Parents/relatives own the home. • Rent your home. • Stay in someone else’s home e.g., relatives/friends. • Squatting/informal housing • Homeless
Water facilities	• Indoor running hot and cold water • Indoor running cold water only. • Outside tap only. • Water from borehole only • Water from tank only • Water from river only
Toilet facilities	• Flush toilet inside house • Flush toilet only outside house • Pit latrine only • Bucket system only • Other type of toilet
Specify other:	
Electricity facilities	• Eskom • Solar • Eskom and solar • Generator • None
Cooking facilities	• You have a gas stove. • You have a paraffin stove. • You have a coal/wood stove. • You have an electric stove or plates to cook on • You have gas and electric stove

Transport	• You own or your spouse owns a motor car. • You own or your spouse owns a motor bike. • You travel by taxi or other public transport only. • Other family member owns a car/motorbike.
Household possessions	• There is a fridge in the home where you stay. • There is a microwave in the home where you stay. • There is a washing machine in the home where you stay/ • You have a bed. • There is a TV in the home where you stay. • You have DSTV. • You have a computer/laptop/tablet. • You have WIFI or 3G connectivity
Telephone	• You have a smart cell phone. • You have a cell phone that is not a smart phone. • You have no phone. • You have only a landline
Use of technology	• Can look for health information on computer. • Can look for health information on mobile phone. • Cannot use either computer or mobile phone to look for health information
Province of birth (In South Africa)	• Gauteng • Northwest • Limpopo • Mpumalanga • KZN • Free State • Eastern Cape • Northern Cape • Western Cape
Country of birth (if not South Africa)	
Perceived Social Support	
• Do you have someone to turn to for suggestions about how to deal with a personal problem?	• Yes • No
• Do you have someone to help with daily chores if you were sick?	• Yes • No
• Do you have someone to show you love and affection?	• Yes • No
• Do you have someone to do something enjoyable with?	• Yes • No

Clinical ***(ask the patient – do not use the clinical notes)***	
Primary Cancer Diagnosis	
Date of diagnosis (Month/year ok if exact date is not known)	
Stage of cancer	• I • II • III • IV • Unknown
Patient Reported Co-morbidities	• Hypertension • Diabetes • Heart Disease/Stroke • Kidney Disease/failure • Liver disease/failure • Asthma/COPD • Arthritis • Psychiatric illness • HIV • TB • Nil • Thyroid disease • Other
If other co-morbidity, specify:	
Chronic Medicines *(Is the patient taking chronic medicines?)*	• Yes • No
If yes, Total no of tablets a day What other medications/supplements are you taking?	
Previous cancer treatment *(May be more than one)*	• Nil • Surgery • Chemotherapy • Radiation therapy • Other therapy
What other therapy?	
ECOG Performance Status *(Ask the patient about their level of activity according to the ECOG scores)*	• 0 (Fully active & same performance as before cancer) • 1 (Can walk and do light work, but no strenuous activities) • 2 (Cannot do any work but able to be out of bed/chair for half the day or more) • 3 (Limited selfcare – washing, feeding; in bed/chair more than half the day) • 4 (No selfcare; completely disabled and bedbound)
Perceived current health status?	1. Relatively healthy 2. Relatively healthy but terminally ill 3. Seriously ill but not terminally ill 4. Seriously and terminally ill

For the following questions, circle the answer from the patient. (Remember to reassure the patient that strict confidentiality will be maintained)	
Do you think doctors see you as a whole person (more than a person with an illness)?	• Not at all • A little • A lot
Do you think the doctors here treat you with respect?	• Not at all • A little • A lot
Do you respect the doctors here?	• Not at all • A little • A lot
Do you understand most of what the doctors explain to you?	• Not at all • A little • A lot
Are you comfortable asking the doctors questions about your health?	• Not at all • A little • A lot
Are you comfortable asking the doctors questions about your care or treatment?	• Not at all • A little • A lot
Do you trust the doctors treating you?	• Not at all • A little • A lot
How often do the doctors ask you how you are coping with your illness?	• Not at all • A little • A lot
How often do the doctors ask how your family members are coping with your illness?	• Not at all • A little • A lot
Are there things about your health or treatments that you do not understand but want to know about?	• Yes • No
What are the things you would like to know more about?	
Do you believe in taking the medicines your doctor gives you?	• Yes • No
Are you seeing a traditional/complementary healer?	• Yes • No • Did not answer
Are you taking traditional/complementary medicine?	• Yes • No • Did not answer

APPENDIX K: Paper 2. Health Literacy Test – Limited Literacy (HELT-LL): English

Questions and response options ***Instructions: Only read the questions to the participant.*** ***Do not explain any meaning.*** ***If they ask for explanation, just read the question to them again.***	**Start Time:**	**Score**
1. If you don’t understand what the nurse/doctor/pharmacist has told you about your health or medicines, do you usually ask them to give you more information and explain things to you?	0 = never 1 = sometimes 2 = often	
2. Do you know how to use a computer or cell phone to answer your health-related questions?	0 = no 1 = unsure/maybe 2 = yes	
3. If you are worried about a health problem, do you usually ask your friends and neighbours first for information and advice before going to the clinic?	0 = yes 1 = unsure/maybe 2 =no	
4. If you go to the clinic on the 7th of March and you are asked to return to the clinic two weeks later, what will the date be?	0 = incorrect 2 = correct	
5. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist?	0 = always/often 1 = occasionally/ sometimes 2 = never	
6. You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one?	0 = incorrect 2 = correct	
7. You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	0 = incorrect 2 = correct	
8. Do you think that health information from the internet on your cell phone or computer is always good information that you can trust?	0 = incorrect 2 = correct	
9. Which blood pressure reading is closest to a normal blood pressure reading?	0 = incorrect 2 = correct	
10. Can you get TB if you use the same toilet as someone with TB?	0 = incorrect 2 = correct	
11. Can HIV/AIDS be cured?	0 = incorrect 2 = correct	
12. Herbal/traditional medicines are natural and are from plants. Are they always safe to take?	0 = incorrect 2 = correct	
Total Score (out of 24)		
Time taken (mins)	**End Time:**	

APPENDIX L: Paper 2. Health Literacy Test – Limited Literacy (HELT-LL): isiZulu

Ukuhlolwa Ngolwazi Lwezimpilo- Limited Literacy (HELT-LL): Zulu *Instructions: Only read the questions to the participant.* *Do not explain any meaning.* *If they ask for explanation, just read the question to them again.*	**Start Time:**	**Score**
1. Uma ungazwisisi okushiwo umhlengikazi/ udokotela/ usokhemisi akutshele kona ngempilo yakho noma mayelana namakhambi ophiwe wona, uyaye ubuze ukuchazelwa kabanzi na?	0=Cha 1=Kwesinye isikhathi 2=ngivamisile	
2. Unalo ulwazi lokusebenzisa umakhala ekhukhwini noma ikhompiyutha ukuphendula imibuzo ngesimo sempilo yakho?	0=Cha 1=Mhlawumbe/ anginasiqiniseko 2=Yebo	
3. Uma ukhathazekile ngesimo sempilo yakho uyaye ubuze umngani noma omakhelwane kuqala ngaphambi kokuya emthola mpilo?	0=Yebo 1=Mhlawumbe/ anginasiqiniseko 2=Cha	
4. Uma uvakashela emtholampilo mhlaka 7 kuNdasa (7 March) ucelwe ukuthi ubuye emavikini amabili azayo, ubuyela ngomhla kabani enyangeni?	0=Akunjalo 2=Kunjalo	
5. Ujwayele kangakanani ukubuzisisa komunye umuntu ngemininingwane ebhalwe ngu Dokotela / umhlengikazi/ noma usokhemisi?	0=Njalo/ ngivamisile 1=Kwesinye isikhathi 2=Angikaze	
6. Utshelwe ukuthi uphuze iphilisi elilodwa kathathu ngosuku, njalo emva kwamahora ayisishiyagalombili. Uma uphuza elokuqala ngehora lesikhombisa (7am) ekuseni, uliphuza sikhathisini elilandelayo?	0=Akunjalo 2=Kunjalo	
7. Utshelwe ukuthi unikeze ingane umuthi ongu 2ml owuketshezi kwisimpontsho, ngicela ungikhombisa lapho uzowugcwalisa khona	0=Akunjalo 2=Kunjalo	
8. Ucabanga ukuthi ulwazi lwezempilo olutholakala kumakhalekhukhwini kanye ne internet lwanele na futhi lwethembekile	0=Akunjalo 2=Kunjalo	
9. Ngabe ilona liphi izinga lokufunda iBP (kumfutho wegazi) olujwayelekile?	0=Akunjalo 2=Kunjalo	
10. Ungasithola isifo sofuba uma usebenzisa indlu yangasese eyodwa nomuntu onaso isifo sofuba?	0=Akunjalo 2=Kunjalo	
11. Singalapheka yini isandulela ngculazi/ingculazi (HIV/AIDS)?	0=Akunjalo 2=Kunjalo	
12. Amakhambi wesintu ayimvelo. Ngabe kuphephile yini ukuwasebenzisa?	0=Akunjalo 2=Kunjalo	
Total Score (out of 24)		
Time taken (minutes)	**End Time:**	

APPENDIX M: Paper 2. Health Literacy Test – Limited Literacy (HELT-LL): Supplementary notes

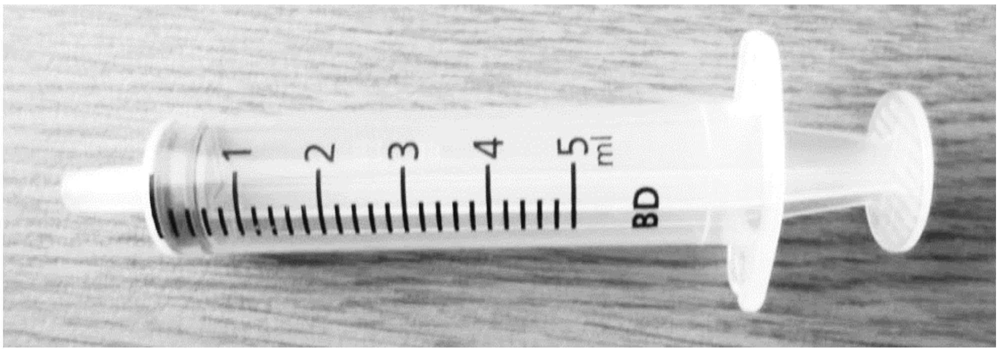
Question 5

Use the laminated *<u>Panado</u>* Patient Information Leaflet

1. **Ask the question first, hand the leaflet to the patient, and let them look at the whole document (either English or Afrikaans depending on their preference).**
2. **If there is not an immediate response, just ask again.**
3. **If they answer always/often - then they get zero.**
4. **If they answer never or sometimes/occasionally, ask them to read the section "Warnings and special precautions" (in the box) out loud. Check if they understand only a little/nothing (score 1) or most of it (score 2).**

Question 7

Participant to indicate 2 ml mark on the syringe.



Question 9

Participant to indicate the blood pressure reading closest to a normal acceptable reading.

$\frac{150}{100}$	$\frac{90}{160}$	$\frac{120}{80}$

Answers to Questions:

- **Question 4**
    - **Correct answer: 21 March**
- **Question 6**
    - **Correct answer: 3pm**
- **Question 8**
    - **Correct answer: No**
- **Question 10**
    - **Correct answer: No**
- **Question 11**

  - **Correct answer: No**
- **Question 12**
  - **Correct answer: No**

APPENDIX N: Paper 2. Decision Control Preferences

Study No.	**Date:**
Site: *(circle applicable site)* **CHBAH CMJAH GH**	**Interviewer Initials:**

How do you like to make decisions about your healthcare or health treatment?
Ask the patient to select the most appropriate preference.
(Patient may only select one option)

1	**By myself**	
2	**By myself after hearing the doctor's opinion or input**	
3	**By myself after hearing my family's opinion or input**	
4	**By myself after hearing both my family's and the doctor's opinion or input**	
5	**By my family**	
6	**By my family after hearing my opinion and input**	
7	**By my family after hearing my doctor's opinion and input**	
8	**By my family after hearing both my doctor's and my opinion and input**	
9	**By the doctor**	
10	**By the doctor after hearing my opinion or input**	
11	**By the doctor after hearing my family's opinion or input**	
12	**By the doctor after hearing both my family's and my opinion or input**	
13	**Shared between myself and the doctor**	
14	**Shared between myself and my family**	
15	**Shared between myself and both my family and my doctor**	

APPENDIX O: Paper 2. Questions from the “Decision Conflict Low Literacy” Tool

Considering *your* preferred option, please answer the following questions.		
Ask Q1-Q4 for all patients:	Yes	No
1. Do you think you are sure about what to choose?	Yes	No
2. Have you had enough advice or information to make a choice?	Yes	No
3. Have you been given enough support from others to make a choice?		
• Doctors	Yes	No
• Family	Yes	No
• Friends/others	Yes	No
4. Are you choosing without pressure from others?	Yes	No
If choice is to have chemotherapy, ask question 5 and 6		
5. You have decided to proceed with Chemotherapy - *(as per your answer above)* - do you know the side effects of hemotherapy?	Yes	No
6. Can you explain the reason for your choice?		
If choice is not to have chemotherapy, ask question 7, 8 and 9		
7. You have decided NOT to proceed with Chemotherapy - *(as per your answer above)* - do you know the side effects of chemotherapy?	Yes	No
8. Does knowledge of the side effects influence your decision?	Yes	No
9. Can you explain reasons for your choice?		
If unsure about what to choose: ask questions 10 and 11		
10. You are Undecided/not sure regarding whether to proceed with Chemotherapy or not - *(as per your answer above)* - do you know the side effects of chemotherapy?	Yes	No
11. What would help you to make a choice?		
12. Are you satisfied with your choice? (Ask all patients)	Yes	No

APPENDIX P: Paper 2. Decision conflict of patients choosing chemotherapy

HL	English Literacy	DCP	Pre-consultation Information Need	Enough information to make a choice	Enough support to make a choice.			Choosing with some pressure from others	Reason for choosing chemotherapy	Sure about/Satisfied with choice
					Doctor	Family	Friends			
Marginal^{a}	Understand, speak, read	Shared	What is chemo, what does it do and how it's going to help me	No	No	No	No	Yes	I don't what is chemo	No/No
Inadequate^{b}	Understand, speak, read	Active	How did I get the illness, is there a way to prevent it in the future should I get cured and what are some of the things I should avoid eating?	No	No	No	No	Yes	It wasn't by choice it was chosen for me.	No/No
Adequate^{c}	Understand, speak read	Active	What will happen if I have taken the chemo?	Yes	Yes	No	No	Yes	The doctors advised me about chemo.	Yes/Yes
Marginal^{a}	Understand & speak	Active	No	Yes	Yes	Yes	Yes	No	I have grandchildren to look after, and I know that chemo will make me better	Yes/Yes
Marginal^{b}	Understand, speak, read	Active	No	Yes	Yes	Yes	Yes	Yes	I think it might help relieve the pain I'm experiencing.	Yes/Yes
Marginal^{b}	Understand, speak, read	Passive	What is leukaemia, what is it doing to my body, what is the cause	Yes	Yes	Yes	Yes	No	Patient had no answer	No/Yes
Inadequate^{b}	Nil	Active	No	Yes	No	Yes	Yes	No	It was the only option I was given	Yes/Yes
Inadequate^{b}	Understand only	Passive	No	Yes	Yes	Yes	Yes	No	It is the correct treatment for my illness.	Yes/Yes

Education level: ^{a} Primary ≤ grade 7, ^{b} senior (Grade 7 to Grade 12), ^{c} tertiary/college

APPENDIX Q: Paper 3. Information sheet for patients for qualitative study

Protocol Title: **Developing an intervention to improve informed decision-making for oncology patients in South Africa**

Principal Investigator: Dr Charmaine Blanchard

STUDY INFORMATION SHEET – PATIENTS (Qualitative)

Introduction

Good day, my name is: Name _____________ Surname _________________ and I am a research assistant at the CMJAH Oncology clinic ☐, CHBAH Haematology Oncology Clinic ☐, Greys Hospital Oncology Clinic ☐. (*Select relevant hospital clinic*).

I would like to invite you to consider taking part in an interview as part of the research study called "**Developing an intervention to improve informed decision-making for oncology patients in South Africa."** because as an oncology patient, you are needing to make decisions about your treatment.

Before deciding whether to take part, it is important that you read and understand the following explanation of the purpose of the study, study procedures, any possible or minor risks and your right to withdraw from the study at any time. This information sheet is to help you decide if you would like to take part in the study, it may contain words that you do not understand. You need to understand what is involved before you decide whether to take part in this study, so please ask the study staff to explain any words or information that you do not clearly understand.

The study is being performed at the oncology clinics of Charlotte Maxeke Johannesburg Academic Hospital, Chris Hani Baragwanath Academic Hospital and Greys Hospital (in KZN). Should you agree to participate in this interview, you will be asked some questions about yourself, and then have a discussion with the interviewer about how you understand your illness and treatment as well as how you would normally make health related decisions and how this process could be improved for you and other patients. This will take approximately 45 minutes of your time.

Purpose of study

We are doing this study to find out more about how cancer patients make decisions about their treatments. We want to find out what are the challenges to you to better understanding your illness and treatments and to making informed decisions about your treatment. We would like to know what can be done to make the decision process easier for you.

The information we receive from those who participate will help us to develop tools that will help healthcare providers to communicate a patient's diagnosis and treatment in a way that is easier to understand and to help patients make informed decisions about their treatment.

Study Procedures

If you agree to take part in this study, you will first be asked to sign a consent form before proceeding with the interview and discussion. The whole process will take about 45 minutes. You will be taken to a private room for the interview and we will ensure that you are not delayed in the queue if you agree to participate.

All information obtained during this study will be kept strictly confidential. Your identity will always be kept confidential, and at all times only the study team will have access to the information you provide. All of your personal and study information will be identified by a study number. This information (it is called anonymized because your name is not shown anywhere on the information) will be used for analysis by the study team. We plan to present the results at research meetings and use the results to write articles in medical journals. Only anonymized data will be presented, and your confidentiality will be maintained at all times.

If you need to make a special trip to the clinic for this interview, you will be compensated for your transport costs. There will be no other payment for the interview.

If you have any questions, please do not hesitate to ask me. You should not agree to take part unless you are satisfied with all the procedures involved.

Your participation in this study is entirely voluntary and you can decline to take part, or stop at any time, without giving any reason. Your withdrawal will not affect your access to medical care in any way.

If you have any questions, please feel free to contact the study doctor, Dr Charmaine Blanchard by telephone on 082 880 1608, or either of her supervisors, Professor Shane Norris on 082 928 2381, or Professor Moosa Patel on 072 437 4680.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg. A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Dr Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.penny@wits.ac.za . The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

If you decide to take part in this study, you will be asked to sign the consent document to confirm that you understand the study, what will be needed from you and agree to participate.

Thank-you for reading this Information Sheet.

February 2021

Participant questions raised:
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APPENDIX R: Paper 3. Information sheet for participants of focus groups

Protocol Title: Developing an intervention to improve informed decision-making for oncology patients in South Africa

Principal Investigator: Dr Charmaine Blanchard

STUDY INFORMATION SHEET

Introduction

Good day,

I am Dr Charmaine Blanchard, PhD student and principal investigator of a research project: "**Developing an intervention to improve informed decision-making for oncology patients in South Africa."** I would like to invite you to take part in a focus group discussion as a part of the research project because you are a healthcare provider managing oncology patients.

The project is being undertaken at the oncology clinics of Charlotte Maxeke Johannesburg Academic Hospital, Chris Hani Baragwanath Academic Hospital and Greys Hospital (in KZN). As part of the need's analysis for the project, we will be conducting focus group discussions at each facility. Each group will include doctors, nurses and counsellors who support oncology patients and manage their treatments. The focus group discussion should take about 45 – 60 minutes and will be arranged at a time most suitable for participants.

Purpose of study

The research project aims to develop and pilot a decision support intervention which will assist oncology patients to make informed treatment decisions throughout the illness continuum. The first part of the project comprises a needs analysis, which includes patient interviews and focus group discussions with healthcare providers. The focus group discussions aim to explore healthcare provider understanding of health literacy and the barriers and facilitators of oncology patient informed decision making. The information from the need's analysis will be utilised in the development of the decision support tool. Your participation in the focus group discussion will be greatly appreciated.

Study Procedures

If you agree to take part in the focus group discussions, I will arrange a date and time that is most suitable for participants for each site. The discussion will take place at the facility to minimise travel, unless there is no suitable meeting place, in which case an alternative venue will be sought. The session will be audio-recorded for later analysis; however, all data will be anonymised, and while participant confidentiality will be maintained by the researchers, it cannot be guaranteed that all participants will keep confidentiality. Once the analysis is completed, the results will be circulated to all who participated to check for concurrence of the themes that emerge from the analysis.

Your participation in this study is entirely voluntary and you can decline to take part or stop at any time.

If you have any questions, please feel free to contact the Principal Investigator: Dr Charmaine Blanchard on 082 880 1608.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg. A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Paul Ruff, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za . The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

If you decide to take part in this study, you will be asked to sign the consent document to confirm that you understand the study, what will be needed from you and agree to participate.

Participant questions raised:

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APPENDIX S: Paper 3. Information sheet for audio-recording

Protocol Title: **Developing an intervention to improve informed decision-making for oncology patients in South Africa**

Principal Investigator: **Dr Charmaine Blanchard**

University of the Witwatersrand

PARTICIPANT INFORMATION SHEET: AUDIO-RECORDING & TRANSCRIPTION

Dear Participant,

My name is: Name _____________ Surname _________________ and I am a research interviewer at the CMJAH Oncology clinic ☐ , CHBAH Haematology Oncology Clinic ☐, Greys Hospital Oncology Clinic ☐ . (*Select relevant hospital clinic*).

This research study involves the audio recording of your interview with the research interviewer. Neither your name nor any other identifying information will be associated with the audio recording. Only the research team working on this project will be able to listen to the recordings.
The recordings will be transcribed (which means a researcher will listen to the recording and type onto a document/paper everything that is said) by the researcher and erased once the transcriptions (the typed conversations) are checked for accuracy. Transcripts of your interview may be reproduced in whole or in part for use in presentations or written papers that result from this study. Neither your name nor any other identifying information (such as your voice or picture) will be used in presentations or in written papers resulting from the study.
Do you have any questions?

Questions raised by the participant.
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APPENDIX T: Consent for audio-recording

INFORMED CONSENT FOR AUDIO-RECORDING & TRANSCRIPTION

Protocol Title: **Developing an intervention to improve informed decision-making for oncology patients in South Africa**

Principal Investigator: **Dr Charmaine Blanchard**

University of the Witwatersrand

By signing this form,

I am allowing the researcher to audio-record the interview with me as part of this research study. I also understand that this consent for recording is effective until the following date: 15 December 2023. On or before that date, the tapes will be destroyed.

I have received, read and understood the above written information in the Audio-Recording Information Leaflet for this study.

PARTICIPANT

____

Printed name Signature/ thumbprint Date

INTERVIEWER

I herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

____

Printed Name Signature Date

WITNESS STATEMENT (if required):

As an impartial third party, I witnessed the entire consent discussion and the participant's signature on the form. I attest that this entire form was read to the participant named above. This person had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

____

Printed Name Signature Date

***Participant received IC copy**: Signature ___________________________ Date ____________*

APPENDIX U: Paper 3. Patient in-depth interview guide

Objective of the interview is:

To understand patient experiences and factors (facilitators/enablers and challenges/barriers) impacting on informed cancer treatment decision making.

- To explore what the patient knows and understands about their illness and treatments.
- To hear from patients, their experience of the diagnosis of their illness and decision-making process. (Physical, mental, emotional, and social aspects).
- To further understand patients' challenges making decisions about their treatment.
- To learn from patients what would make it easier for them to make informed decisions while achieving their desired role in decision-making.

Patient Interview Guide

Thank-you for agreeing to speak to me today about your experiences in making treatment decisions for your cancer.

NB: Mention participant number and date on recording

1. Firstly, please tell me a little about yourself (*a few minutes)*.
2. Thinking about when you were first diagnosed with cancer, share with me how that was? *(How were you feeling (physically, emotionally)? What were your thoughts at the time? Who did you talk to about your illness? Who was able to support you?*
3. What did you understand about your illness? (*Tell me what you know about your illness. What have the doctors told you about your illness? What do you think is happening in your body? Have you tried to find out more about your cancer and if yes, where, or how. If not, why?*
4. Thinking about making decisions about your treatment, share with me how that was? *(What do you remember about the appointment with the doctor to make the decision? How did you feel during the process of making treatment decisions? How did you make the decision? Would you have preferred to have a family member or friend present? Who did you speak to, other than the doctors, about your decision-making?*
5. When deciding about a serious illness like cancer, who would you prefer to make the decision? *Were you satisfied with how you made your decision, and why?)*
6. What do you know about your treatments? (*What have the doctors told you about your treatment? What do you know about the side effects (other effects on your body) of your treatment? Did knowing the side-effects affect your decision about treatment? If you could ask your doctor or nurse about your treatment, what would you like to know? Have you spoken to anyone else*

about your treatment or tried to find more information? -Who, where how? (e.g. social media, pamphlets, magazines, internet, word of mouth)

7. What would have helped you to understand your illness and your treatment better? *Would you have liked to have written information, or something you can listen, or watch (like a video), or some counselling about how to cope with cancer and treatment. (physically and emotionally)*
8. What do you expect from your treatment? (*What is your biggest hope with the treatment? What are your worries or fears about the treatment?*
9. What are your biggest challenges in getting the treatment you need? (*How does your day begin when you need to go to the hospital? What is the most difficult part of going to a hospital to get your treatments?)*
10. How would you like to be informed about your illness and treatment decisions? (This may have been partially answered before, may need clarification) (*Is there anything that would make it easier for you to talk to the doctor, or to understand what is being said about your illness and treatment? Have you thought about some of the difficulties doctors may have when talking to their patients about their illness and treatments?)*
11. What is the most important thing about you that you would like your doctor to know about? *(What would you like the doctor to understand about you and maybe your circumstances when talking about starting new treatment?)*
12. Is there anything you would like to say/talk about that we have not discussed today?

APPENDIX V: Paper 3. Focus group facilitator guide

Health Care Provider Focus Group Guide

Welcome and introduction to the study – rationale and aims.

Introduction to topics to be discussed.

Topics:

Health literacy

What do you understand by the term “health literacy”?

What do you think is the level of health literacy of patients in this clinic in general? (high, moderate, low)

Do you try to assess patients’ health literacy and how do you assess their health literacy?

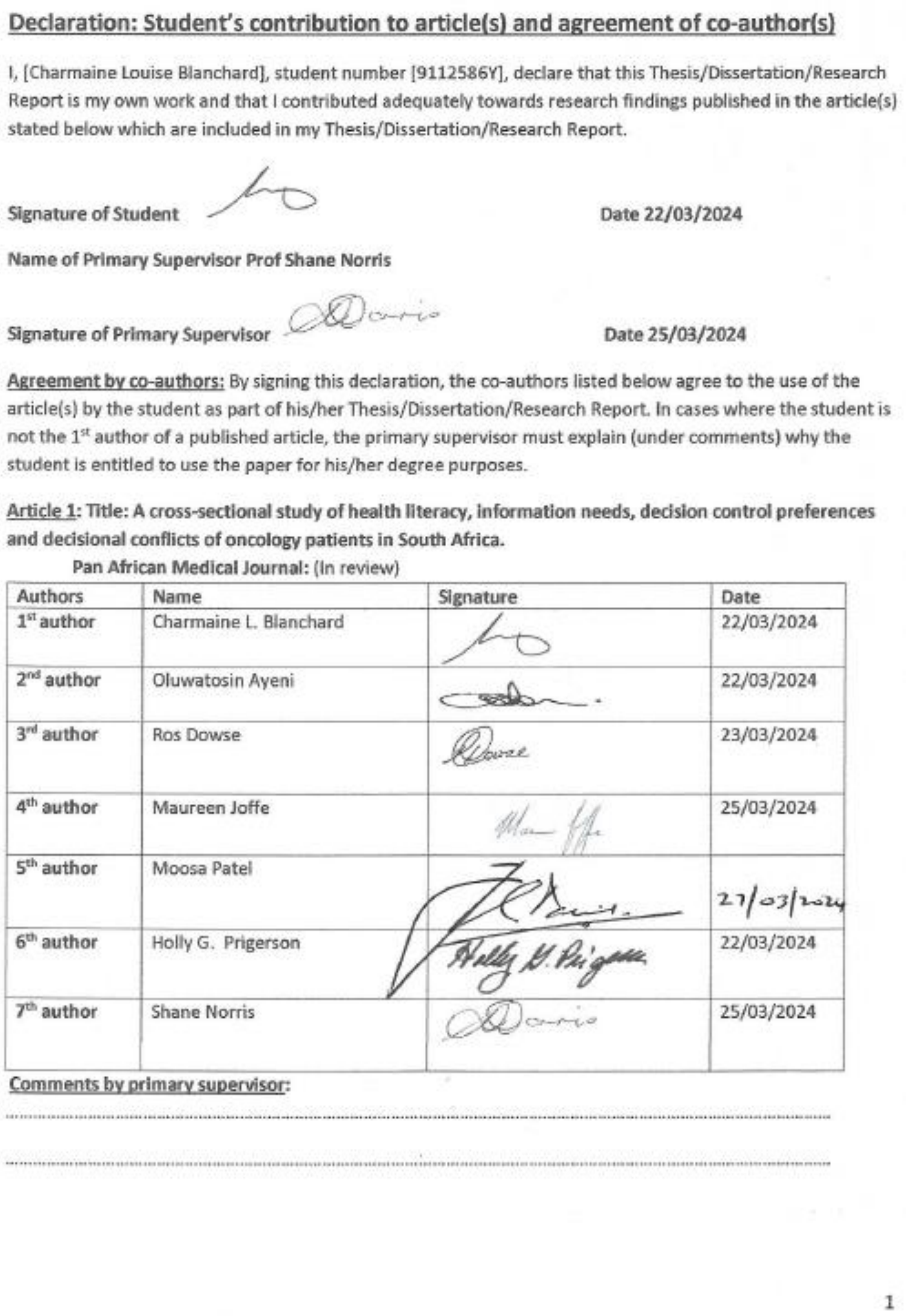
How do you adapt your approach depending on your assessment of the patient’s ability to understand?

Decision making

How do you think patients feel when making their chemotherapy decision? (They may have expressed this to you, or you may assess this from your interactions with them)	Exploring patient emotions, concerns, thoughts
What is the patients’ level of knowledge?	
Where do patients get their information?	
What makes the decision-making difficult for patients?	Personal characteristics or challenges, social circumstances, health system challenges
What are patients’ expectations of treatment?	Example: palliative chemotherapy
How do you help patients make decisions?	Patient education Patient support Patient decision role
What factors make it difficult for you (or the others in the clinic) to support your patients’ decision making?	
What factors make it easier for you (or the others in the clinic) to support your patients’ decision making?	
Who else besides yourself / the healthcare team, and the patient is usually involved in making this decision?	• Family, friends, other healthcare providers? • Do they tend to make the decision for the patient, share the decision-making or provide support for the patient to make the decision themselves?
What would help patients to make a chemotherapy treatment decision?	
Examples	
1. Counselling from a health practitioner (doctor, nurse, other health care team members). If so, what types of counselling?	
2. Discussion groups of people facing the same decision. If so, what type of groups	

3. Information materials: Content: Cancer, treatment, risks and benefits and probabilities, help evaluating for personal importance, guidance on steps of making a decision. Format: Booklets, pamphlets, Internet website links, internet-based decision tools, Videos/DVDs/audio, others?
Is there anything else that would help you to support your patients' decision making?
Is there anything else that you think is important to raise regarding patient informed treatment decision-making, which we have not covered in the discussion today?

APPENDIX W: Co-authors declaration



Declaration: Student's contribution to article(s) and agreement of co-author(s)

I, [Charmaine Louise Blanchard], student number [9112586Y], declare that this Thesis/Dissertation/Research Report is my own work and that I contributed adequately towards research findings published in the article(s) stated below which are included in my Thesis/Dissertation/Research Report.

Signature of Student **Date 22/03/2024**

Name of Primary Supervisor Prof Shane Norris

Signature of Primary Supervisor **Date 25/03/2024**

Agreement by co-authors: By signing this declaration, the co-authors listed below agree to the use of the article(s) by the student as part of his/her Thesis/Dissertation/Research Report. In cases where the student is not the 1st author of a published article, the primary supervisor must explain (under comments) why the student is entitled to use the paper for his/her degree purposes.

Article 1: Title: A cross-sectional study of health literacy, information needs, decision control preferences and decisional conflicts of oncology patients in South Africa.

Pan African Medical Journal: (In review)

Authors	Name	Signature	Date
1st author	Charmaine L. Blanchard		22/03/2024
2nd author	Oluwatosin Ayeni		22/03/2024
3rd author	Ros Dowse		23/03/2024
4th author	Maureen Joffe		25/03/2024
5th author	Moosa Patel		27/03/2024
6th author	Holly G. Prigerson	Holly G. Prigerson	22/03/2024
7th author	Shane Norris		25/03/2024

Comments by primary supervisor:

Article 2: **Title: A mixed methods review of oncology treatment decision support interventions amongst vulnerable populations.**

MDM Policy and Practice: (In review)

Authors	Name	Signature	Date
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2nd author	Patricia McInerney		25/03/2024
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4th author	Maureen Joffe		25/03/2024
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6th author	Holly G. Prigerson	Holly G. Prigerson	22/03/2024
7th author	Shane Norris		25/03/2024

Comments by primary supervisor: