Working towards patient-centred decision making in cancer care

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Submitted for fulfilment of the award of Doctor of Philosophy

in Behavioural Science in Relation to Medicine

Submitted December 2017

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THESIS

Declarations

I hereby certify that the work embodied in the thesis is my own work, conducted under normal supervision.

The thesis contains published scholarly work of which I am a co-author. For each such work a written statement, endorsed by the other authors, attesting to my contribution to the joint work has been included.

The thesis contains no material which has been accepted, or is being examined, for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968 and any approved embargo.

02/12/2017

Anne Herrmann Date

Acknowledgments

I am fortunate to have spent the two and a half years of my PhD candidature surrounded by colleagues, friends and family who provided me with the most supportive and enabling environment one could wish for.

Rob, I could enthuse over your inspiring thoughts on healthcare, your sharpness of thinking and your relentless efforts to “do the best research we can”. However, I decided not to. This is because what often struck me most was your kindness, compassion and support. I thank you for every lesson I learnt along the way and every conversation we had. Also, thank you for sharing a very distinct sense of humour and helping me become “a dinkum Aussie at last”.

Alix, thank you for going through every part of my work with an extraordinary degree of dedication and detail, and for sharing so much of your time and wisdom in such a generous and kind manner. I am grateful for every advice you gave me, and every laugh we had together. It still astonishes me how much you underestimate yourself. I think you are amazing, both as a researcher and a person.

Nick, thank you for opening the door to this PhD adventure and for providing me with many opportunities along the way. I am very grateful that you enriched my work with your clinical expertise (for instance by patiently answering every question on breast cancer I could think of).

To my colleagues and friends from the Health Behaviour Research Collaborative: You are one of the most helpful and hard-working bunch of people I have come across. I feel very fortunate to be a member of your team which has helped me grow in many ways. Specifically, I would like to thank future Dr Shepherd and future Dr Hyde for being the

best friends one could wish for. It is hard to express my gratitude for all the love, support and laughter you shared with me. Thank you amigos!

I would also like to thank the team of the Ethox Centre for both an exciting and enriching site visit at the University of Oxford. I had a great time and am looking forward to collaborating with you on future projects.

To my parents: Liebe Eltern, danke dafür, dass ihr die besten Eltern der Welt seid und mich in allen noch so ungewöhnlichen und ambitionierten Vorhaben unterstützt! Dank eurer unendlichen Liebe und Unterstützung habe ich alle möglichen Länder bereisen können, in dem Versuch herauszufinden, „was die Welt im Innersten zusammenhält“. Ich kann euch nicht dankbar genug sein. Ich hab euch ganz doll lieb. Eure Schnuspel.

To the Johns family: I am exceptionally grateful for the very warm welcome to your family and every joyful get together we had in the last years. Thank you for being so kind, generous and supportive. You always helped us out when we needed it most for which I cannot be thankful enough.

To my future husband: Thank you for always listening to all the ideas I told you about with sparkling eyes. Thank you for taking the backseat to my work too often. Thank you for “grounding me” when I needed it. I am looking forward to spending my future with an incredibly strong and amazingly humble man.

Finally, I would like to thank the patients, their support persons and the clinic staff who were involved in the studies included in my thesis. I believe we researchers cannot thank you enough for your time and effort. It allows us to do the best we can to help ensure that healthcare does not only cure diseases but cares for and about every individual patient and their family.

Funding support

I would like to recognise and thank the University of Newcastle and the Hunter Cancer Research Alliance for the scholarship support they provided me with. Also, I acknowledge both the Priority Research Centre for Health Behaviour and the Hunter Medical Research Institute for their funding and infrastructure support.

Editor's contribution

I would like to acknowledge Dr Gloria Webb from Jabiru Publishing for her role in professional editing and proofreading of this thesis. Dr Webb's role was in accordance with the University of Newcastle's Editing of Research Theses by Professional Editors Policy. Dr Webb has a PhD in Behavioural Science from the University of Newcastle and is experienced in editing theses in this and other academic fields.

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List of citations of publications included in this thesis

1. **Herrmann A**, Hall A, Sanson-Fisher R, Zdenkowski N, Watson R, Turon H: Not asking cancer patients about their preferences does make a difference. A cross-sectional study examining cancer patients' preferred and perceived role in decision making regarding their last important cancer treatment [submitted to *Supportive Care in Cancer*] (see Appendix 1.2)
2. **Herrmann A**, Hall A, Zdenkowski N: A qualitative study of women's experiences with deciding on neoadjuvant systemic therapy for operable breast cancer. *Asia-Pacific Journal of Oncology Nursing*. [e-publication ahead of print] (see Appendices 2.1 and 2.3)
3. **Herrmann A**, Zdenkowski N, Hall A, Boyle FM, Butow P: Exploring women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer. *Health Science Reports* 2017, e213. (see Appendices 3.1 and 3.3)
4. **Herrmann A**, Sanson-Fisher R, Hall A, Wall L, Zdenkowski N, Waller A: A discrete choice experiment to assess cancer patients' preferences for when and how to make treatment decisions. *Supportive Care in Cancer* 2017. [e-publication ahead of print] (see Appendices 4.1 and 4.3)
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6. **Herrmann A**, Mansfield E, Hall A, Sanson-Fisher R, Zdenkowski N: Wilfully out of sight? A literature review on the effectiveness of cancer-related decision aids and implementation strategies. *BMC Medical Informatics and Decision Making* 2016, 16(1):1-9. (see Appendices 6.1 and 6.3)

List of citations of additional relevant publications not included in this thesis

Published conference abstracts (see Appendices 7.1 and 7.4)

1. Zdenkowski N, **Herrmann A**, Hall A, Boyle FM, Butow P: Abstract P3-11-02: Women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer. *Cancer Research* 2017, 77, Supplement 4: P3-11-02-P13-11-02.

   [Poster citation: Herrmann A, Zdenkowski N, Hall A, Boyle FM, Butow P: Women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer. 39th Annual San Antonio Breast Cancer Symposium, 6th – 10th Dec 2016, iPoster URL: http://sabcs16.posterview.com/nosl/i/P3-11-02]

2. **Herrmann A**, Hall A, Zdenkowski N: Exploring how women make decisions on neoadjuvant systemic therapy (NAST) for operable breast cancer. *The Breast* 2016, 29, Supplement 1, S27.

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6. **Herrmann A**, Horn R: Overcoming some of the barriers to implementing advance directives and decision aids into clinical practice. Do we have to dig deeper? [submitted to *BMC Health Services Research*, in revision]
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8. Carey M, **Herrmann A**, Hall A, Mansfield E, Forshaw K: Exploring health literacy and preferences for risk communication among medical oncology patients [submitted to *Patient Education and Counselling*]
9. Mackenzie L, Mansfield E, **Herrmann A**, Grady A, Sanson-Fisher R, Evans TJ: Breast cancer patients' involvement in treatment decision-making: experiences, preferences and needs [submitted to the *Journal of Cancer Survivorship*]
10. Sanson-Fisher R, Forshaw K, Waler A, Bryant J, Mackenzie L, **Herrmann A**: Assessing segments of care along the treatment pathway [submitted to *Psycho-Oncology]*

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ABSTRACT

Many cancer patients have to choose between a variety of treatment options. Optimal cancer care should involve patients in their treatment decisions, to the extent they desire. It should align with patients' needs and preferences. Patient-centred decision making constitutes a core component of a high-quality healthcare system. However, it is not always delivered to cancer patients. This thesis examines cancer patients' preferences for and experiences with making treatment decisions. It consists of six papers, an introduction and a discussion. The findings of this thesis make an important contribution to increasing our understanding of how treatment decision making could be improved in clinical practice. The introduction provides an overview of the literature on patient-centred decision making and its relevance to cancer care in Australia and worldwide. The six manuscripts included in this thesis report on the findings of two quantitative and one qualitative study of cancer patients and their support persons who were recruited from medical and radiation oncology waiting rooms of treatment centres across New South Wales and Victoria. The thesis aims to:

1) Examine whether not asking cancer patients about their decision-making preferences is associated with their care experience (Paper One)
2) Explore in-depth how cancer patients made a difficult treatment decision (Paper Two), and which strategies could be used to assist with this process (Paper Three)
3) Examine cancer patients' (Paper Four) and their support persons' (Paper Five) preferences for the number and length of consultations and the format of information provided when making a cancer treatment decision
4) Review the literature on decision aids to examine where research effort has been directed to over time, and where the focus of future studies should lie (Paper Six)

The thesis concludes with a discussion summarising the key findings and outlining the potential implications for future research and clinical practice. The strengths of this thesis include using both qualitative and quantitative methods to assess cancer patients' decision-making preferences and experiences. Methodologically robust and innovative approaches were employed to collect and analyse data from heterogeneous samples of Australian cancer patients and their support persons. Following a mixed-methods approach, the qualitative data was used to develop strategies to improve patient-centred decision making in cancer care. The generalisability of these strategies was examined with the help of a larger, more heterogeneous sample of cancer patients and their support persons using a cross-sectional design. The integration of this data informed the development of an intervention which is described in the discussion section of this thesis. The thesis limitations include the restriction to English-speaking cancer patients, over-representation of female breast cancer patients and the use of a cross-sectional design. Recommendations for how future research could extend on the thesis findings are provided, including suggestions for a cluster randomised controlled trial that should investigate the impact of different consultation styles on patient outcomes.

EXPLANATORY OVERVIEW

Deciding on their cancer treatment can be very challenging for patients. They are often confronted with an array of information on the potential benefits and risks of the treatment options available to them, and have to cope with the distress and anxiety related to their cancer diagnosis. Individual patients vary considerably in their preferences for how decisions regarding their treatment should be made. Optimal patient-centred cancer care should include that clinicians elicit patients' preferences and tailor their care accordingly. The publications included in this thesis make an important contribution to describing cancer patients' experiences and preferences for deciding on their cancer treatment. The findings of this body of work highlight the need for clinicians to ask patients about their decision-making preferences, and to consider offering patients two consultations, along with written and online information regarding their treatment options.

This thesis by publication includes an introduction, six manuscripts and a discussion providing thesis implications and conclusions. The manuscripts included in this thesis report findings from a literature review, two cross-sectional surveys and one qualitative study of cancer patients and their support persons who were recruited from medical and radiation oncology waiting rooms of treatment centres across New South Wales and Victoria. This thesis uses a mixed methods approach. The qualitative data informed the development of strategies to improve patient-centred decision making in cancer care. These strategies were then presented to a larger, more heterogeneous sample of cancer patients and their support persons to test the generalisability of the findings. The data was synthesised to provide suggestions for clinical practice and help develop an intervention which is described in the discussion section of this thesis and may be tested by future research. All papers have been submitted to peer-reviewed journals. Four papers have been published.

The **Introduction** describes the concept of patient-centred care as a model for optimal healthcare. It is argued that involving patients in their healthcare decisions is a crucial component of patient-centred care. A brief overview of the burden of cancer in both the global and the Australian context is used to highlight the need for a patient-centred approach towards cancer treatment decisions. The literature on cancer patients' experiences with deciding on their treatment is reviewed, and barriers to delivering optimal patient-centred decision making are identified. The introduction concludes by pointing out the need to deepen our understanding of cancer patients' experiences and preferences for making difficult treatment decisions and the factors that should be taken into account when designing and implementing decision support for patients. It is argued that having such knowledge will progress both the research and the implementation of patient-centred cancer care.

If care is to align with patients' needs and preferences, it is important that clinicians elicit cancer patients' wishes regarding how to make treatment decisions. However, no study has assessed whether not asking cancer patients about their preferences might have an impact on their care experience. **Paper One** addresses this gap. It reports on the findings of a cross-sectional study which was part of a larger study aimed at identifying areas of need for cancer patients. The findings suggest that almost a third of cancer patients (31%) did not attain their preferred involvement in decision making. Most of these patients (72%) were less involved than they would like to be. The data also indicate that patients who were not asked by their clinicians how involved they would like to be, although they wanted this, had higher odds of reporting discordance between their preferred and perceived level of involvement in their treatment decision.

It has been argued that deciding on cancer treatment can be a complex and complicated process. Little is known about the social processes that underlie decision making between

patients, their support persons and their clinicians. **Paper Two** examines in-depth a treatment decision that can be particularly difficult for patients by exploring women's experiences with deciding on having neoadjuvant systemic therapy (NAST) prior to surgery. This study was part of a larger intervention trial testing the effectiveness of a decision aid designed to facilitate this decision. While survival outcomes are equivalent for both NAST and upfront surgery, the decision about treatment sequence can be difficult due to its complexity and perceived urgency. The findings suggest that a number of women felt overwhelmed and perceived they were not offered a treatment choice. Women struggled with comprehending the preference-sensitive nature of the decision on NAST and facilitated decision making by reducing deciding factors. Most women reported that they made the final decision although they did not feel actively involved in the decision-making process. They appreciated being provided with additional written information and having some time to consider their options before making a decision.

Paper Three examines in-depth women's use and perceived benefit of a decision aid provided in-between two consultations. Like Paper Two, it reports on the findings from a qualitative study which draws on data obtained from a larger intervention trial. Patients perceived the decision aid as useful for becoming more informed and involved in making a decision as to whether they receive NAST. Patients' ability to review the decision aid at home in-between the consultations with their surgeon and their medical oncologist allowed women to better understand their treatment options and confirm their decision. This seemed to be an acceptable and feasible way of integrating the decision aid into patients' care.

Based on the findings of the qualitative studies, **Paper Four** broadens the focus of this thesis by using a large heterogonous sample of cancer patients to examine their preferences for different characteristics of oncology consultations. This study was part of

a larger cross-sectional study comparing patients', support persons' and oncologists' perceptions of different aspects of cancer care. Paper Four assesses cancer patients' preferences for: i) attending one 40-minute consultation or two 20-minute consultations, and ii) receiving written only or both written and online information, when making a cancer treatment decision. Most patients (70%) preferred being provided with written and online information rather than just written information. Statistically significantly more patients preferred two shorter consultations rather than one longer consultation when this was combined with written and online information ($p < 0.01$). Providing this consultation style may help patients "digest" the presented information and support them in making informed treatment decisions.

If care is to be patient-centred, it needs to incorporate patients' preferences and sociocultural factors, such as support persons' wishes. Cancer patients' support persons often play an important role in making treatment decisions. Support persons can be the most important information source for patients who often value their support persons' involvement in treatment decision making. **Paper Five** examines cancer patients' support persons' preferences for the consultation styles examined in Paper Four. It also compares patients' with support persons' preferences. The findings highlight that most support persons preferred to receive two shorter consultations and both written and online information when making a cancer treatment decision. No statistically significant difference in the proportions of support persons' and patients' preferences for the other options was found. Both patients and support persons seem to be driven by the same preferences for how to make cancer treatment decisions. The results of Papers Four and Five suggest that clinicians should consider offering two consultations and information on the available treatment options presented in multiple formats.

Providing two consultations along with additional information in-between these consultations could facilitate the implementation of decision support strategies, such as decision aids. Decision aids provide specific, evidence-based information on the available healthcare options. They aim to engage patients in the decision-making process and to guide them towards making decisions that align with their preferences. Little is known about the direction and progression of research effort in this area over time. **Paper Six** is a literature review which helps fill this gap. It highlights that while the number of studies testing the effectiveness of decision aids has increased, the majority of research has focused on screening and prevention decision aids for only a few cancer sites. Also, there is little attempt to translate evidence into meaningful benefits for patients.

The **Discussion** describes the key findings of this thesis and outlines the potential implications of these findings for future research and clinical practice. The strengths of this thesis include the use of both qualitative and quantitative methods to assess cancer patients' preferences for and experiences with deciding on their treatment. Methodologically robust and innovative approaches were employed to collect and analyse data from heterogeneous samples of Australian cancer patients and their support persons. The thesis limitations include the restriction to English-speaking cancer patients, over-representation of female breast cancer patients and the use of a cross-sectional design. Future research should employ intervention studies to investigate the impact of different consultation styles on patient outcomes. A cluster randomised controlled trial is proposed to address this gap.

INTRODUCTION

I1. Healthcare should be focused on the patient as a person, not just the disease itself

I1.1 The rise of patient-centeredness as a model for optimal healthcare

Healthcare is shifting from a paternalistic, doctor-centred approach to a patient-centred approach, focusing on the patient as a person [1]. This is based on deep respect for patients as unique human beings, and the obligation to provide care according to what is meaningful and valuable to the individual patient [2]. It has also been recognised that in modern medicine there is often not a single best type of treatment [3]. For example, Charles and colleagues have suggested that treatment decision making has become "murky" and complex, involving different types of trade-offs between the risks and potential benefits of the treatment options available to patients [4]. As a result, patient-centred care has been passionately supported by researchers, patient advocates and policy-makers worldwide [5]. Awareness of the patient-centred model was heightened by the 2001 Institute of Medicine report *'Crossing the Quality Chasm'*, which defined patient-centred care as a core component of a high-quality healthcare system [6]. In 1999, the US National Cancer Board released its influential report *'Ensuring Quality Cancer Care'*, further advocating for the idea of putting the patient as a person at the centre of healthcare service delivery [7].

I1.2 What is patient-centred care?

The concept of patient-centred care has been widely advocated but not always been well-understood [8]. It has often been defined by what it is not. For example, it is not technology-centred, doctor-centred or disease-centred [8]. Mead and Bower have reviewed the literature on patient-centred care and identified five conceptual dimensions: i) a biopsychosocial perspective on illness and health, considering social and psychological factors alongside biomedical factors; ii) the 'patient-as-person',

understanding the personal meaning of the illness for each individual patient; iii) sharing power and responsibility between doctor and patient; iv) the therapeutic alliance, attending to the social and emotional aspects of consultations to optimise therapeutic potential; and v) the 'doctor-as-person', awareness of the influence of the personal qualities and emotions of the doctor on the doctor-patient relationship [1].

Based on this definition, patient-centred care means that the doctor and patient build a relationship based on mutual understanding, compassion, empathy and trust [9]. Patient-centred care takes into account patients' needs and preferences and tailors care accordingly [10]. This involves a number of domains and requires that healthcare services: i) are responsive to patients' needs, values and preferences; ii) are integrated and co-ordinated; iii) relieve physical discomfort; iv) provide emotional support; v) allow for the involvement of family and friends; and vi) support the provision of information and communication to enable patients to understand their options and make informed healthcare decisions [6, 11].

I1.3 What are the benefits of patient-centred care?

Providing patient-centred care has been found to improve a number of patient outcomes. Steward and colleagues conducted an observational cohort study with 39 family physicians and 315 of their patients in order to assess the association between patient-centred communication in primary care visits and subsequent health and medical care utilisation [12]. Patient-centred communication was associated with better recovery for patients in terms of less discomfort, better emotional health, and fewer diagnostic tests and referrals [12]. Further studies have confirmed that the implementation of patient-centred care could improve the use of resources in healthcare and decrease healthcare-related costs [21, 22].

It has been shown that patient-centred consultations are associated with patients feeling respected, involved, engaged and knowledgeable about their disease and treatment options, which might mitigate patients' distress and concerns associated with their illness [2, 13]. Studies suggest that delivering patient-centred care can decrease patients' symptoms and improve patients' physiologic outcomes [14, 15]. Also, it has been argued that delivering patient-centred care can increase patients' satisfaction with the consultation and their clinician [14, 16, 17]. For example, in a sample of 177 physicians and 670 patients, Krupat and colleagues found that patients were highly satisfied with their doctors if their doctors' orientations and preferences towards the consultation were either as patient-centred or more patient-centred than those of patients. Comparatively, it was found that patients whose doctors were not as patient-centred were significantly less satisfied [18].

I1.4 Do patients want patient-centred care?

There is considerable evidence to suggest that patients wish to receive a patient-centred approach towards their care. Little and colleagues surveyed a representative sample of 824 patients in a primary care setting about their preferences for patient-centredness in the context of an impending consultation with a doctor [19]. Factor analysis identified three domains of patient-centredness patients were likely to prefer: i) communication, which included patients wanting their doctor to listen to everything they have to say about their problem, explore their concerns and requirements for information, and clearly explain the problem and what should be done (agreed with by 88-99%); ii) partnership, which included particular aspects of communication to find "common ground", such as discussion of and mutual agreement about the patient's problem and treatment (77-87%); and iii) health promotion, which included advice on how to stay healthy and reduce the risks of future illness (85-89%) [19].

It has been argued that patients strongly desire all aspects of a patient-centred approach [20]. Particularly, studies have shown that most patients want to be well-informed about their disease status and treatment options [21-23]. Choice seems to have an intrinsic value for patients, as the majority of patients appear to like the idea that they should be offered choices regarding their care, such as the choice of clinician and, in particular, the choice of treatment [24]. Although there has been debate about whether offering treatment choices might confuse patients and increase their anxiety, considerable evidence suggests that patients want to be asked about their preferences for which action to take [25]. The vast majority of patients want their clinicians to take their wishes and preferences into account when making decisions on their care [26].

I2. Patient-centred decision making is key to patient-centred care

I2.1 Patient-centred care requires involving patients in medical decision making, to the extent they desire

Following the principles of patient-centred care, medical decision making should be a shared, collaborative process [10]. This means that clinicians, patients and their support persons should establish a partnership to ensure that healthcare decisions are based on joint participation and mutual agreement [5, 11]. For example, a recent Cochrane review examining the effects of interventions designed to promote a patient-centred approach in clinical consultations, emphasised that patient-centred care may involve sharing control of the consultation and decisions about health management interventions between the doctor and patient [27]. In this review, shared decision making is considered a key factor of patient-centred care.

I2.2 What is decision making in healthcare?

Decision making in healthcare can be a complex process. It requires that the doctor and patient come to a judgement about which of a number of healthcare options is best at a given time [28]. This includes that the doctor and patient: i) identify alternative courses of action; ii) identify possible consequences of each action; iii) assess the probability of each consequence occurring; iv) choose the best alternative; and v) implement the decision [28]. Given that decision making in healthcare should be based on mutual participation and respect, Rimer and colleagues add that in order to make an informed healthcare decision, doctors and patients need to understand patients' values and preferences and clarify patients' decisional preferences [29].

I2.3 What is patient-centred decision making?

Patient-centred decision making includes that patients understand their condition being addressed and comprehend what each healthcare option available to them involves [30]. This includes understanding each option's benefits, risks, limitations, potential alternative, and uncertainties. Patients need to consider their own preferences, participate in decision making, to the degree they desire, and make a decision consistent with their preferences [31]. Thus, patient-centred decision making is respectful of and responsive to patients' needs and preferences [5].

Clinicians have been encouraged to support patients with making decisions based on their informed preferences [27, 32, 33]. To do this, clinicians need to understand and respond to patients' wishes for the information they would like to receive and how involved they would like to be in the decision-making process [34]. This may mean that a patient chooses not to decide on their care but leaves the decision up to their clinicians [35]. Consequently, patient-centred decision making differs from the idea of shared decision making which assumes that doctor and patient contribute equally to deciding on a

particular healthcare option and share the responsibilities for the decision being made [36].

I2.4 Four reasons why patient-centred decision making should be part of routine healthcare

I2.4.1 Patient-centred decision making has been passionately supported by patients and policy-makers worldwide

"Nothing about me without me" has been a guiding principle for patients, policy-makers and patient advocates all over the world. The catchphrase was adopted by participants from 29 countries at a 1998 Salzburg global seminar [24]. The seminar was convened to develop ideas regarding how to improve the quality of healthcare by involving patients [24]. Since then, numerous initiatives have been developed to promote the idea of involving patients in their healthcare decisions, to the extent they desire. The slogan, "*Nothing about me without me"*, also guided the United Kingdom government's plan for improving the National Health System in England, identifying patient choice and shared decision making as key components of a patient-centred and quality-focused healthcare system [24]. In Australia, the idea of involving patients in their healthcare decisions has been included in the Charter of Healthcare Rights which was endorsed by the Australian Health Minsters in 2008 who recommended its use nationwide [37]. The Charter outlines the roles of patients, clinicians and health service organisations across different facets of healthcare. It states: "*To obtain good health outcomes, it is important for patients and consumers to participate in decisions and choices about their care and health needs. This provides the basis for informed consent and informed decision making*" [38].

I2.4.2 There is an ethical imperative for providing patient-centred decision making

Patient autonomy is a guiding principle of modern medicine [39]. It protects the integrity of the patient as an independent and rational decision maker who is capable of self-

determination [40]. Clinicians have a responsibility to facilitate patient autonomy in healthcare decision making, as patients and their support persons are the ones who need to manage the consequences of these decisions [41]. Consequently, it has been argued that there is an ethical obligation to involve patients in their healthcare decisions, to the extent they desire [42]. A patient-centred approach towards medical decision making differs from decision making under the doctrine of informed consent. Whereas informed consent emphasises clinician disclosure, a patient-centred approach towards decision making advocates for mutual agreement and joint participation. The latter approach is considered to be of a higher ethical standard than simple informed consent [31].

I2.4.3 Patient-centred decision making may decrease both costs to the healthcare system and clinical practice variation

There is evidence to suggest that involving patients adequately in their healthcare decisions can decrease costs to the healthcare system by minimising costs associated with counteracting unnecessary psychosocial distress for the patients and costs associated with unnecessary treatment [43, 44]. For example, it has be shown that some clinicians are unsure about how to talk to terminally ill cancer patients about their prognosis [45]. This might hinder adequate education and informed decision making on aggressive or futile treatment options at the end of life, such as chemotherapy, which is received by a number of cancer patients in the last six months of their lives [46].

Also, it has been argued that in many cases clinicians' professional judgements and preferences, rather than patients' preferences, determine which treatment a patient receives, and this can result in clinical practice variation [47]. For example, clinicians vary in their preferences for providing invasive or conservative treatments [48, 49]. Depending on which clinician a patient sees, they might receive varying recommendations regarding the "right" treatment choice. Involving patients in their

healthcare decisions, to the extent they desire, may decrease practice variation by making treatment decisions based on patients' rather than physicians' preferences [50]. Also, through a combination of education and participation, patients who participate in the decision-making process may be less ready to accept aggressive treatments [51].

I2.4.4 Patient-centred decision making can improve patient outcomes

Actively involving patients in their healthcare decisions can decrease patients' unmet information needs, and their decisional conflict, anxiety and distress [36, 52-54]. It can increase patients' knowledge and understanding of their healthcare options, and improve patients' satisfaction with their healthcare consultations [55, 56]. It has been suggested that actively involved patients have higher trust in their clinician [57]. They seem to be more confident in their own decisions and elect to have less invasive procedures [58, 59]. Their decisions appear to be based on more accurate expectations about the negative and positive consequences of a procedure and are more consistent with patients' personal values and preferences [42]. Actively involved patients often have higher physical and social functioning and significantly less fatigue [60]. A patient-centred approach towards medical decision making can ultimately improve patients' overall quality of life [61, 62]. Involving a patient's support persons in the decision-making process may have similar positive impacts on patient outcomes [63-65]. For example, patients who are accompanied by their support persons have been shown to have higher recall rates and are likely to benefit from the extra information that their companions remember [63]. Support persons can further assist patients in becoming actively involved in deciding on their care and help patients feel more certain about their decisions [64, 66].

I3. Why focus on patient-centred decision making in cancer care?

I3.1 Cancer affects millions of people worldwide

It has been estimated that 14.1 million new cancer cases and 8.2 million cancer deaths occurred worldwide in 2012 [67, 68]. The most commonly diagnosed cancers were lung, breast, and colorectal cancer [67]. The most common causes of cancer death were lung, liver, and stomach cancer [67]. In Australia, cancer is the leading cause of death, surpassing cardiovascular disease [69]. It has been estimated that 130,466 new cancer cases were diagnosed in Australia in 2016 [69]. On average, one in two men and one in three women will be diagnosed with a form of cancer during their lifetime [70]. In 2008-2012, male cancer patients had a 67% chance of surviving for five years compared with the general Australian population, while female cancer patients had a 68% chance [69]. Cancer incidence rates have been increasing over the past decades [71, 72]. Simultaneously, medical progress has resulted in a growing number of cancer prevention, screening and treatment options. Many cancer patients are thus confronted with a variety of healthcare options available to them. They may be faced with complex and challenging decisions regarding their care [36].

I3.2 Cancer treatment decisions can be particularly difficult for patients

More and more cancer treatment decisions are probabilistic which can create ambiguity and uncertainty among doctors and patients [36]. Many of these decisions involve options which show similar medical effectiveness but have various side-effects and impacts which may be valued differently by different patients. Such decisions are called “preference-sensitive” [73, 74]. Preference-sensitive decisions can be complex and very difficult for patients, as the “best choice” cannot be pre-defined. It depends on patients’ preferences and often involves weighing-up uncertain risks against uncertain benefits of the options available to patients [36]. For example, patients may have to be willing to

trade-off slightly higher survival rates against severe treatment side-effects [75-77]. Patient-centred care is particularly relevant to these patients to ensure they receive healthcare that is in line with their needs and preferences.

Many cancer patients are anxious when facing the threat of their disease and the options available to them [78, 79]. After receiving their cancer diagnosis, patients often have much information to consider and need to cope with the distress of the potential outcomes of their disease and treatments [80, 81]. Many patients receive a cancer diagnosis for the first time and have no experience to guide them through complex treatment decision-making processes [41]. Further factors, such as patients' age, beliefs and current life situations, can impact on patients' treatment decisions [82, 83]. For instance, whether the treatment would affect their ability to have children in the future may impact on patients' treatment decisions. Making preference-sensitive decisions in such emotionally charged situations can be very challenging for patients, their support persons and the treating clinicians [49, 84]. To ensure optimal, patient-centred care is delivered to these patients, it is crucial that they are involved in their treatment decisions, to the extent they desire, and that they are adequately supported in making such decisions. This can help maximise patient outcomes [36, 66, 85].

I3.3 Providing patient-centred decision making can be difficult because patients' preferences for information provision and decision making vary

Although the majority of patients want to take an active role in deciding on their care, not every patient wishes to be involved in difficult treatment decisions [35]. Previous research suggests that there are considerable differences in patients' willingness to participate in making healthcare decisions [86, 87]. Also, patients vary in their preferences for which and how much information they wish to receive and the way in which the information is presented to them [88, 89].

Patient characteristics, such as age, gender, socioeconomic status, religion and cultural background, can influence their preferences for information provision and involvement in decision making [87, 90]. For example, younger and female patients seem to prefer taking a more active role in medical decision making than older and male patients [86, 91]. It has been suggested that patients from lower socioeconomic levels often have less knowledge and understanding of the options available to them and prefer a more passive role towards decision making than patients from higher socioeconomic levels [92-94]. Patients with a lower socioeconomic status also often overrate the degree to which they have been informed about and understand their diseases [95]. This results in a disconnect between apparent high patient satisfaction with care and poor understanding and participation in care [96].

Patients' preferences for information provision and decision making can change over time, for instance, when situational factors change, such as a patient's disease status [86, 97]. Butow and colleagues surveyed 80 cancer patients attending outpatient consultations with their medical oncologists at a university teaching hospital [83]. They found that patients whose condition had recently worsened were more likely to want less involvement in decision making [83]. Degner and colleagues conducted a cross-sectional study with 1012 women with a confirmed diagnosis of breast cancer who were scheduled for a visit at one of four participating hospital oncology clinics [89]. They found that breast cancer patients who had been diagnosed for less than six months were less likely to prefer an active role than those who had been diagnosed for more than six months [89]. Given the potential differences and changes in patients' wishes regarding information provision and decision making, it can be difficult for clinicians to understand patients' preferences and tailor care accordingly [98, 99].

I3.4 Cancer patients do not always feel adequately supported when deciding on their treatment

Patients are often dissatisfied with the amount and nature of information they receive during consultations with their clinicians [100]. Many patients point out gaps in cancer care with respect to reviewing information, asking questions, obtaining answers, and making decisions [101, 102]. Many patients do not feel as involved in medical decision making as they would like to be [103, 104]. Some patients receive a more directive, less participatory consulting style, which is characterised by less information giving and less partnership building from their doctor [105]. Such disadvantages are often due to clinicians' misconceptions about patients' desire and need for information and their ability to be involved in their care [105]. Although evidence-based guidelines for effective communication in healthcare have been developed to guide a patient-centred approach towards medical decision making [106, 107], many clinicians fail to effectively elicit patients' decision making preferences and enable patients to take a collaborative role in decisions regarding their cancer treatment [108-111].

It has been suggested that many clinicians are reluctant to relinquish their role as the single, paternalistic authority in the decision-making process [112]. Some resist training designed to help them become more effective coaches, or partners, who help patients make difficult healthcare decisions [66, 113]. This might include asking the patient, *"What is the matter?"* and *"What matters to you?"* [66]. Say and Thomson argue that clinicians may not have the necessary competences for appropriate patient involvement in decision making, with communication of risks related to cancer and its treatment remaining particularly challenging [32]. Gravel and colleagues conducted a systematic review incorporating the views of more than 2784 health professionals from 15 countries on barriers and facilitators to the implementation of shared decision making in clinical

practice [114]. They suggest that clinicians may be screening a priori which patients they believe are eligible for active involvement in decision making. This is concerning, given that clinicians may misjudge patients' decision-making preferences [114]. Further studies have found that clinicians ask for patients' preferences about which healthcare option they would like to choose only about half the time [111, 115]. For example, Zucca and colleagues conducted a cross-sectional survey of 244 medical oncology outpatients about their clinicians' asking behaviours across six dimensions of patient-centred care defined by the Institute of Medicine [116]. They found that 56.71% (n = 117) of patients did not report to have been asked about their concerns and preferences, or volunteered this information, on at least one indicator of patient-centred care. Younger age, not being born in Australia, and higher educational qualifications were associated with being infrequently asked [116].

I3.5 What are the impacts of insufficient decision support for cancer patients?

Failure to adequately inform and involve patients in their treatment decisions has been shown to increase patients' distress and anxiety, and to lead to treatment decisions which do not align with patients' needs and preferences [43]. Further adverse effects include patients' non-adherence to their therapy and increased likelihood of patients declining all or part of their recommended cancer treatment [117, 118], patients' use of costly alternatives to the therapy suggested by their clinician [119] and patients' exposure to drug interactions [120].

If patients are not adequately informed about their options and involved in their treatment decisions, this may result in litigation and substantial costs to the healthcare system [121]. The anxiety of patients who experience poor communication with their doctors results in the need for increased time and effort to counteract the resultant distress and misinformation [44]. Patients' dissatisfaction is also reflected in the substantial number

of healthcare complaints. For example, in 2015-16, the Australian New South Wales Healthcare Complaints Commission received 6,075 complaints, an increase of 15.4% on the previous year [122]. The most common areas of complaint were about treatment (42.3%) and communication (17.2%). With regard to complaints about treatment, the most common issues were inadequate treatment (34.8%), unexpected outcomes (14.6%), and diagnosis (11.7%). Other common issues in this category were inadequate care (11.6%), delay in treatment (6.6%), and inadequate or inappropriate consultations (5.3%). With regard to communication complaints, more than half of the issues concerned the attitude and manner of the health practitioner (57.6%). Other communication-related issues were inadequate (31.2%) or incorrect/misleading information provided by the clinician (9.9%) [122].

I3.6 Interventions have been developed to improve patient-centred decision making

Various interventions have been designed and tested to help patients become adequately informed and involved in deciding on their treatment. For example, providing audiotapes of consultations has been found to increase how much information patients remember [123]. Recalling the provided information on available treatment options is important for patients' understanding regarding the decision to be made and their ability to participate in the decision-making process [124]. Also, question prompt lists have been developed to facilitate a patient-centred approach towards medical decision making [125]. Question prompt lists consist of a structured list of questions that patients may wish to ask their doctors about their disease and treatments [125]. They help patients ask questions during the consultations with their doctors and encourage patients to take a more active role in the decision-making process [126]. Further interventions include coaching sessions for

clinicians and patients to help improve patient participation in decision making and their information-seeking skills in the consultation [127].

One strategy that has received a lot of attention and research effort are patient decision aids. Patient decision aids provide specific, evidence-based information on the available healthcare options and aim to assist patients with clarifying and communicating the value they associate with each option [128].[1] Decision aids are designed to engage patients in the decision-making process and to guide them towards making deliberated healthcare decisions that align with their preferences [129]. Decision aids explicitly state the decision to be made and explain in detail the risks and benefits of the options available to patients. Thus, they help patients comprehend and weigh up the risks and benefits of the options available to them and support patients in clarifying their preferences [130]. Decision aids supplement the consultation, rather than replace it. They can be provided before, during or after the consultation [131]. Decision aids are available in various formats, such as face-to-face, written booklets and web-based tools [56].

I3.7 What are the benefits of such interventions?

Interventions to increase patient involvement in medical decision making have been shown to improve a number of patient outcomes, such as increased patient satisfaction with their consultations, increased knowledge and understanding of the healthcare options available to them, and decreased decisional conflict related to feeling uninformed and unclear about their personal values [127, 132]. For example, considerable research effort has been directed towards testing the effectiveness of decision aids [59, 133-138]. A number of Cochrane reviews have suggested that decision aids are effective in improving certain patient outcomes. The first Cochrane review on the effectiveness of decision aids was published in 2001. It concluded that decision aids can improve patients' knowledge

[1] Hereafter referred to as decision aids.

about the options available to them, reduce their decisional conflict related to feeling uninformed, and help patients become more active in decision making [139]. Updated versions of this review, published in 2003, 2009, 2011 and 2014, supported these findings [56, 140-142].

I3.8 Barriers to delivering patient-centred decision making in cancer care have been identified

Despite their apparent effectiveness, the uptake of decision support strategies in day-to-day cancer care remains low [66, 143]. Efforts have been made to improve the implementation of patient-centred decision making. Research has identified a number of barriers indicating significant resistance to the use of decision support strategies. Some of the main barriers are briefly discussed below.

I3.8.1 System-related barriers

Research on decision support strategies operates in a policy context where little or no rewards or incentives exist to promote the use of such strategies [143]. For example, decision aids' healthcare accreditation is lacking [112, 144]. It has been suggested that healthcare organisation priorities fail to mandate the use of decision support strategies, such as decision aids, as a quality indicator or as a requirement for obtaining informed consent [145]. Also, decision support strategies may result in an overall reduction in demand for more invasive procedures [56]. This could potentially lead to reductions in clinicians' workload, waiting lists and/or costs, and may motivate healthcare professionals, administrators and organisations to use them [146]. However, device manufacturers, pharmaceutical suppliers and fee-for-service clinicians may fear negative financial implications if patients choose less aggressive treatments as a result of informed choice [112, 147]. Several studies have suggested that financial implications might influence clinicians' treatment recommendations [148-150].

Also, developing, testing, distributing and maintaining decision support strategies can be costly, and this may hinder their development and implementation [145]. Many sites do not have an organised, consistent way of providing appropriate decision support to patients to facilitate its use in routine care [151, 152]. In 2006, the National Health and Medical Research Council (NHMRC), Australia's leading expert body for the development and maintenance of public and individual health standards, summarised system-related barriers to effective patient participation in medical decision making in Australia [153]. The NHMRC highlighted that: i) the infrastructure of healthcare organisations often does not support patient participation; ii) organisations lack skills and confidence in collaborating with patients; iii) patients need skills in presenting their views and advocacy; iv) vulnerable groups have little opportunity for input; v) there are weak links between health information developers, patients and community organisations; and vi) the dissemination of health information often occurs without patient input [153]. Little has been achieved in tackling the barriers identified in this report [38, 154].

I3.8.2 Barriers related to clinicians and the design of decision support strategies

Many clinicians are not aware of the need for decision support strategies or their benefits, and report insufficient training in the area of patient-centred decision making [155, 156]. It has been suggested that some clinicians might prefer to play the role of the single authority in the treatment decision-making process and thus often fail to implement patient-centred decision making in routine care [32, 113, 145, 157]. Some clinicians may, unwittingly, subvert patients' involvement in treatment decisions by assuming that in a life-threatening situation there are no "real options" [108, 158]. Consequently, patients might feel pressured to accept certain treatments [159, 160].

Clinicians' time constraints and concerns about how to integrate decision support strategies into their workflow are further barriers to implementing such strategies into

day-to-day clinical practice [32, 98]. There may also be the assumption that evidence-based strategies are already being used in practice. For example, O'Brien and colleagues reported that some clinicians have high confidence in their own communication skills and believe that patients fully understand the information they have conveyed [161]. Clinicians in this study reported the use of informal decision support, such as hand-drawn diagrams designed to explain treatment options [161]. Although such informal decision support is often not subject to objective quality control, some clinicians have argued that there is no need to conduct research to implement evidence-based decision support into routine care [161].

Also, there has been a lack of guidance about quality standards for the development and evaluation of decision support strategies [144, 162, 163]. Many clinicians express concerns about how comprehensive and current the contents of decision support strategies are [112]. Others have raised concerns about whether the use of decision support can actually improve patient outcomes or the decision-making process [114]. There are reservations about information overlap and overload, and about how appropriate the provided content is for different patient populations and clinical situations [114, 164].

I3.9 Research on how to improve patient-centred decision making in cancer care is lacking

Perhaps the effort to implement strategies to improve patient-centred decision making was made too early. More research is needed to address the underlying social processes of patient decision making which may mitigate the implementation of a patient-centred approach [143]. This reflects more general theoretical findings on how to drive change in clinical practice. For example, Grol and Wensing have argued that to bridge the gap between scientific evidence and patient care we need an in-depth understanding of the barriers and incentives to achieving change in practice [165]. Various factors, such as the

nature of the consultation or the type of information provided, may affect the successful implementation of decision support for patients [166, 167]. We need to better understand how such factors impact on cancer treatment decisions before we can improve patient-centred decision making in routine cancer care. Future research should try to overcome the identified limitations, which include the areas discussed below.

I3.9.1 Lack of knowledge about eliciting patients' decision-making preferences

Clinicians may not always understand when and how patients would like to receive information on their treatment options [168, 169]. They may overestimate patients' comprehension of the provided information, and underestimate patients' preferred level of involvement in treatment decisions [104, 170, 171]. Evidence-based guidelines recommend that clinicians elicit patients' preferences for information provision and decision making [172, 173]. However, research suggests that this does not always occur in clinical practice [111, 116]. Evidence is lacking regarding whether asking patients about their decision-making preferences is associated with their care experiences.

I3.9.2 Lack of in-depth understanding of patient decision making

Decision making on cancer treatment can be a complex and complicated process. It has been suggested that patients can be overwhelmed when being provided with their cancer diagnosis and treatment options, and asked to make decisions regarding their care [174]. There is a need to further investigate in-depth the social processes that underlie decision making between patients, their support persons and their clinicians. Specifically, we need to better understand why and how patients decide for or against a specific procedure and how this process can be assisted by decision support strategies. This type of research would also facilitate decisions on how to best implement decision support strategies into clinical practice in order to improve patient outcomes [143].

I3.9.3 Lack of knowledge of how and when to use what kind of decision support

Although an increasing number of studies have tested decision support strategies, questions remain regarding their effectiveness. It is unclear which intervention modalities actually make decision support strategies effective. Further research is required to investigate these "active ingredients" [137]. Also, there has been debate about the content and structure of decision support, including the format, breadth and depth of information provided to patients [41, 175]. Further gaps have been identified with respect to the most effective timing for delivery of decision support strategies. For instance, it is unclear whether it is better to use decision support before or during the consultation [56]. Having such knowledge could enhance our understanding of how to introduce decision support strategies most practically and cost-effectively into clinical practice. It might also highlight which types of decisions are most suitable for the use of decision support strategies.

I3.9.4 Narrow view on shared decision making

Much of the work that has been done to support patients with making difficult healthcare decisions is based on the concept of shared decision making [99]. Whereas shared decision making asks clinicians and patients to share information and decisions, patient-centred decision making puts great emphasis on taking into account patients' preferences for information provision and decision making, and responding appropriately [176]. As a result, patients may choose not to decide on their treatment but leave the decision up to their treating clinician [35]. However, it has been argued that most patients want their clinicians to understand their preferences even if they do not wish to make the final decision [24]. Patient-centred decision making offers patients a choice of how they would like to make treatment decisions and tailors care according to their preferences [5].

I4. How this thesis will help work towards patient-centred decision making in cancer care

In order to improve patient-centred decision making in cancer care, it is important that we deepen our understanding of patients' experiences and preferences for making difficult treatment decisions. We also need to examine what factors should be taken into account when designing and implementing decision support for patients (see I3.9). Conducting methodologically robust research in this area will progress both the research and the implementation of patient-centred cancer care. This thesis will help achieve this by answering the following research questions:

1) Does asking cancer patients about their preferences for involvement in decision making have an impact on their care experiences?
2) What are patients' experiences with and preferences for making a difficult treatment decision, and which strategies could be used to facilitate the decision-making process?
3) What are patients' and support persons' preferences for different characteristics of oncology consultations?
4) Where has research effort in the area of decision support strategies been directed to over time, and where should the focus of future studies lie to improve decision support for cancer patients?

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PAPER ONE

Not asking cancer patients about their preferences does make a difference. A cross-sectional study examining cancer patients' preferred and perceived role in decision making regarding their last important cancer treatment

There is considerable evidence to suggest that cancer patients vary in their preferences for how involved they would like to be in decisions regarding their care [1, 2]. In order to be patient-centred, care needs to align with patients' preferences for information provision and decision making [3]. However, this does not always occur in clinical practice [4-6]. Many cancer patients are more or less involved in treatment decisions than they would like to be [7, 8]. Previous research on the decision-making preferences and experiences of cancer patients has had limited generalisability. Many studies in this area focused on only one specific type of cancer or a specific type of decision, or recruited patients from a very limited number of clinics [9-11]. Most studies have been conducted outside Australia [12]. Due to the differences in social contexts between different countries, it is important that we further explore patients' preferences for involvement in treatment decisions and whether these are met.

Also, clinicians have been encouraged to elicit patients' preferences for involvement in decision making, and tailor care accordingly [13]. However, studies suggest that clinicians do not always ask patients about their preferred involvement in decision making [13]. It seems logical that not asking patients about their preferences may hinder the provision of their preferred level of involvement in decision making. However, no study has assessed whether not asking patients about their decision-making preferences is linked with their care experiences. Paper One will help fill this gap using a large, heterogeneous sample of Australian cancer patients.

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Not asking cancer patients about their preferences does make a difference. A cross-sectional study examining cancer patients' preferred and perceived role in decision making regarding their last important cancer treatment

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1.1 Abstract

Background: Optimal, patient-centred cancer care aligns with patients' needs and preferences. Patients may miss out on receiving patient-centred care if they are not asked about how involved they would like to be in deciding on their treatment.

Aims: We examined whether not having been asked by their clinicians about how involved cancer patients would like to be in their treatment decisions is related to discordance between patients' preferred and perceived involvement in treatment decision making.

Methods: A cross-sectional survey of adult cancer patients recruited from five medical and radiation oncology outpatient clinics in Australia. Discordance between patients' preferred and perceived decision-making roles was assessed via an adapted version of the Control Preferences Scale. Logistic regression modelling was conducted to assess the relationship between role discordance and whether patients were not asked but wanted to be asked about how involved they would like to be in deciding on their treatment.

Results: Of 423 study participants, almost a third (n=128, 31%) reported discordance between their preferred and perceived involvement in their treatment decisions. Of those reporting discordance, 72% (n=92) were less involved than they would have liked to be. Not being asked about their preferences for involvement in treatment decisions, despite wanting this, was associated with discordance between patients' preferred and perceived involvement in treatment decision making ($p < 0.04$).

Conclusion: To achieve patient-centred care, it is vital that clinicians seek patients' views about how involved they would like to be in deciding on their cancer treatment.

1.2 Background

Patient-centred decision making is a cornerstone of optimal cancer care

Patient-centred healthcare is respectful of and responsive to patients' needs and preferences [1]. For this to occur, patients must comprehend their disease and treatment options, consider their own preferences, participate in decision making to the degree they desire and make a decision consistent with their preferences [2]. Providing patient-centred decision making may increase patients' understanding of their treatment options, improve their satisfaction with their decision and the consultation, and decrease patients' decisional conflict [3, 4].

Patient-centred decision making is not always delivered to cancer patients

Despite the importance of involving patients in treatment decisions to the extent they desire, numerous studies suggest that some clinicians do not adequately involve patients in decisions regarding their cancer treatment [5-7]. For example, Tariman and colleagues performed a systematic literature review to examine the concordance between cancer patients' preferred and perceived decision-making roles [8]. All 22 studies showed disagreements between patients' decision-making preferences and experiences [8]. Most found that patients wanted more involvement in decision making than what they felt occurred [8].

Effective communication is essential to delivering patient-centred decision making

Patients' preferences for involvement in treatment decisions can vary considerably by patient- and disease-related characteristics, such as age, gender and stage of cancer [9, 10]. They can also change over time, for example when situational factors change, such as patients' disease status [11]. Inadequate patient involvement can be due to clinicians' misperceptions of patients' preferences for decision making [12]. For example, there is

evidence to suggest that clinicians may not always understand when and how patients would like to receive information on their available treatment options [13]. They may also overestimate patients' comprehension of information and underestimate their preferred level of involvement in treatment decisions [14, 15]. As such, it is important that clinicians understand patients' preferences for information provision and involvement in decision making [16]. Although there are evidence-based guidelines available which recommend that clinicians elicit patients' preferences for how to make treatment decisions, clinicians do not always ask patients about their decision-making preferences [16, 17].

Research on patient involvement in decision making has been limited

A considerable number of studies have looked at whether patients' preferences for involvement in decision making match their experiences [18, 8]. Also, numerous studies have suggested that in order to provide patient-centred decision making in cancer care, clinicians should ask patients about their preferences for involvement in decision making regarding their care [16, 19]. However, to our knowledge, no study has assessed whether asking patients about their decision-making preferences is associated with discordance between patients' preferred and perceived involvement in deciding on their cancer treatment. Without having such information, we cannot confidently conclude that being asked about their preferences has an impact on patients' care experiences. This study aims to help fill this gap. Examining the importance of asking patients about their decision-making preferences can help provide adequate recommendations for clinical practice and improve communication skills training for clinicians.

1.3 Aims

To examine whether patients who are not asked by their clinicians about their desire for involvement in treatment decisions, experience discordance between preferred and perceived involvement in their last important treatment decision.

1.4 Methods

Design

A cross-sectional study assessing decision-making preferences and experiences in outpatients attending five medical or radiation oncology units within three local health districts in New South Wales, Australia. The data included in this paper reflect one module of a larger study. A completed STROBE checklist for this study can be found in Appendix 10.2.

Inclusion criteria

Patients were eligible for this study if they: i) were aged 18 years or older; ii) were judged by clinic staff as able to read and write in English, and physically capable of taking part in this study; iii) had been diagnosed with cancer (any type); and iv) were attending at least their second outpatient appointment in the previous six months at one of the participating treatment centres. The last criterion was to ensure that patients could report on at least one recent oncology consultation.

Ethics approval

This study was approved by the Hunter New England Human Research Ethics Committee (approval number: 15/04/15/4.04, see Appendix 8.1).

Recruitment

A trained research support person or a clinic staff member provided patients with information about the research and gained patients' informed written consent to participate (see Appendix 10.1). The age and gender of eligible non-consenters were recorded, with patients' permission, to assess for consent bias.

Data collection

Eligible consenting patients were asked to complete a paper and pencil survey while waiting for their oncology appointment. The full survey took approximately 15-20 minutes to complete (see Appendix 9.1). Participants were also provided with a reply-paid envelope, to allow them to complete and return their survey to the researchers at a later date if they wished. A reminder letter was mailed to non-responding consenting patients after a period of two weeks. A second reminder letter was sent after a further two weeks of non-response.

Outcome measures

Discordance between patients' preferred and perceived decision-making role was assessed via an adapted version of the Control Preferences Scale, as used in previous studies [8]. In relation to their last important treatment decision, patients were asked to indicate 1) how involved they were and 2) how involved they would like to be in making this decision. For the first question patients were asked to select one of the following response options: *i) "I made the decision about which treatment I would receive"; ii) "I made the final decision about my treatment after seriously considering my doctor's opinion"; iii) "Both my doctor and I shared responsibility for deciding which treatment was best for me"; iv) "My doctor made the final decision about which treatment would be used, but seriously considered my opinions"; v) "I left all decisions regarding my treatment to my doctor"*. When being asked about their preferred involvement in decision

making, patients were encouraged to select one of the following response options: *i) "I prefer to make the decision about which treatment I will receive"; ii) "I prefer to make the final decision about my treatment after seriously considering my doctor's opinion"; iii) "I prefer that my doctor and I share responsibility for deciding which treatment is best for me"; iv) "I prefer that my doctor makes the final decision about which treatment will be used, but seriously considers my opinions"; v) "I prefer to leave all decisions regarding my treatment to my doctor"*. The first two response options of each question were categorised as "active" treatment decision making. "*Sharing responsibility for the treatment decision*" was considered as "collaborative" decision making; while the last two response options were classified as "passive" decision making. The Control Preferences Scale has been used extensively in cancer populations and has evidence of reliability and validity [12, 10].

Experiences with being asked about involvement in decision making

Patients answered the following author-derived question: "Did a doctor, nurse or other healthcare provider ask you how involved you would like to be in making decisions about your cancer care?" The following response options were used: *i) "Yes, and I wanted this", ii) "Yes, but I did not want this", iii) "No, but I wanted this", iv) "No, but I did not want this", v) "Not applicable"*. This question was informed by a review of the literature and discussions among the research team and clinical experts.

For the analysis, the response options were divided into the following categories: being asked vs. not being asked although patients wanted this vs. not being asked but patients did not want this. This work was informed by the principles of patient-centred care which suggest that care should align with patients' preferences. As such, we looked specifically at the patient subgroup who indicated that their care did not meet their wishes (i.e. patients who wanted to be asked but were not asked), in order to examine whether this might be

associated with discordance between their preferences for and experiences with involvement in their treatment decisions. Nine patients (2.5%) indicated that they were asked, but did not want to be asked, about their preferred level of involvement in treatment decision making. Of these, three patients (0.8%) reported discordance between their preferred and perceived level of involvement in their last important treatment decision. As the number of patients in this subgroup was too small to allow for meaningful regression analysis, this group of patients was combined with those patients who indicated that they were asked and wanted to be asked about their preferred involvement in making decisions regarding their cancer treatment.

Independent measures

The following self-reported details were also collected from the survey and used in this study: date of birth, gender, home postcode, education, cancer type, time since diagnosis, and stage of cancer at diagnosis.

Statistical analysis

All analyses were conducted in Stata 14.2. Consent bias for age and gender was assessed using Chi-square tests. Frequencies and percentages of patients' preferences for and experiences with treatment decision making were calculated. Incomprehensible or blank survey responses were treated as missing (see Appendix 10.3). Weighted kappa statistics with user-defined weights was used to assess the concordance between patients' preferred and perceived roles played in their last important treatment decision. We assigned "partial credit" according to how much patients' preferences and experiences differed on the five-point Control Preferences Scale: 0 for a one-point difference, 0.25 for a two-point difference, 0.5 for a three-point difference and 0.75 for a four-point difference [21]. Logistic regression modelling was conducted to assess the association between discordance between patients' preferred and perceived involvement in treatment decision

making and whether patients were asked and wanted to be asked about how involved they would like to be in the treatment decision-making process. The final model was adjusted for patient age and gender. Listwise deletion was used to remove observations with missing data; so only complete data were included in the final model. The Hosmer-Lemeshow Goodness of fit test was used to assess the fit between the model and the data, with a p-value above 0.05 considered adequate. Multicollinearity was assessed, while the area under the ROC curve was evaluated to assess the final model's discriminative ability, with an area under the ROC curve (AUC) of 0.7 or more considered acceptable.

1.5 Results

Participants

Seven hundred and eighty-four eligible oncology patients were approached. Of these, 527 (67%) consented to participate and 423 (54%) returned a completed questionnaire that was included in this study. Participants had a mean age of 64 years (see Table 1.1). More than half of the participants were female (n=234, 55%). Approximately a third of the cancer patients included in this study were receiving treatment for breast cancer (n=133, 31%) and were diagnosed more than two years before (n=141, 34%). Fourteen patients did not answer the question about cancer type. However, as patients' cancer diagnoses were confirmed via medical records, these patients were included in this study. Also, 21 patients reported that they had more than one type of cancer. As the exact cancer type was not known for these patients they were categorised as having an "Unknown" cancer type. There were no statistically significant differences between consenters and non-consenters with regard to age and gender ($p > 0.05$).

Table 1.1 Sociodemographic and cancer-related characteristics of participants

(see Appendix 1.3)

Characteristic	Patients n=423 (%)[a]
Age in years mean (SD)	64 (12)
Gender	
Male	189 (45)
Female	234 (55)
Education	
High school or below	237 (58)
Trade or vocational training	115 (28)
University degree	50 (12)
Other	6 (1.5)
Cancer type	
Breast cancer	133 (31)
Colon cancer	53 (13)
Prostate cancer	56 (13)
Lung cancer	38 (9)
Other	108 (26)
Unknown	35 (8)
Time since diagnosis	
0-3 months	44 (11)
4-6 months	82 (20)
7-12 months	79 (19)
1-2 years	66 (16)
More than 2 years	141 (34)
Stage of cancer at diagnosis	
Early	208 (51)
Advanced and/or incurable	135 (33)
Don't know	62 (15)

[a] not all columns sum to 423 due to missing data

Preferences for and experiences with involvement in treatment decision making

Table 1.2 shows patients' preferred and perceived level of involvement in treatment decision making. Seven patients did not complete these survey items. Thus, 416 patients (98% of all study participants) were included in the analysis. One hundred and thirty-one patients (32%) preferred an active role in making their last important treatment decision. One hundred and sixty-two patients (39%) preferred to make the decision collaboratively

with their doctor; while 123 patients (30%) preferred a passive role in decision making. Most patients (n=288, 69%) reported having their preferred decision-making role (see Table 1.2). However, almost a third of participants (n=128, 31%) were not involved to the extent to which they would have preferred. Agreement between preferred and perceived role was moderate, with a weighted Kappa coefficient being 0.52 (95% CI: 0.44 – 0.53). Of those reporting a role discordance, 72% (n=92) indicated that they would have liked to be more actively involved in making their last important treatment decision than they were, whereas 28% (n=36) wanted a more passive role.

Table 1.2 Level of agreement between preferred and perceived involvement in last important treatment decision

Perceived involvement n=416 (%)	**Preferred involvement n=416 (%)**					**Total**
	Patient only	**Mainly patient**	**Collabor - ative**	**Mainly doctor**	**Only doctor**	
Patient only	**10 (2.4)**	9 (2.2)	3 (0.7)	0	0	22 (5.3)
Mainly patient	5 (1.2)	**77 (19)**	10 (2.4)	1 (0.2)	1 (0.2)	94 (23)
Collaborative	1 (0.2)	22 (5.3)	**118 (28)**	6 (1.4)	1 (0.2)	148 (36)
Mainly doctor	0	3 (0.7)	20 (4.8)	**24 (5.8)**	5 (1.2)	52 (13)
Only doctor	0	4 (1)	11 (2.6)	26 (6.3)	**59 (14)**	100 (24)
Total	16 (3.9)	115 (28)	162 (39)	57 (14)	66 (16)	416 (100)

Association between role discordance and not being asked about preferences for involvement in treatment decisions

Of those who answered this question (n=365, 86% of all study participants), more than half (n=202, 55%) were asked how involved they would have liked to be in decision making; 81 patients (22%) were not asked. Patients who indicated that this question was not applicable to them were excluded from the analysis (n=82, 22%). When adjusting for age and gender, we found a statistically significant association between discordance between patients' preferred and perceived involvement in their last important treatment decision and patients reporting having not been asked how involved they would like to be in treatment decision making, although they wanted this ($p < 0.04$; OR: 2.37; 95% CI: 1.07 – 5.20). Patients who reported having not been asked how involved they would like to be in their treatment decision, although they wanted this, had significantly higher odds of experiencing discordance between their preferred and perceived involvement in their last important treatment decision, compared with those patients who reported having been asked how involved they wanted to be.

1.6 Discussion

Asking the patient is the first step towards delivering patient-centred care

Our study results emphasise that not asking patients about their preferred involvement in cancer treatment decision making may lead to care that does not align with patients' wishes. We found that almost a third of cancer patients in our study did not attain their preferred decision-making role, and most of these patients were less involved than they would like to be. Our data also indicate that patients who were not asked by their clinicians how involved they would like to be, although they wanted this, had higher odds of reporting discordance between their preferred and perceived level of involvement in their treatment decisions. In order to deliver patient-centred care, clinicians should ask

patients about their decision-making preferences, rather than making assumptions about what patients want, or deciding on their behalf [22]. Clinical judgement of patients' decision-making preferences does not always reflect patients' actual preferences [15, 23]. It may also be inappropriate to rely on patient characteristics or stereotypes, such as age or gender, to assume what patients' preferences for involvement in treatment decision making may be [24]. Eliciting patients' decision-making preferences by asking them how they would like to make treatment decisions may help provide high-quality patient-centred cancer care [1].

Why some healthcare providers may not ask their patients about their preferences for involvement in decision making

Some healthcare providers have raised concerns that asking patients about their decision-making preferences and tailoring care accordingly may increase clinicians' time pressure [25]. However, evidence is lacking as to whether more time is required to engage patients in medical decision making [26, 27]. Some healthcare providers may believe that their patients do not want to be asked about their decision-making preferences as they do not want to take any responsibility for the treatment decision [28]. Yet, there is considerable evidence to suggest that although not all patients wish to be involved in healthcare decision making, they would like their clinician to ask them about their preferences and take their preferences into account when making treatment decisions [29]. It is also possible that some clinicians do not feel capable of adequately asking patients about their preferences due to a lack of skills or experience [30]. A direct question regarding a patient's preferred involvement in decision making may not be understood by the patient [31]. Clinicians may need to use various communication techniques to ascertain how involved patients wish to be.

How to help clinicians ask patients about their preferences and adequately involve them in treatment decisions

In order to provide optimal, patient-centred care, it is essential that clinicians are open to discussions around the variance in patients' preferences for decisional control. It may be helpful to discuss with patients how much and what kind of information they would like to receive, and how much time they need to familiarise themselves with the risks and potential benefits of their available treatment options [32]. Such discussions may be a first step towards eliciting how engaged patients would like to be in deciding on their care. To help facilitate this, numerous training programmes on patient-centred decision making have been introduced into professional development for clinicians [33]. However, training in patient-centred decision making has not yet been widely implemented into clinical practice [33]. More research is warranted to examine which components of decision-making programmes are most effective and why, in order to increase clinicians' confidence in such programmes and facilitate their implementation into routine cancer care [34].

Also, training on patient-centred decision making should be provided on a continuous basis given that communication skills can decline over time [35]. Ongoing formal or informal coaching on patient-centred decision making may increase clinicians' confidence in involving patients in decisions regarding their care. For example, it has been suggested that such coaching may assist clinicians and patients with using self-administered strategies designed to improve adequate patient engagement in healthcare decisions [36]. One such strategy are decision aids which provide patients with evidence-based information on the options available to them and support patients with choosing the option that aligns with their preferences [37]. Decision aids intend to encourage patients to communicate their preferences and participate more in the decision-making

process [38]. Numerous studies have shown that decision aids improve a number of patient outcomes, for instance by reducing patients' decisional conflict and increasing patients' understanding of the options available to them [39]. However, the routine use of decision aids in clinical practice is not yet commonplace [40]. Early evidence suggests that coaching on patient-centred decision making may help increase the use of such decision support strategies in clinical practice [41, 42].

Limitations

Recall bias may have occurred with those patients who had a relatively long period of time between their last important treatment decision and survey completion, providing incomplete or inaccurate responses. Prospective studies in this area are needed to reduce the likelihood of recall bias occurring. Also, patients' preferences for decision making may have changed over time and might have been different at the time when the decision was made compared to the time when they completed the survey for this study. Longitudinal studies may help investigate this issue. The survey did not ask patients to reflect on one specific type of treatment; rather, patients were asked to reflect on their last important treatment decision. Consequently, patients may have been referring to different types of treatments and may have different preferences for treatment decision making depending on the treatment they are deciding on [9]. The final regression model had an AUC of 0.55, which suggests that its discriminative ability was poor. However, AUC thresholds are context dependent and an AUC of > 0.5 may be acceptable in this setting [43, 44].

Finally, this study only assessed patients' perceived involvement in their last important treatment decision. We did not assess their actual involvement, and whether clinicians actually asked patients about their preferences. Examining patients' perceived involvement in treatment decision making is important because if patients are not

perceiving they received their preferred care, patient-centred care is not being delivered to them. However, it is possible that there is a difference between patients' perceived and their actual involvement in making their last important treatment decision. Observational studies are needed to examine whether patients' perceived role matches their actual role in decision making regarding their cancer treatment. This may be done through qualitative analysis of audio- or video-recordings of the consultations during which the treatment decisions were made [45].

1.7 Conclusion

Providing care that is respectful of and responsive to patients' needs and preferences is a cornerstone of high-quality cancer care. Most patients in our study preferred playing an active or collaborative role when making cancer treatment decisions. While the majority of study participants received care that aligned with their preferences, there is room for improvement. Almost a third of cancer patients in our study were identified as not being involved in decision making to the extent they desired. Not being asked about involvement in treatment decisions, despite wanting this, was associated with discordance between patients' perceived and preferred level of involvement in decision making. Clinicians should explore patients' preferences for how involved they would like to be in their cancer treatment decisions, and tailor care accordingly. Strategies, such as training programmes on patient-centred decision making or the use of decision aids, may improve doctor-patient communication and help adequately involve cancer patients in their treatment decisions.

Acknowledgements

We would like to thank our study participants. We acknowledge funding support from a Strategic Research Partnership Grant [CSR 11-02] from the Cancer Council New South Wales to the Newcastle Cancer Control Collaborative [New-3C], and infrastructure funding from the University of Newcastle and Hunter Medical Research Institute.

Funding

This work was supported by the Cancer Institute New South Wales through a consultancy contract with the University of Newcastle. Nicholas Zdenkowski is supported by the Hunter New England Local Health District. Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship and a University of Newcastle and Hunter Cancer Research Alliance Research Scholarship. She has also received funding support from the Hunter Cancer Research Alliance Implementation Science Flagship Program as part of the 2017 Research Higher Degree Student Award initiative. The funding agreements ensured the authors' independence in designing the study, interpreting the data, and writing and publishing the report.

Conflicts of interest

All authors declare that they have no competing interests.

Contribution of co-authors

Please see Appendix 1.1.

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PAPER TWO

Women's experiences with deciding on neoadjuvant systemic therapy for operable breast cancer: a qualitative study

Patient decision making can be a complex process which is influenced by various factors that may impact on patients' treatment choice and their satisfaction with the decision [1]. Little is known about the interplay of these factors, such as the time patients take to make a decision or how they use different information sources within the decision-making process [2]. We have not yet fully understood how cancer patients make difficult treatment decisions and what we can do to adequately support them when they are deciding on their treatment [3, 4] . In order to provide optimal, patient-centred care, we must deepen our understanding of when and with whom they make their decisions, what strategies they find helpful in supporting the decision-making process, and what factors they find impede this process.

Paper Two addresses this gap by focusing on one treatment decision that can be particularly difficult for patients. For this paper, qualitative research methods were used. These are particularly suited to provide a theoretical understanding of how and why patients decide for or against a specific treatment [5, 6]. Conducting this type of research can enhance our understanding of existing quantitative data by providing valuable in-depth insights into patients' views of and experiences with complex decision-making processes [7, 8]. Using qualitative research methods can further inform future quantitative studies by providing suggestions for how to design and implement decision support strategies that are tailored to patients' needs and preferences [9, 10].

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Women's experiences with deciding on neoadjuvant systemic therapy for operable breast cancer: a qualitative study

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Citation: Herrmann A, Hall A, Zdenkowski N: A qualitative study of women's experiences with deciding on neoadjuvant systemic therapy for operable breast cancer. *Asia Pac J Oncol Nurs*. doi: 10.4103/apjon.apjon_60_17

2.1 Abstract

Aims: We explored, qualitatively, in a sample of Australian early-stage breast cancer patients eligible for neoadjuvant systemic therapy (NAST): (i) their understanding of the choice of having NAST; (ii) when and with whom the decision on NAST was made; and (iii) strategies used by patients to facilitate their decision on NAST.

Methods: A sub-sample of patients participating in a larger intervention trial took part in this study. A total of 24 semi-structured telephone interviews were analysed using framework analysis.

Results: A number of women perceived they were not offered a treatment choice. Most patients reported that the decision on NAST was made during or shortly after the initial consultation with their doctor. Women facilitated decision making by reducing deciding factors and "claiming" the decision. Most women reported that they made the final decision, although they did not feel actively involved in the decision-making process.

Conclusion: When patients are deciding on NAST, patient-centred care is not always delivered to them. Clinicians should emphasise to patients that they have a treatment choice, explain the preference-sensitive nature of deciding on NAST and highlight that patients should be involved in this treatment decision. Providing patients with appropriate time and tailored take-home information may facilitate patient decision making. Process-orientated research is needed to adequately examine patient involvement in complex treatment decisions.

2.2 Background

Patient-centred decision making implies that patients are offered a treatment choice, are enabled to participate in the decision-making process and have the final say regarding their treatment decisions [1, 2]. This has been shown to increase patients' understanding of their treatment options, and improve patients' satisfaction with their care and their overall quality of life [3-5]. Clinicians have been encouraged to help patients become involved in deciding on their treatment, to the extent they desire [6]. However, treatment decision making can be challenging. Treatment choices are increasingly involving differing outcomes, such as efficacy and toxicity, which may be valued differently by different patients [7, 8]. Such preference-sensitive decisions often add complexity and uncertainty at a time when patients are likely to be distressed from the initial cancer diagnosis.

A potentially difficult preference-sensitive decision is the choice as to whether to receive neoadjuvant systemic therapy (NAST) or not. Early-stage breast cancer patients with larger operable or highly proliferative disease may be offered this option. It involves the receipt of chemotherapy or endocrine therapy before cancer-removing surgery. Based on current prospective randomised data of 3,946 patients with operable breast cancer, survival rates and disease progression are equivalent for NAST compared with upfront surgery, regardless of cancer type [9]. However, the impacts of the two options are different. Some patients may value NAST due to a higher chance of breast-conserving surgery rather than mastectomy [10]. NAST also allows a better understanding of tumour response and biology. This can facilitate prognostication [9, 11], and may decrease patients' anxiety associated with their cancer [12, 13]. However, some patients may prefer having upfront surgery as they fear that their cancer could get worse while receiving NAST, and thus wish to have the tumour surgically removed as soon as possible [14].

Adequate patient involvement in such difficult treatment decisions is not always applied in clinical practice [15, 16]. Elwyn et al. have argued that the specific underlying issues that militate against the adoption of adequate patient involvement are still under-investigated [17]. To guide the development and implementation of appropriate decision support for cancer patients, we need to better understand how patients make difficult treatment decisions and what we can do to adequately support them when they are deciding on their treatment [18].

2.3 Aims

This paper reports a qualitative analysis of telephone interviews conducted as part of a prospective, single-arm pre- and post-trial. The trial aimed at evaluating a decision aid which has been designed to help women decide on NAST. We explored, qualitatively, in a sample of early-stage breast cancer patients eligible for NAST: (i) their understanding of their treatment choice; (ii) when and with whom their decision on NAST was made; and (iii) strategies used by patients to facilitate this decision. Another analysis focusing on women's use and perceived benefit of the decision aid is presented in Paper Three of this thesis.

2.4 Methods

Setting and sample

A purposeful sample of 24 patients attending breast cancer treatment centres in New South Wales and Victoria, Australia, was used. Recruitment continued until data saturation (no new themes in three consecutive interviews) was perceived to be achieved.

Inclusion and exclusion criteria

Patients were eligible for this study if, at the time of enrolment, they i) were female; ii) were aged ≥18 years; iii) had a histological diagnosis of operable invasive breast cancer;

iv) were considered for NAST as a treatment option with curative intent; and vi) were willing and able to access the trial information through the internet and complete a telephone interview. Patients were excluded if: i) <3 months duration of NAST was planned; ii) they had a hearing or another impairment or insufficient English language skills for participation in a telephone interview; iii) they had inflammatory, metastatic, or inoperable breast cancer; iv) they were considered by the treating investigator to have a medical or psychiatric condition precluding informed consent; and vi) they were unable to be contacted via telephone.

Ethics approval and consent to participate

This study was developed and conducted in accordance with the tenets of the Declaration of Helsinki and principles of Good Clinical Practice. All participants provided voluntary informed consent to join the study, which had been approved by the regional research ethics committee (approval number: 14/12/10/4.05, see Appendix 8.2) and conducted according to local site governance processes.

Recruitment

The treating clinician identified all eligible patients attending their clinic for a consultation, introduced the larger intervention trial and obtained written consent to be contacted by the Australia and New Zealand Breast Cancer Trials Group for study registration (see Appendix 10.4). Consenting patients were emailed a link with access to the trial information letter and online consent form for the larger intervention trial, which gave participants the option to opt out of a follow-up telephone interview. Patients who consented to a telephone interview were contacted via telephone by a researcher to schedule the interview (see Appendix 10.5).

Data collection

All interviews were conducted by one researcher who had been trained extensively in qualitative research methods. Participants were informed that the interviews would be audio-recorded and transcribed but that their information would remain de-identified. They were asked to tell how they made their decision on NAST, in the way they preferred, without interruption from the interviewer. This narrative was followed by semi-structured questions about the information provided to patients, their information-seeking behaviour, the decision-making process and psychological concerns (for questions in each domain of the question guideline please see Additional file 1 and Appendix 9.2). At the end of the interview, patients were given the option to provide additional comments. The questions were informed by a previous study and discussions among the research team [14]. Participants were asked as many questions as needed to gain the required information, with prompting used to elicit topics not spontaneously spoken about by patients.

Data analysis

Interviews were transcribed verbatim. Transcripts were checked for accuracy by one researcher and analysed using framework analysis (AH) [19]. Conclusions drawn from the data were double-checked by another researcher (NZ). Disagreement was resolved by discussions among all members of the research team. According to Gale et al., the framework analysis approach belongs to a broad family of qualitative data analysis methods often related to as “thematic analysis” or “qualitative content analysis.” As suggested by these approaches, we aimed to draw both descriptive and explanatory conclusions from the data, which were clustered around themes [19]. The transcripts were read line by line, and their content was examined, compared, and categorised to apply a paraphrase or label (a “code”) that describes what was interpreted in the passage as

important. “Open coding” took place, i.e. anything was coded that could have been relevant from as many different perspectives as possible [19]. Codes were then grouped to start the development of more complex categories. An analytical framework was developed based on key categories, and data were assigned to the codes and categories in the framework [20].

An iterative approach was followed, with newly developed and existing codes and categories constantly being compared with each other and revised if necessary [21]. This enabled us to develop interpretive concepts that describe or explain aspects of the data (i.e. themes) [19]. The coding process was accompanied by writing analytical memos to help document the research process and preliminary findings. This approach to qualitative data analysis provided a systematic model for mapping and interpreting the data and was thus considered appropriate for developing a profound understanding of patients’ decision-making experiences [19]. Demographics are presented using appropriate summary statistics.

2.5 Results

Patients were interviewed between February 2016 and February 2017. Fifty-nine patients consented to participate in the trial, 30 (51%) consented to be interviewed and 24 (41%) were available for an interview, by which time saturation was achieved. The median time since diagnosis was 91 days (interquartile range = 49,169). Participants’ median age was 51 (standard deviation [SD] = 7.3, Table 2.1). The results are organised around three themes: (1) patients’ perceptions of being provided with a treatment choice; (2) decision making in a situation of perceived emergency; and (3) strategies used to facilitate decision making.

Table 2.1 Sociodemographic and cancer-related characteristics of participants

Characteristic	Patients n=24 (%)
Age in years, mean (SD)	51 (7.3)
Marital status	
De facto	4 (17)
Married	17 (71)
Single	3 (13)
Education	
Secondary school	4 (17)
Vocational	3 (13)
University	17 (71)
Lymph nodes involved	
Yes	10 (42)
No	14 (58)
Treatment decision	
Neoadjuvant	21 (88)
Adjuvant	3 (13)
Surgery	
Mastectomy only	10 (42)
Breast-conserving surgery only	13 (54)
Both	1 (4.1)

Patients' perceptions of being provided with a treatment choice

Many patients did not feel that they had a choice of whether or not to receive NAST. This was for three main reasons. First, some women perceived that they were not offered a treatment choice at all. They felt that their doctor provided them with a treatment plan without discussing alternative options. This did not allow women to participate in the decision-making process. However, due to the power imbalance between doctor and patient, women accepted their doctor's treatment choice.

> *She (=the surgeon) said, you're going to have chemo anyway, so let's have it first. Shrink the tumour, and yeah – that was very simple. We didn't even discuss other options at all. She made the decision. (…) I heard that it usually goes, surgery first, then chemo. When I told her I want to have surgery first, then chemo, she*

said, that's not going to happen, and then I said, okay, you know best; and that was all. (P8)

Second, even when they perceived they were offered a treatment choice, many women did not feel that they had a say in the treatment decision. They reported that the decision was strongly guided by their doctors. Doctors were seen to have a preference for the "best" treatment choice and were perceived to have guided the decision-making process both in an explicit way (i.e. providing a treatment recommendation) and in an implicit way (i.e. implying a preferred treatment option through the way in which options were presented to patients). All women followed their doctors' treatment advice. Some women felt that they were "in their doctors' hands" (P2) and that they could only participate in the decision-making process if they were agreeing with their doctors' treatment recommendation. In these instances, decision making on NAST was predominantly characterised by clinicians' disclosure and explanation of information, rather than being a shared process which involves joint participation between doctor and patient.

Ultimately they both (=the surgeon and the oncologist) heavily heavily heavily recommended that I make this decision that favours what they decided. So whether it's – they gave me the information which was pretty hard to say no to. Whether they made the decision and then decided to convince me that it was the best option, or whether I was just – you know I go with the experts. (…) I suppose I did make the decision, but it was after some pretty heavy pressuring. (P 16)

It was pretty much this is what we recommend. He (=the oncologist) did present it as you have a choice but all of the advice led down that path (=to have NAST). (P 21)

Third, some women struggled with comprehending and accepting the preference-sensitive nature of the decision on NAST. Although survival outcomes are equivalent for

NAST and upfront surgery, women found it hard to understand that their preferences needed to be involved in the decision-making process to determine the "best" treatment choice. These women perceived the decision on NAST as a no-win situation. They felt that no matter which option they chose, it would not lead to a perceived gain, given that survival benefits are similar for NAST and upfront surgery, and given that they would have chemotherapy anyway. Some women experienced the decision-making process as a burden, rather than a chance to make a treatment decision in line with their individual preferences.

> *Either way wasn't really going to make any difference. I guess I felt by doing it beforehand (=chemotherapy before surgery), I'm not disadvantaging myself (.) It seems that the results and so on are the same, or there doesn't seem to be much in difference. (P 12)*

> *Unfortunately it's such a grey area that there are pros and cons to both sides. So you're like shit, there's no obvious answer at the end. (P 22)*

Decision making in a situation of perceived emergency

Many women felt that the decision on NAST needed to be made quickly and perceived they were in an emergency situation which required urgent action to prevent a worsening of their cancer. The majority of patients reported that the decision was made during or shortly after the initial consultation with their doctor. A mean of 5 days (SD = 4.6) elapsed between study consent and treatment decision. A number of women reported having little time between the consultations with their medical specialists during which their treatment options were discussed. Some women noted the limited amount of time they had with their doctors during these consultations. Many women felt rushed when deciding on NAST. This did not allow them to comprehend and weigh up the information provided to them and make a considered treatment decision.

It was all really quite quick for me. I only found out in the morning and (was) then at the doctor's the same day, both the breast surgeon and the oncologist. So there wasn't very much down time for me. (…) So I was straight into, okay, you've been diagnosed, and straight into acting on it straight away. (P 5)

Because when you are in a surgeon appointment, it's only a limited amount of time. Like it's specific to, boom, boom, boom, the things that have to be dealt with. (P 17)

A number of women felt a loss of control over the situation in which the decision was made. They were overwhelmed by the fear associated with their diagnosis and the potential treatment outcomes. Many patients reported a lack of medical expertise and did not feel capable of taking an active role in the decision-making process. A number of women perceived the lack of information as a "vicious circle" as it did not allow them to ask further questions which might have helped overcome their perceived lack of understanding. Some women felt that it was their responsibility to escape this "vicious circle" by seeking additional decision support.

Obviously it was overwhelming because it's not something that you obviously hope on anybody. (P 5)

Maybe I would have wanted to know more about prognosis and survival rates, but, if I wanted to know more, I should have asked more. (P 8)

Most women made the decision with their doctors and their support persons and perceived them to be the most important information sources for deciding on NAST. Some women reported they appreciated it if their doctor suggested a treatment plan and offered to change the course of treatment at any time. These women perceived that the "right" treatment choice was determined by treatment success. Having the option to change the

treatment plan if NAST was considered unsuccessful seemed to help women feel more satisfied with their decision.

> *Yeah, like I really didn't know either way, so – but I was happy with the decision that was made knowing that at any time we could stop the chemo and have surgery if they felt the cancer was progressing or wasn't reacting or – yeah, if there were any other signs going on. (P 2)*

Strategies used to facilitate decision making

Women used a number of strategies to facilitate decision making on NAST. The most commonly used strategies included: i) reducing deciding factors; ii) "claiming" the decision; and iii) using additional information. These strategies are described below.

Most women did not contemplate the variety of potential reasons for or against having NAST. They seemed to base their decision on one or two key factors which they perceived as most important to them, at the time when the decision was made, such as having breast-conserving surgery rather than a mastectomy, or having a treatment that would affect the whole body, not just the breast. The reasons why women decided for or against NAST did not only relate to the medical effectiveness of the treatment options available to them. Some women decided on NAST based on their personal circumstances or on what they considered emotionally "bearable." For example, some women made the decision on NAST based on their family commitments or the fear associated with their cancer. This highlights that when deciding on NAST, the "right" treatment choice depends heavily on patients' individual preferences and needs.

> *So if it doesn't affect the prognosis and/or the percentages of survival, and it does help you in other words in a few ways, in that the cancer can be reduced in size which means that the operation is not such a major one. Number one (1). Number*

two (2), if the cancer does reduce in size, they know that the chemo actually works. (P 16)

I suppose in the back of your mind you're thinking because as it's (=the chemotherapy) blasting the whole body and even if it is somewhere in my body, you can only hope that it has been blasted by this chemotherapy. (P 4)

I think the main clincher with me was finally feeling the size of the lump after the dressing's come down and everything. Then just thinking that I couldn't cope with that (=not getting the tumour removed immediately) and not knowing if it was going to get bigger or spread. (P 9)

I thought, well, I would rather get the chemo out of the way first because we've also got something coming up later in the year and I didn't want to be going through chemo when that happened. Our daughter's wedding is in the middle of the year, so that's why I was happy to do the chemo first. (P 7)

Most women described the decision-making process in the passive voice. Although they did not seem to play an active role in deciding on NAST, most women reported that they made the final decision and thus "claimed" the decision. In these instances, patients' perceived involvement in the decision-making process differed from their perceived involvement in the final decision.

I guess it was my decision at the end of the day but I was really just guided by what the doctors were saying. (P 2)

I guess you sign the paper and you say I'm making the decision but I do think that definitely the surgeon and the oncologist had both said this is what we would recommend. (P 21)

Women used additional written information, such as the decision aid that was part of the larger trial, to confirm their decisions on NAST, rather than changing them.[1] Using additional information helped women supplement the information provided by their doctors and reassure themselves that their treatment decision was not solely determined by their doctors' opinions, but based on women's individual circumstances and preferences. Some women reported that using additional information helped them comprehend that they had a treatment choice and thus enabled them to better understand the preference-sensitive nature of the decision on NAST.

> *Then she (=the breast surgeon) said, we've got this trial which is a decision tool. Would you be interested in being part of that? I said, yes that would be good, because I'd like to make sure that the decision that I am making is not being influenced by my healthcare practitioners who were telling me what they thought was better. So this helped me confirm that the decision that we were making together was the right decision. (P 13)*

> *As I went away and started reading the literature in between sessions, it suddenly dawned on me that this is actually a choice. I could choose. (P 23)*

Women who used additional information in-between the consultations with their surgeon and their medical oncologist appreciated having sufficient time to make sense of the information provided by their doctors. It helped them better cope with the perceived emergency of the situation and feel more involved in deciding on NAST.

[1] An in-depth qualitative analysis of the use and perceived benefit of the decision aid is presented in Paper Three of this thesis.

I think it was important to speak to the surgeon and get his view on it all, but I think it was also very helpful to have the written information that was in the decision aid so I could sit and read that at my own pace. (P 17)

2.6 Discussion

Our data suggest that preference-sensitive decision making in the context of NAST can be difficult for patients. Some did not feel that they were offered a treatment choice or received a strong treatment recommendation. This is in line with previous studies. Ziebland et al. analysed pancreatic cancer patients' perceptions of treatment decision making and found that doctors were often perceived to have presented surgery as the obvious course of action, rather than offering a treatment choice that patients might have been involved in [22]. It is possible that the treatment recommendations of some clinicians may be at odds with patients' values [23, 24]. Clinicians should emphasise that patients have a treatment choice and make it clear that patients can be involved in decision making. This could be done by offering to explain the available evidence to patients, help patients comprehend the risks and benefits of their options, check for patients' understanding, and ask patients about their preferences for information provision and decision making [25]. A patient-centred approach towards medical decision making could help patients consider "what matters most to them" and facilitate their involvement in treatment decisions [26, 27]. This is important as there is evidence to suggest that patients make decisions regarding their cancer care not only based on statistical risk assessment but based on a broad range of experiential factors, including family history of cancer and information sought from their personal network of family and friends [28, 29].

The patients in our study felt that the decision on NAST needed to be made quickly. Many felt overwhelmed by their diagnosis and treatment options, which is in line with previous studies on other cancer treatment decisions [27, 30, 31]. It is vital to provide patients with

appropriate time to consider their options and make sense of the information presented to them. Where possible, clinicians should emphasise to patients that it is usually safe to consider their options for a few days before making a decision. Offering a second consultation may be a strategy worthy of investigation to help improve patients' understanding of their options and their participation in decision making [26]. Also, providing additional written information for patients to review at home could take the pressure off having to provide and receive all required information within the consultation. This could counteract patients' feeling of being overwhelmed and allow for considered decision making, which may reduce patients' decisional regret [32, 33].

A patient-centred approach towards medical decision making may also reduce costs to the healthcare system as there is evidence to suggest that patient-centred communication may be associated with better recovery from discomfort, better emotional health, and fewer diagnostic tests and referrals [34, 35]. A recent Cochrane review on interventions to support patient involvement in decision making indicated that consultations that involved such interventions were on average only 2.5 min longer (median: 2.55 min) [36]. Patient-centred communication about treatment decisions patients have to make soon after their diagnosis may also lead to more succinct treatment discussions later in patients' care trajectory [37]. As a consequence, emphasising that patients have a treatment choice and involving patients in treatment decision making could ultimately lead to more efficient and effective patient care.

"Claiming" the decision to maintain cognitive consonance and the need for process-orientated research

Many women reported having made the final decision on NAST, although they did not feel that they had been actively involved in the decision-making process. Festinger's Theory of Cognitive Dissonance may help explain why this occurred. This theory

suggests that people strive to achieve a state of harmony by maintaining consistency between their beliefs, values and behaviours, to avoid psychological discomfort [38]. It might be that patients perceived they made the final decision, although they did not feel that they played an active role in the decision-making process, to align their behaviour with their understanding of the situation. It is likely that women perceived an obligation for being involved in their own healthcare decisions, as it is the patients who have to manage the consequences of treatment decisions [2]. In line with the premise of cognitive dissonance theory, it might be that this strategy of "claiming" the final decision helps patients maintain cognitive consonance and thus psychological comfort by protecting themselves from any distress they may experience as a result of their views not aligning with their behaviour.

Decision making is a dynamic process where patients' preferences and needs may change [39]. When measuring patients' decision-making preferences and experiences, researchers should focus on the decision-making process rather than patients' perceptions of the final decision. However, many instruments in this area, including the widely used Control Preferences Scale, focus on patients' views about the final decision rather than the process of decision making [40]. Such measures can be misleading as patients are often unaware that decisions need to be made and do not feel that they should have participated in them [41]. Process-orientated measures might help better understand patient involvement in treatment decisions by examining different components of the decision-making process [26, 41, 42]. This is likely to increase the progress in the research and the implementation of patient-centred care.

Limitations

The study findings are not intended to be numerically representative. They rather provide in-depth insights into how women decided on NAST. As such, we avoided a potentially

misleading numerical description of our results. We conducted telephone interviews, which may be a less productive mode of data collection than face-to-face interviews [43, 44]. However, evidence is lacking on whether telephone interviews produce lower quality data [45-47]. Also, patients may feel more relaxed and able to disclose sensitive information when being interviewed on the telephone, in the comfort of their homes and without having to face the interviewer [45]. Furthermore, there is evidence to suggest that rearranging a telephone interview by calling back at a more convenient time for the interviewee might cause study participants less embarrassment and difficulty than rearranging a face-to-face interview [43]. This was considered to be of particular importance for this study as many women asked to rearrange the interview because they felt too unwell to do the interview, or because they had to attend the clinic. As a consequence, it was assumed that conducting telephone interviews, rather than face-to-face interviews, would reduce research-related burden on patients.

Some women participated in the interview months after deciding on NAST (median time between study consent and interview: 102 days). This introduces the possibility of recall bias that could lead to inaccurate narratives [48]. Also, most study participants were well-educated and younger. Older women and those with lower levels of education may have different experiences with deciding on NAST [49]. Clinicians' communication skills and styles may have influenced how women decided on NAST. For example, clinicians' skills in communicating risks might have had an impact on patients' understanding of their options [50, 51]. As we do not have recordings of the consultations where the decision on NAST was discussed, we do not know how clinicians' communication skills and styles may have influenced patient decision making.

2.7 Conclusion

Although the patients in this study presumably had a choice between two equally effective treatment regimes, a number of women felt overwhelmed and believed that they were not offered a treatment choice. Clinicians should emphasise to patients that they have a treatment choice, explain the preference-sensitive nature of NAST and highlight that patients should be involved in this decision, to the extent they desire. Strategies to support patient involvement in deciding on NAST might include providing patients with appropriate time and further written information to consider at home. Where possible and reasonable, clinicians should emphasise to patients that it is usually safe to take a few days to consider their options before a decision is made. Also, many of the study participants "claimed" the decision and reported having made the final decision, although they did not feel actively involved in deciding on NAST. Process-orientated research is warranted to examine changes in patients' preferences for and experiences with making cancer treatment decisions.

Acknowledgments

We would like to acknowledge funding support from a Strategic Research Partnership Grant (CSR 11-02) from Cancer Council New South Wales to the Newcastle Cancer Control Collaborative (New-3C) and infrastructure funding from the University of Newcastle and Hunter Medical Research Institute. The ANZ1301 DOMINO study is funded by an HCF Research Foundation grant and by the Breast Cancer Institute of Australia.

Financial support and sponsorship

Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship and a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship and has received funding support from the Hunter Cancer Research Alliance Implementation Science Flagship Program as part of the 2017 Research Higher Degree Student Award initiative. Nicholas Zdenkowski is supported by the Hunter New England Local Health District.

Conflicts of interest

All authors declare that they have no competing interests.

Contribution of co-authors

Please see Appendix 2.2.

2.8 References

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2.9 Additional files

Additional file 1 – Questions in each domain of the question guideline

Questions on information provided to patients included asking patients: i) where they received information to help them make a decision about whether to have chemotherapy before surgery; ii) which of these information sources they found most useful; iii) what exactly the information was that helped them make the decision; iv) whether they felt they were given enough information to allow them to make a decision; v) if they felt they were not given enough information, what other information they would like to have received; and vi) how they would like information presented to them (written, face-to-face, online).

Questions regarding the decision-making process and psychological concerns included asking patients: i) who made the decision in the end; ii) what was difficult about making the decision; iii) how certain they were about the decision at the time when they made the decision; iv) how certain they were then that they made the right decision; and v) if their certainty had changed, why it changed. Patients were further asked whether: vi) they do or did worry that their cancer would get worse whilst having chemotherapy; vii) what period during chemotherapy and surgery they found most difficult, mentally and physically; and viii) whether they worried that their cancer would come back.

Questions regarding other factors which might have influenced patients' decisions included asking patients whether and if so, how the following factors influenced their decision: i) having breast-conserving surgery (lumpectomy); ii) being able to know whether the cancer responded to chemotherapy; iii) having treatment sooner for the whole body, not just for the breast; iv) being involved in a clinical trial (and whether their doctor talked to them about this); v) their ability to have children in the future. Patients were

further asked whether vi) they were aware that breast cancer can be inherited in the family and whether that was relevant to their decision; vii) what other issues they considered when making the decision, such as financial or logistic issues; and viii) whether they had considered having breast reconstruction.

PAPER THREE

Exploring women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer

Paper Two highlighted that some patients felt rushed when deciding on their cancer treatment and appreciated being provided with additional information to consider at home, in-between two consultations with their doctors. Paper Three looks specifically at women's use and perceived benefit of a take-home decision aid designed to help patients decide whether or not to undergo neoadjuvant systemic therapy for breast cancer.

Numerous studies have suggested that decision aids can help patients make decisions regarding their care, for example by assisting them with becoming more involved in the decision-making process and increasing their satisfaction with their decision [1, 2]. However, questions remain regarding: i) how patients use decision aids; ii) what aspects of decision aids they find particularly helpful when deciding on their treatment; and ii) how decision aids may be best implemented into patient care [1, 3]. This paper will address these questions, by supplementing the findings of quantitative studies in this area and providing an in-depth understanding of patients' use and perceived benefit of a decision aid designed to help them decide on whether to undergo neoadjuvant systemic therapy. Also, Paper Three draws on qualitative data from a wider evaluation project which may enhance our knowledge on how decision aids can be successfully integrated into the patterns of doctor-patient communication [4].

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Exploring women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer

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Citation: Herrmann A, Boyle F, Butow P, Hall AE, Zdenkowski N: Exploring women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer. *Health Sci Rep* 2017;e213. doi: 10.1002/hsr2.13

3.1 Abstract

Background: Some women with operable breast cancer have a choice between receiving upfront surgery followed by chemotherapy, or neoadjuvant systemic therapy (NAST) prior to receiving surgery. While survival outcomes are equivalent for both options, the decision about treatment sequence can be difficult due to its complexity and perceived urgency. A decision aid has been developed to help patients decide on whether to receive NAST.

Aims: To explore, qualitatively, women's use and perceived benefit of a decision aid to help with their decision on NAST.

Methods: A framework analysis process was conducted on a purposeful sample of 20, one-on-one, semi structured telephone interviews with early-stage breast cancer patients eligible for NAST. Participants had recently decided whether or not to have NAST.

Results: Patients perceived the decision aid as useful to becoming more informed and involved in making a decision as to whether they receive NAST. They described the information provided in the decision aid as reliable, relevant, sufficient in terms of amount, and tailored to their needs. Reading and rereading the decision aid at home in-between the consultations with their surgeon and their medical oncologist allowed women to better understand their treatment options and easily integrate the decision aid into their care. The decision aid seemed to confirm but not change women's decisions on NAST.

Conclusion: The decision aid appears to help breast cancer patients support their decision about whether to receive NAST. Patients' ability to review the decision aid in-between two consultations seems to be an acceptable and feasible way of integrating the decision aid into patients' care.

3.2 Background

Breast cancer treatment decisions can be challenging

To maximise their outcomes, patients should be involved in their treatment decisions, to the extent they desire [1]. This can decrease patients' distress and anxiety, and increase their satisfaction with the consultation and overall quality of life [2]. However, breast cancer patients can be overwhelmed by the number of treatment options available to them [3]. In addition to the large number of treatment options available, the complexity of each treatment choice can further complicate the decision-making process. For instance, treatment choices are increasingly involving differing outcomes, such as efficacy and toxicity, which may be valued differently by different patients. Such decisions are called "preference-sensitive." [4, 5] They can be very difficult for patients, as the "best choice" cannot be predefined; it depends on patients' preferences and involves each individual patient weighing up the risks against benefits of the options available. It is essential that patients are adequately supported by the healthcare system when deciding on their treatment [6].

Deciding on neoadjuvant systemic therapy can be particularly difficult for patients

Some early-stage breast cancer patients with larger operable or highly proliferative disease may be offered a choice about whether to have neoadjuvant systemic therapy (NAST), i.e. chemotherapy or endocrine therapy before surgery. This is a particularly difficult decision to make, as the concept of NAST adds complexity and uncertainty at a time when patients are likely to be distressed from the initial diagnosis of cancer. However, patients may value the neoadjuvant approach due to a higher chance of breast-conserving surgery, rather than mastectomy [7]. Neoadjuvant systemic therapy also allows a better understanding of tumour response and biology, which can facilitate prognostication [8]. Improved prognostication can decrease patients' anxiety and

depression associated with their cancer and potential treatment outcomes [9, 10]. Survival and recurrence rates are equivalent for NAST followed by surgery compared with receiving surgery first [8]. However, some patients fear that their cancer could get worse while receiving NAST and thus prefer to have the tumour surgically removed as soon as possible [11]. Therefore, for women with operable breast cancer, the decision for or against NAST relies heavily on patients' preferences [12]. To allow these patients to make informed treatment decisions, they need to be provided with adequate, evidence-based information.

Decision aids can improve patient outcomes

Decision aids provide patients with evidence-based information regarding the healthcare options available to them. Decision aids aim to assist patients with clarifying and communicating the value they associate with each option [13]. They are designed to engage patients in the decision-making process and to guide them towards making deliberated decisions that align with their preferences [14]. A number of Cochrane reviews have shown that decision aids are effective in improving certain patient outcomes, including increased knowledge and understanding of the options available, and reduced decisional conflict, when compared with usual care [15]. Although decision aids have been developed for numerous health conditions, one was not available for the decision on NAST before this study commenced [16]. To fill this current gap, our group designed a decision aid to help women become more informed and more involved in deciding on NAST. The decision aid is being evaluated in a prospective, single-arm pre-post trial. Here, we report on the qualitative analysis of telephone interviews included in the larger trial to assess women's use of, and perceived benefit from, the decision aid. This sub study aims to provide in-depth insights into women's perspectives on the

effectiveness of the decision aid and helps explore whether it may be a valuable tool to facilitate decision making on NAST in clinical practice.

3.3 Aims

The aim of this study was to explore, qualitatively, in a sample of early-stage breast cancer patients eligible for NAST, the use and perceived benefit of a decision aid that was designed to provide women with relevant information to assist their decision on NAST.

3.4 Methods

Development and testing of a decision aid on neoadjuvant systemic therapy

The development of the decision aid was informed by: i) a qualitative study conducted to examine the information needs of patients receiving NAST [11]; ii) a literature review to define treatment options and the positive and negative outcomes associated with those options; and iii) identification of relevant issues important to the decision on NAST by an expert consensus panel. The structure of the decision aid was based on the International Patient Decision Aid Standards Collaboration (IPDAS) standards and included a balanced description of adjuvant and neoadjuvant therapy. The decision aid includes an introduction that helps newly diagnosed breast cancer patients understand basic concepts about their treatment modalities. This was important, as these patients may not have received other written general information at the time when NAST was discussed. The decision aid further includes brief general information about breast cancer and the treatments commonly used, an explanation of the options for the timing of chemotherapy and surgery, the advantages and disadvantages of neoadjuvant and adjuvant therapy, a values clarification exercise (i.e. a worksheet to help patients consider how they value key aspects of the decision on NAST), a page for notes, a glossary, and information about where to find additional resources. To improve patients' risk perception and lead to better

informed decision making, key components of risk are presented in visual, numeric, and narrative formats using appropriate labelling. The decision aid is designed to be compatible with online and paper delivery. The IPDAS criteria for judging the quality of decision aids have been adhered to (see Additional file 1 for a completed IPDAS checklist and Appendix 10.6. for a copy of the decision aid) [17-19]. Consumers and members of a breast cancer support organisation (Breast Cancer Network Australia) reviewed and helped refine the content and comprehensibility of the decision aid. Care was taken to make use of the shortest words and simplest sentence structures possible. Word and sentence length had to be balanced against the overall length of the decision aid. An excessively long decision aid was not considered likely to be approachable by those with low literacy. To avoid duplication of information, the decision aid refers to other information sources which are routinely made available by breast care nurses to women who have been diagnosed with breast cancer.

Setting and sample

A purposeful sample of 20 patients attending breast cancer treatment centres in New South Wales and Victoria were interviewed one-on-one via telephone. Recruitment continued until data saturation (no new themes in three consecutive interviews) was perceived to be achieved.

Inclusion and exclusion criteria

Patients were eligible for this study if, at the time of enrolment, they: i) were female; ii) were aged ≥18 years; iii) had a histological diagnosis of operable invasive breast cancer; iv) were considered for neoadjuvant systemic (chemo or endocrine) therapy (NAST) as a treatment option with curative intent; and v) were willing and able to access the trial information and the decision aid via the Internet and complete the telephone interview.

Patients were excluded if: i) < 3-month duration of NAST was planned; ii) they had hearing or other impairment that would preclude a telephone interview; iii) they had insufficient English language skills for participation in a telephone interview; iv) they had inflammatory, metastatic, or inoperable breast cancer; v) they were considered by the treating investigator to have a medical or psychiatric condition precluding informed consent; and vi) they were unable to be contacted via telephone. We excluded those patients who were going to receive less than three months of chemotherapy because the outcome probabilities presented do not apply to those patients. The intent was to include patients who were going to receive a full course of neoadjuvant chemotherapy, which is typically three months or more. This duration is required for maximal benefit from neoadjuvant chemotherapy.

Recruitment

The treating clinician identified eligible patients attending their clinic for a consultation, introduced the trial, and obtained written consent to be contacted by the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) for study registration (see Appendix 10.4). The clinician then completed a screening form and faxed it to ANZBCTG. The screening form contained an eligibility checklist, investigator assessment of information needs and distress at that time, consent for release of information to the ANZBCTG, and patient email address and telephone number for further contact. Patients who consented to further study contact were emailed a link with access to the trial information letter and online consent form, which patients could access after the consultation with their treating clinician. The consent form asked patients to provide consent to take part in the larger intervention trial and gave participants the option to opt out of a follow-up telephone interview. Once patients had consented to participate in the trial they entered their demographic details and completed a series of patient-

reported outcome measures in an online survey. Patients were then provided with access to the decision aid, which they could read online or print out. Patients who consented to a telephone interview were contacted via telephone by a member of the research team (AH) to schedule the interview (see Appendix 10.5). Most interviews took place two to three months after study consent (median time between study consent and interview: 93 days). Women were not asked to have the decision aid on hand during the interview.

Data collection

All interviews were conducted by a single researcher (AH) who has been trained in qualitative research methods. Participants were informed that the interviews would be audio-recorded and transcribed but that their information would remain confidential and de-identified. They were then asked to tell the interviewer how they made their decision to have chemotherapy before or after surgery. Participants were encouraged to tell their story in the way they preferred, without interruption from the interviewer. This narrative was followed by semi-structured open-ended questions that included asking patients about the information provided to them, their information-seeking behaviour, the decision-making process, psychological concerns, and experiences with the decision aid. The question guide is described in Additional file 2 and Appendix 9.2. At the end of the interview, patients were given the option to provide additional comments. The questions were informed by a previous study and discussions amongst the research team [11, 19]. Participants were asked as many questions as needed to gain the required information, with prompting used to elicit topics not spontaneously spoken about by patients.

Data analysis

Interviews were transcribed verbatim. Transcripts were checked for accuracy by one researcher (AH) and analysed using a framework analysis process. Transcripts and

conclusions drawn from the data were double-checked by another member of the research team (NZ). Disagreement was resolved by discussions between AH and NZ. The framework method was considered appropriate to develop a profound understanding of patients' experiences with the decision aid, as it provides a systematic model for managing and mapping the interview data and for generating themes by making comparisons within and between cases [20]. After the research team familiarised themselves with the data, AH examined, compared, and categorised segments of content to assign codes and to start the development of categories. A category in this sense was a group of codes that shared a commonality [21]. After identifying initial codes and categories, AH developed a coding matrix and assigned data to the codes and categories in the coding matrix [22]. This coding matrix was then discussed and refined with one member of the research team (NZ). Throughout the coding process, an iterative approach was applied. Newly developed categories and existing ones were constantly compared with each other and revised if necessary. To do this, the interviews were analysed individually and then compared with each other [23, 24]. The coding process was accompanied by writing analytical memos. This helped document the research process and preliminary findings. These techniques contributed to the intersubjectivity of the procedure and allow to reconstruct or repeat the analysis [25]. Demographics are presented using appropriate summary statistics.

Ethics

This study was developed and conducted in accordance with the tenets of the Declaration of Helsinki and principles of Good Clinical Practice. All participants provided voluntary informed consent. The study was approved by a recognised Human Research Ethics Committee and conducted according to local site governance processes (see Appendix

8.2). The parent intervention trial was prospectively registered on the Australia and New Zealand Clinical Trials Registry (www.anzctr.org.au, ACTRN12614001267640).

3.5 Results

Demographics

Patients were interviewed via telephone between February and September 2016 by one researcher (AH). Of 59 patients who consented to the larger trial, 42 consented to be interviewed and 20 were interviewed; by this time, saturation was achieved. Interviews lasted between 15 and 37 minutes. Participants' median age was 52 years (SD = 6.9); median time since diagnosis was 82 days (IQR = 49 141). The majority of patients decided on NAST (85%), while the remaining 15% underwent upfront surgery. Most patients were married or living with a partner (85%) and had a university-level degree (75%, Table 3.1).

The use and perceived benefit of the decision aid

The following themes emerged from the data: i) integration of the decision aid into care; ii) improved knowledge and understanding of treatment options; iii) provision of customised, reliable information; and iv) facilitation of involvement in decision making. Our data suggest that by providing customised and reliable information to patients, the decision aid helped women better understand their options and thus facilitated the decision-making process. Most women used the decision aid in-between the consultations with their doctors. Thus, the decision aid could be easily integrated into women's care pathway. The themes are described in detail below.

Table 3.1 Sociodemographic and cancer-related characteristics of participants

Characteristic	Patients n=20 (%)
Age in years, mean (SD)	52 (6.9)
Marital status	
De facto	3 (15)
Married	14 (70)
Single	3 (15)
Education	
Secondary school	3 (15)
Vocational	2 (10)
University	15 (75)
Lymph nodes involved	
Yes	9 (45)
No	11 (55)
Treatment decision	
Neoadjuvant	17 (85)
Adjuvant	3 (15)
Surgery	
Mastectomy only	9 (45)
Breast conserving surgery only	10 (50)
Both	1 (5)

Integration of the decision aid into care

Most women used the decision aid just after the initial consultation with their surgeon about their treatment options, prior to their consultation with the medical oncologist, and perceived this as the right timing. A mean of five days (SD = 2.3) elapsed between study consent and treatment decision. Reading and rereading the decision aid at home in-between the two consultations allowed women to easily integrate the decision aid into their care. They appreciated the opportunity to reconsider their options at their own pace after consulting their surgeon. This was particularly important for those women who thought that the initial consultation with their surgeon did not provide sufficient time to answer all the questions they had. Many women felt that the decision on NAST needed to be made quickly and welcomed using the time in-between the consultation with their

surgeon and their medical oncologist to think about their options with the help of the decision aid.

> *I think it was important to speak to the surgeon and get his view on it all, but I think it was also very helpful to have the written information that was in the decision aid so I could sit and read that at my own pace. (…) When you are in a surgeon appointment, it's only a limited amount of time. Like it's specific to, boom, boom, boom, the things that have to be dealt with. It felt like it (=the decision aid) was more information than what I'd had from him (=the surgeon). It was also that I was able to absorb it better because I could sit down and take the time to read it. (patient ID: 13010041)*

While most women received the decision aid after the initial consultation with their surgeon, many women made the decision during or just after this initial discussion and some wished they had the decision aid "right from the start" (patient ID: 13010035), i.e. just after their diagnosis. Although using the decision aid in-between two consultations seemed appropriate, some patients reported they would have liked to receive the decision aid during rather than after the initial consultation with their surgeon.

> *The book that I was sent after I did that survey, I would have loved to have had access to that book from the get go. (patient ID: 13010034)*

Some patients did not use the decision aid as they felt that they (or their doctors) had already made the decision. However, most women read the entire decision aid at least once and then reread the passages they perceived to be most relevant to them. The amount of information provided was seen to be appropriate. Patients appreciated that they could read the decision aid from beginning to end or only focus on those parts they were most interested in.

You could read more into it if you wanted, but for me, I read bits and pieces of the bits that weren't relevant to me – and all of what was relevant to me but I think it was enough information that if you weren't quite sure you could always go and get more if you wanted (…) for me it was the right amount of information. (patient ID: 13010033)

Improved knowledge and understanding of treatment options

The decision aid enhanced patients' knowledge and understanding of the treatment options available to them by summarising and extending the information provided by their doctors. It helped women comprehend and make sense of their cancer and treatment options. Many women reported that the decision aid made up for their perceived lack of medical expertise by providing structured, objective information and by answering questions patients had after the consultation with their doctor.

Sometimes you just need it clearly laid out in front of you, this is your options, without having different people who had their own agendas telling you what is right and what is wrong, or what you should do. (patient ID: 13010033)

It enhanced what my surgeon had told me and allowed me to process it and understand it at a greater depth than I would have been able to if I hadn't had the decision aid. (patient ID: 13010034)

It was very simply written and also to the point. I suppose there were some questions that I might have been asking myself and they were being answered in that booklet. (patient ID: 13010035)

Some women indicated that the included graphs and statistics were particularly helpful for understanding the potential risks and benefits of their treatment options. Others found that the explanation of different types of breast cancer helped them better understand why

different patients received different treatments. Some participants with medical backgrounds felt that the decision aid could have provided them with more detailed information, for example, on potential risks and benefits of NAST and upfront surgery according to different age groups. However, they thought that the decision aid provided the right depth and breadth of information to suit the needs of the heterogeneous group of breast cancer patients, which includes patients with very different educational backgrounds and literacy levels.

> *It did give figures for chances of it (=the cancer) disappearing altogether and chances of it coming back, the different types of cancer and yeah, I became a bit more of an expert about breast cancers and the different types that I had been before. (patient ID: 13010048)*

> *I found it interesting to read a little bit about the other cancers and make the decision on me and my situation rather than everyone's situation. (patient ID: 13010033)*

> *I think that the particularly relevant bit was understanding the different types of cancer and the explanation of the HER2 and the other types of cancer, and how they are all slightly different, because I didn't know any of that before I got cancer. (…) So yes, the relevant thing, I think, was understanding all the different types of cancer and how one size doesn't fit all. Not everyone should have the same approach. (patient ID: 13010041)*

The decision aid also helped women deal with the fears associated with their treatment options and assisted them in making an informed, rational decision based on their individual circumstances and preferences.

I felt after reading it (=the decision aid) that my fears about the tumour remaining there were abated really. (…) My cancer was triple negative and I understood that it had potentially grown quite fast. Once I understood the rationale for why I might have chemotherapy first, I actually felt it was a better option for me to start the chemotherapy sooner rather than later, given that it also had spread to my lymph nodes. (patient ID: 13010033)

Providing customised, reliable information

Women appreciated that information was provided in both face-to-face and written format. Many women preferred the printed decision aid over the online version due to ease of access, viewing, portability, and ability to make notations. Also, patients preferred using the decision aid instead of information they found by searching online. They perceived the information provided in the decision aid to be more trustworthy and targeted to their needs, compared with sources that they identified on the Internet.

I just found that the information that I was Googling on the Internet, it was too much, it was too airy fairy. Whereas this (=the decision aid) was just straight to the point, it was just in great user friendly language and that's what I really loved about the book. (patient ID: 13010035)

I was a little bit overwhelmed and I wanted reliable information, so I chose not to Google, not to do a Google doctor. (patient ID: 13010034)

All patients who used the decision aid described the information provided in the decision aid as reliable and tailored to their needs. They liked how the decision aid was organised, including the use of graphics, tables, and sufficient white space that reduced the crowding of text. Most patients found the decision aid easy to understand and balanced (not in

favour of NAST or upfront surgery). Some patients perceived it to be in favour of NAST and wished it contained more information on upfront surgery.

> *The way it's laid out, it's quite spacious on the pages and there are lots of diagrams and stuff. So it's not, you know, it's quite intimidating if it was all heavy text closely together. (patient ID: 13010015)*

> *I think it was more slightly biased in terms of chemotherapy first but it could have just been my reading of it because I was already in that frame of mind. (patient ID: 13010041)*

Facilitating involvement in decision making

The decision aid not only enabled patients to make an informed decision on NAST but also helped them become more involved in the decision-making process, for example, by prompting additional questions to ask their doctors during the consultation. Some women took parts of the decision aid to the next consultation with their specialist. This served as a platform for further discussion about their preferences and concerns and helped women remember the questions they wanted to ask their doctor. One patient found the step-by-step approach for how to arrive at a treatment decision particularly helpful. This section of the decision aid included guidance to patients to understand, review, prioritise, and discuss the information provided (see Additional file 3).

> *I felt like I was more involved in the decision and I was making the decision in a more informed way than I maybe would have been able to if I'd just relied on the surgeon's information, if that makes sense. (patient ID: 13010033)*

> *It (=the decision aid) was opening up other questions for me to think about, to help me think about. (patient ID: 13010024)*

I actually then just pulled out pages that I thought were more towards what I was thinking. (…) I took that with me to the oncologist appointment. Just so I had things that reminded me of what I wanted to ask. (patient ID: 13010026)

Some women reported that their family members used the decision aid as well and thus became more informed and involved in the decision-making process. This saved patients from spending time and effort educating their support persons about the risks and benefits of the different treatment options available to them.

My husband went through the decision aid as well, and also my two adult daughters. I think it was quite helpful for them. I saved my breath, if you know what I mean, in terms of having to explain and justify why one option might be a better choice than another. (patient ID: 13010034)

All patients received a treatment recommendation from their doctor and chose the recommended option. The decision-making process was guided by their doctors' opinions and based on patients' trust in their doctors' medical expertise and experience. Although the decision aid helped patients understand their options, confirm their decision, and increase their involvement in the decision-making process, it did not change women's decisions on NAST. Women who felt they made an informed decision on NAST and were involved in the decision-making process seemed to be more satisfied and certain about their decision.

It (=the decision aid) just kind of clarified and confirmed to me what I was doing, and the decision I made. (patient ID: 13010032)

I felt that having chemo first was the right decision – and the information in there (=the decision aid) helped me confirm that that was the right decision. I just think it's something that should be out there for all women in this situation (…) It's such

an important tool to have to make sure that you're making the decision that's right for you. (patient ID: 13010033)

3.6 Discussion

Fitting decision aids into the clinic workflow: a feasible prospect

These results suggest that the decision aid was a useful tool to support breast cancer patients in deciding on whether to have NAST. The themes that emerged from the data were of integration of the decision aid into care, increased knowledge and understanding of treatment options, provision of customised, reliable information, and involvement in the decision-making process. The decision aid supported women's comprehension of their cancer and the treatment options available to them. It facilitated their participation in deciding on NAST and helped women confirm that they made the right decision. This is in line with current evidence supporting the effectiveness of decision aids in improving patient outcomes [15, 26]. The degree of patients' engagement with this decision aid demonstrates the feasibility of patient involvement in decision making in the context of a confronting diagnosis accompanied by a variety of decisions, rather than expecting clinician-led decision making.

Although decision aids have been shown to be effective in improving patient outcomes, widespread clinical use is not yet commonplace [27]. More efforts need to be made to explore how to best integrate decision aids into routine doctor-patient communication. Depending on the format and the decision being made, individual decision aids may be better suited to use either during the consultation or afterwards [15]. The breast cancer patients in our sample appreciated reading the decision aid in-between having a consultation with their surgeon and their follow-up consultation with their medical oncologist. Patients received the decision aid after the initial consultation with their surgeon, while waiting to see their medical oncologist. This allowed the decision aid to

be easily integrated into their care pathway. It also gave women the opportunity to reconsider their options and feel more certain about choosing a treatment. This is in line with previous studies reporting reductions in patients' decisional conflict, decisional regret, and depression after the use of decision aids, which had been delivered as a post-consultation supplement [15, 28, 29]. Further studies have suggested that using a decision aid prior to the consultation during which a healthcare decision is made might increase patients' feeling of being informed about their options, as well as patients' ability and willingness to participate in the decision-making process at hand [30-32].

Although using the decision aid in between patients' consultation with their surgeon and their consultation with their medical oncologist seems to be appropriate, some women said that the intervention should be introduced and endorsed during the initial consultation with their surgeon. Such an approach may be possible with sufficient resources. However, it may be difficult to broadly incorporate into routine practice, given many clinicians' reluctance regarding the provision of decision aids during the consultation [33, 34]. For example, it has been suggested that clinicians might fear that the use of decisions aids would increase their time pressure [35, 36]. Further barriers include clinicians' lack of awareness of decision aids and their belief that decision aids are not applicable to the circumstances of each individual patient [37].

The study processes precluded investigators from providing participants with the decision aid at the initial consultation with their surgeon, because pre-decision-aid questionnaires were required for the larger intervention trial in which this qualitative study was embedded. However, investigators were given a card showing key images and graphs from the decision aid to demonstrate within the consultation. In routine clinical practice, the decision aid could be briefly introduced during the initial consultation with the surgeon. Face-to-face communication between doctor and patient may be best suited to

introduce and explain the preference-sensitive nature of the decision on NAST and the potential benefits of the decision aid [38]. This is in line with previous studies that suggest that patients may value having important treatment decisions discussed with their clinician first and having decision aids delivered during the consultation [39, 40]. Patients could then use and engage with the decision aid after the consultation to broaden and deepen their understanding of the conveyed information and prior to making a final treatment decision.

Exploring the benefits of the decision aid on neoadjuvant systemic therapy

The women included in our sample were well-educated and had high health literacy levels, which may have contributed to positive feedback about comprehensibility. We do not know whether women with lower health literacy levels would perceive the same benefits from using the decision aid. However, there is evidence to suggest that if patients with lower literacy levels are provided with appropriate decision support, they would participate equally well and benefit by becoming more aware of their healthcare options [41]. It would be beneficial to administer the decision aid to a more representative sample of breast cancer patients to investigate whether our findings are generalisable.

The decision aid reassured women that they made the right decision on NAST but did not change their decision. Other decision aid studies have demonstrated a variable effect on treatment choice [15]. However, the intent is to inform and involve rather than to change people's minds. All women trusted and followed their doctors' treatment recommendation. Many patients felt that their treatment decision needed to be made quickly and felt overwhelmed by their cancer diagnosis and treatment options. Decision aids, such as the one provided within this study, may be an opportunity to counteract this "rushed" decision making by allowing patients to reconsider and confirm their treatment decision [42, 43]. Because all patients in our study received a treatment recommendation,

this decision aid could be used to educate women on the preference-sensitive nature of the decision on NAST and to highlight the benefits of involving patients' preferences in this decision [44, 45]. Thus, the endorsement by clinicians influenced the decision aid's success. Also, the decision aid gave patients' support persons specific information about the options available and enabled their participation in the decision-making process. This mirrors previous studies that reported that decision aids can increase families' knowledge of the options available to patients and their involvement in decision making [46, 47].

The influence of the decision aid on the decision about neoadjuvant systemic therapy

Although most women felt that the decision aid provided unbiased, balanced information, some women perceived that the decision aid was in favour of NAST. When probed to explain why they felt this way, women reported that they decided on NAST and felt that they might have read the decision aid according to what they had already decided. One could assume that to obtain or maintain cognitive consonance, women who chose NAST read the decision aid to confirm their decision and thus got the impression that NAST was recommended by the decision aid [48]. However, it may be that the decision aid is in fact biased. Further examination is needed to answer this question.

A number of women indicated a preference for more detailed information. Although the decision aid includes links to further information sources, it may be worthwhile to provide an optional supplement to the decision aid for those patients who would like to receive more information on the decision on NAST. Such a supplement could include information on potential risks and benefits of NAST and upfront surgery according to different age groups. This would be more amenable to an online format, which incorporates links and additional pages for those who want more information. Similar approaches have been shown to be valued by patients [49, 50].

Limitations

Our findings are not intended to be numerically representative. They rather provide much-needed in-depth insights into patients' use and perceived benefit of this decision aid, and decision aids in general. As such, we avoided potentially misleading numerical description of our results. A quantitative analysis of the decision aid that includes a larger sample size will be reported elsewhere. Most study participants (85%) chose NAST over upfront surgery. Thus, women's perceptions of the decision aid may have been influenced by their treatment decision. Also, some women used the decision aid months prior to the interview, introducing the possibility of recall bias that could potentially lead to inaccurate narratives [51]. Some patients noted that the shock over their cancer diagnosis and the plethora of information to consider added further difficulty with remembering the decision aid's content.

> *That is a really, really shady period of my life. I can't remember much. You probably know that people do not remember much when they first hear the diagnosis. (patient ID: 13010023)*

We do not have recordings of the consultations during which the decision aid was introduced. Thus, we do not know how the communication skills and styles of the doctors who were involved in the delivery of the decision aid may have influenced patients' use and perceived benefit of the decision aid.

3.7 Conclusion

Our results suggest that the decision aid is a valuable tool for supporting women with their decision on NAST. It seemed to increase women's knowledge and understanding of the options available to them and helped them feel more involved in the decision-making process. The decision aid assisted women with confirming that they made the right decision. For most women, using the decision aid in-between the consultation with their

surgeon and the consultation with their medical oncologist appeared to be an acceptable and feasible way of integrating the decision aid into patient care.

Acknowledgements

We would like to acknowledge funding support from a Strategic Research Partnership Grant (CSR 11-02) from Cancer Council New South Wales to the Newcastle Cancer Control Collaborative (New-3C) and infrastructure funding from the University of Newcastle and Hunter Medical Research Institute. The ANZ1301 DOMINO study is funded by an HCF Research Foundation grant and by the Breast Cancer Institute of Australia.

Funding

Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship and a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship and has received funding support from the Hunter Cancer Research Alliance Implementation Science Flagship Program as part of the 2017 Research Higher Degree Student Award initiative. Nicholas Zdenkowski is supported by the Hunter New England Local Health District. Frances Boyle is supported by the Friends of the Mater Foundation.

Competing interests

The authors declare that they have no competing interests.

Contribution of co-authors

Please see Appendix 3.2.

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3.9 Additional files

Additional file 1 – Completed IPDAS checklist

International Patient Decision Aid Standards (IPDAS) Collaboration

IPDAS 2005: Criteria for Judging the Quality of Patient Decision Aids

Steering Committee: A O'Connor (CA) & G Elwyn (UK) (co-leaders) with A Barratt (AU), M Barry (US), A Coulter (UK), M Holmes-Rovner (US), N Moumjid (FR), H Llewellyn-Thomas (US), M O'Kane (US), R Thomson (UK), D Stacey (CA), T Whelan (CA) **Methods Group:** G Elwyn (leader, UK) with S Bernstein (US), P Shekelle (US), R Thomson (UK), R Volk (US) **Stakeholder Leader:** A Coulter (UK) **Quality Criteria Panels:** A O'Connor (CA) & H Llewellyn-Thomas (US) (editors) with J Austoker (UK), A Barratt (AU), M Barry (US), H Bekker (UK), J Belkora (US), C Braddock (US), P Butow (AU), E Chan (US), A Charvet (Switz), A Clarke (UK), J Davison (CA), J Dolan (US), A Edwards (UK), V Entwistle (UK), A Fagerlin (US), D Feldman-Stewart (CA), J Fowler (US), D Frosch (US), P Hewitson (UK), M Holmes-Rovner (US), T Hope (UK), MJ Jacobsen (CA), A Kennedy (Switz), S Knight (US), M Kupperman(US), B Ling (US), T Marteau (UK), K McCaffery (AU), N Moumjid (FR), A Mulley (US), M O'Connor (US), E Ozanne (US), M Pignone (US), A Raffle (UK), C Ruland (NO), L Schwartz (US), K Sepucha (US), S Sheridan (US), S Stableford (US), D Stacey (CA), D Stilwell (US), V Tait (CA), D Timmermans (NL), L Trevena (AU), T Whelan (CA), C Wills (US), S Woloshin (US), S Ziebland (UK)

What are patient decision aids and why are they needed?
Patient decision aids are tools to help people participate in their health decisions in ways they prefer. They are used when there is more than one medically reasonable option to diagnose or treat a health problem. Each of the options has good and bad features that people value differently. Even when two people are in the same situation, what is important for one person may be different for another person. Therefore, there is no clear answer that applies to everyone. The best choice involves matching which features matter most to a person with the option that has these features. To make a good decision, you need an expert on the facts (e.g. a health practitioner) and an expert on which features matter most (e.g. the patient) and a way to share their views with each other in ways they prefer.

Patient decision aids aim to do three things to prepare a person for decision making. They provide facts about a person's condition, the options and their features. They help people to clarify their values (the features that matter most to them). They help people to share their values with their health care practitioner and others, so a course of action can be planned that matches their values. Patient decision aids do not advise people to choose one option over another. They do not replace counseling from a health care practitioner. Instead, they prepare people to discuss the options with their health care practitioner.

An international group of researchers, known as the 'Cochrane Review Team of Patient Decision Aids' is compiling decision aids and summarizing the results of research trials. The latest review of 34 studies shows that patients and practitioners who use patient decision aids make better decisions. Patients participate more, know more, and have more realistic expectations of what might happen. They are more likely to receive an option with features they most value (O'Connor et al., *Cochrane Library*, 2003).

The **International Patient Decision Aid Standards (IPDAS)** Collaboration is a group of researchers, practitioners and stakeholders from around the world. The goal is to establish an internationally approved set of criteria to determine the quality of patient decision aids. These criteria will be helpful to a wide variety of individuals and organizations that use and/or develop patient decision aids.

Why are standards needed?
There are over 500 patient decision aids available or being developed by many different individuals and groups around the world. However, people have difficulty knowing whether or not a decision aid is a source of reliable health information that can help in decision making.

How were the standards obtained?
There was a 2-stage evidence-informed Delphi consensus process

- Participants included 122 people from 14 countries and 4 stakeholder groups [researchers/developers; health professionals/ patient/consumers; policy makers/health plan administrators]
- A voting document was developed from a series of background papers on 12 quality domains. [The experts who wrote these papers are listed above]. Before voting on the importance of each criterion in judging the quality of a patient decision aid, voters reviewed: definition of decision aids; definition of criterion; theoretical link between criterion and decision quality; and empirical evidence supporting or not supporting its use in decision aids. Evidence was derived from fundamental studies and a Cochrane Collaboration systematic review of randomized trials of patient decision aids.

The standards are summarized in a users' checklist on the next page.
For more information and to obtain copies of the IPDAS documents visit our website at
www.ipdas.ohri.ca

Table 3. IPDAS Patient Decision Aid Checklist for Users

I. Content: Does the patient decision aid ...

Provide information about options in sufficient detail for decision making?

- ☒ describe the health condition 2.1
- ☒ list the options 2.2
- ☐ list the option of doing nothing 2.3
- ☐ describe the natural course without options 2.4
- ☒ describe procedures 2.5
- ☒ describe positive features [benefits] 2.6
- ☒ describe negative features of options [harms / side effects / disadvantages] 2.7
- ☒ include chances of positive / negative outcomes 2.8

Additional items for tests

- ☐ describe what test is designed to measure 2.9
- ☐ include chances of true positive, true negative, false positive, false negative test results 2.10
- ☐ describe possible next steps based on test result 2.11
- ☐ include chances the disease is found with / without screening 2.12
- ☐ describe detection / treatment that would never have caused problems if one was not screened 2.13

Present probabilities of outcomes in an unbiased and understandable way?

- ☒ use event rates specifying the population and time period 3.1
- ☒ compare outcome probabilities using the same denominator, time period, scale 3.2, 3.3, 3.6
- ☒ describe uncertainty around probabilities 3.4
- ☒ use visual diagrams 3.5
- ☒ use multiple methods to view probabilities [words, numbers, diagrams] 3.7
- ☒ allows the patient to select a way of viewing probabilities [words, numbers, diagrams] 3.8
- ☒ allow patient to view probabilities based on their own situation [e.g. age] 3.9
- ☒ place probabilities in context of other events 3.10
- ☒ use both positive and negative frames [e.g. showing both survival and death rates] 3.13

Include methods for clarifying and expressing patients' values?

- ☒ describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional, social effects 4.1
- ☒ ask patients to consider which positive and negative features matter most 4.2
- ☒ suggest ways for patients to share what matters most with others 4.3

Include structured guidance in deliberation and communication?

- ☒ provide steps to make a decision 6.1
- ☒ suggest ways to talk about the decision with a health professional 6.2
- ☒ include tools [worksheet, question list] to discuss options with others 6.3

II. Development Process: Does the patient decision aid ...

Present information in a balanced manner?

- ☒ able to compare positive / negative features of options 9.1
- ☒ shows negative / positive features with equal detail [fonts, order, display of statistics] 9.2

Have a systematic development process?

- ☒ includes developers' credentials / qualifications 1.1
- ☒ finds out what users [patients, practitioners] need to discuss options 1.2, 1.3
- ☒ has peer review by patient / professional experts not involved in development and field testing 1.8a, 1.8b
- ☒ is field tested with users [patients facing the decision; practitioners presenting options] 1.4, 1.5

The field tests with users [patients, practitioners] show the patient decision aid is:

- ☒ acceptable 1.6, 1.7
- ☒ balanced for undecided patients 9.3
- ☒ understood by those with limited reading skills 10.6

Use up to date scientific evidence that is cited in a reference section or technical document?

- ☒ provides references to evidence used 11.1
- ☒ report steps to find, appraise, summarise evidence 11.2
- ☒ report date of last update 11.3
- ☒ report how often patient decision aid is updated 11.4
- ☒ describe quality of scientific evidence [including lack of evidence] 11.5a, 11.5b
- ☒ uses evidence from studies of patients similar to those of target audience 11.6

Disclose conflicts of interest?

- ☒ report source of funding to develop and distribute the patient decision aid 7.1, 7.2
- ☒ report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid 7.3, 7.4

Use plain language?

- ☒ is written at a level that can be understood by the majority of patients in the target group 10.3
- ☒ is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY] 10.4
- ☒ provides ways to help patients understand information other than reading [audio, video, in-person discussion] 10.5

Table 3. IPDAS Patient Decision Aid Checklist for Users

Meet additional criteria if the patient decision aid is Internet based

- ☐ provide a step-by-step way to move through the web pages 8.1
- ☐ allow patients to search for key words 8.2
- ☐ provide feedback on personal health information that is entered into the patient decision aid 8.3
- ☐ provides security for personal health information entered into the decision aid 8.4
- ☐ make it easy for patients to return to the decision aid after linking to other web pages 8.5
- ☐ permit printing as a single document 8.6

Meet additional criteria if stories are used in the patient decision aid

- ☐ use stories that represent a range of positive and negative experiences 5.2
- ☐ reports if there was a financial or other reason why patients decided to share their story 7.5
- ☐ state in an accessible document that the patient gave informed consent to use their stories 5.5

III. Effectiveness: Does the patient decision aid ensure decision making is informed and values based?

Decision processes leading to decision quality. The patient decision aid helps patients to ...

- ☒ recognise a decision needs to be made 12.1
- ☒ know options and their features 12.2, 12.3
- ☒ understand that values affect decision 12.4
- ☒ be clear about option features that matter most 12.5
- ☒ discuss values with their practitioner 12.6
- ☒ become involved in preferred ways 12.7

Decision quality. The patient decision aid ...

- ☒ improves the match between the chosen option and the features that matter most to the informed patient 12.8

Note: numbers behind items correspond to endorsed criteria in Table 2.

Additional file 2 – Questions in each domain of the question guideline

Questions on information provided to patients included asking patients: i) where they received information to help them make a decision about whether to have chemotherapy before surgery; ii) which of these information sources they found most useful; iii) what exactly the information was that helped them make the decision; iv) whether they felt they were given enough information to allow them to make a decision; v) if they felt they were not given enough information, what other information they would like to have received; and vi) how they would like information presented to them (written, face-to-face, online).

Questions regarding the decision-making process and psychological concerns included asking patients: i) who made the decision in the end; ii) what was difficult about making the decision; iii) how certain they were about the decision at the time when they made the decision; iv) how certain they were then that they made the right decision; and v) if their certainty had changed, why it changed. Patients are further asked whether: vi) they do or did worry that their cancer will get worse while having chemotherapy; vii) what period during chemotherapy and surgery they found most difficult, mentally and physically; and viii) whether they worry that their cancer will come back.

Questions regarding patients' experiences with the decision aid included asking patients: i) how much time they spent using the decision aid; ii) whether it provided additional information to that provided by their health professionals; iii) whether the information was relevant to their decision and in what way it was relevant/not relevant; iv) how the information factored into their decision; v) whether the information was trustworthy; vi) whether the information was presented in a way that was easy to understand; vii) whether they perceived the decision aid to be too long, about right or too short; viii) whether the amount of information was too much, about right, or too little; ix) whether the decision

aid favoured NAST, was balanced or favoured surgery; and x) whether they have other comments on the decision aid.

Questions regarding other factors which might have influenced patients' decision included asking patients whether and if so, how the following factors influenced their decision: i) having breast-conserving surgery (lumpectomy); ii) being able to know whether the cancer responded to chemotherapy; iii) having treatment sooner for the whole body, not just for the breast; iv) being involved in a clinical trial (and whether their doctor talked to them about this); and v) their ability to have children in the future. Patients were further asked whether vi) they were aware that breast cancer can be inherited in the family and whether that was relevant to their decision; vii) what other issues they considered when making the decision, such as financial or logistic issues; and viii) whether they had considered having breast reconstruction.

Additional file 3 – One page of the decision aid, describing a step-by-step approach for how to arrive at a treatment decision

Arriving at a treatment decision

The previous pages have outlined the main options available to you now. The following steps may help you to make a decision whether or not to have chemotherapy or hormonal therapy before surgery. The decision-making process may be easier if you follow these seven steps:

1. Understand your diagnosis and your risk of breast cancer recurring (coming back) as fully as you can.
2. Understand your options for treatment and the risks and benefits of these options.
3. Review the pros and cons of those options.
4. Assess the importance to you of the pros and cons.
5. If you are offered neoadjuvant treatment through a clinical trial, prioritise the pros and cons of the trial for you (and your family).
6. Get more information from your doctor or breast care nurse if you are unsure of anything or have more questions.
7. Discuss your preferred treatment option with your surgeon, medical oncologist, family doctor, your family and other significant people in your life.

You have already gone through steps 1-3. To help you complete steps 4-7, and come to the decision that suits you best, we have prepared a worksheet on the following page.

PAPER FOUR

A discrete choice experiment to assess cancer patients' preferences for when and how to make treatment decisions

When deciding on a particular treatment there is usually a vast array of information on each possible treatment option that patients have to consider, comprehend and weigh up [1]. As the availability of possible treatment options increases, the final decision often comes down to the specific values and preferences of each individual patient [2, 3]. As a consequence, many patients feel overwhelmed when being confronted with their cancer diagnosis, prognosis and available treatment options [4].

To help patients make informed healthcare decisions, it has been suggested that patients should be provided with two consultations and some time to consider their treatment options in-between these consultations [5, 6]. This consultation style is supported by the findings presented in Papers Two and Three which suggest that providing additional written and/or online information in-between two consultations seems to be an acceptable and feasible way of integrating decision support into patients' care pathway. However, although the qualitative studies included in this thesis provide valuable in-depth insights into the decision-making process regarding difficult treatment decisions, the results are restricted to very specific and narrow population groups. If we are going to improve patient decision making for the wider population we need to explore this using larger samples. Quantitative data using a large sample of cancer patients are needed to extend on and generalise the findings obtained from the previous qualitative studies. Specifically, understanding patients' preferences for the amount, format and timing of the information they receive will allow the design of decision support strategies that are patient-centred, and increase the useability and acceptability of such interventions.

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A discrete choice experiment to assess cancer patients' preferences for when and how to make treatment decisions

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Citation: Herrmann A, Sanson-Fisher R, Hall A, Wall L, Zdenkowski N, Waller A: A discrete choice experiment to assess cancer patients' preferences for when and how to make treatment decisions. *Support Care Cancer* 2017. doi: 10.1007/s00520-017-3944-9

4.1 Abstract

Background: Cancer patients can be overwhelmed when being confronted with their diagnosis and treatment options. Such information is often provided during one consultation between the patient and treating clinician. In order to achieve optimal cancer care, there may be justification for alternative consultation styles.

Aims: We assessed, in a sample of adult medical oncology patients, their preferences for (i) attending one 40-minute consultation or two 20-minute consultations and (ii) receiving written only or both written and online information, when making a cancer treatment decision.

Methods: This was a cross-sectional survey using a discrete choice design of 159 adult medical oncology patients presenting for their second or subsequent outpatient consultation. Participants were presented with a set of hypothetical scenarios and asked to indicate their most and least preferred scenario. The scenarios contained a caveat explaining that there would be no difference between the available treatment options in terms of when treatment would be initiated and the impact it would have on patients' life expectancy.

Results: One hundred and forty-seven patients completed the discrete choice experiment. Of these, 70% (n = 103) preferred being provided with written and online information rather than just written information. This preference was statistically significant ($p < 0.01$). Fifty-nine percent (n = 86) of patients preferred two 20-minute consultations over one 40-minute consultation when making a treatment decision. Significantly, more patients preferred two shorter consultations rather than one longer consultation when this was combined with written and online information ($p < 0.01$).

Conclusion: When making a cancer treatment decision, clinicians should consider offering patients written and online information, combined with two shorter consultations.

4.2 Background

Involving patients in decisions regarding their cancer care to the extent they desire is considered best practice [1]. However, delivering such care can be challenging. Cancer treatment decisions often introduce patients to unfamiliar concepts, a specialised language and a high degree of uncertainty regarding potential outcomes [2]. Patients may experience distress and anxiety related to their diagnosis and prognosis which can interfere with their ability to understand and recall the considerable array of information they receive about their treatment options [3]. To help ease the burden patients may feel when making treatment decisions, consensus guidelines have suggested that patients should be provided with two consultations with a short time between each consultation, combined with information presented in multiple formats [4]. This strategy aims to ensure patients have adequate time to make an informed decision by affording them the opportunity to consider the information they receive, seek additional information and/or involve others [5]. Despite these potential benefits, patients are commonly provided with only one relatively long consultation when making decisions about their treatment [6, 7]. To our knowledge, no study has assessed patients' preferences for the number and length of consultations and the format of information provided. Having such data will help inform clinicians about how to best conduct consultations with their patients in order to align care with patients' wishes. This is an important step towards delivering optimal, patient-centred cancer care.

Discrete choice experiments to study patients' preferences

A discrete choice design is a methodologically robust approach to measure the strength of an individual's preferences [8]. Discrete choice experiments (DCEs) are based on the assumption that decisions can be described by a number of key attributes and that an individual's choice is influenced by the levels of these attributes [9]. Participants are

presented with a number of hypothetical scenarios comprised of different levels of attributes and are asked to indicate their preferred option for each scenario [10]. Compared with other methodologies used to elicit patients' preferences, DCEs have a number of advantages, which include: i) the elimination of yes-response bias as patients are forced to elicit a preference; ii) an ability to quantitatively assess the overall value people place on different attributes, as well as the trade-offs they are willing to make between these attributes; and iii) reduced participant burden as they are only required to answer one single question [11].

4.3 Aims

The overall objective of this study was to utilise a DCE to assess cancer patients' preferences for two characteristics of oncology consultations. Specifically, we assessed, in a sample of adult medical oncology patients, their preferences for:

i. Attending either one 40-minute consultation or two 20-minute consultations when making a treatment decision about their cancer; and
ii. Receiving either written only or written and online information regarding their treatment options.

The scenarios contained a caveat explaining to patients that there would be no difference regarding patients' survival rates, as well as when treatment would be initiated.

4.4 Methods

Design

This was a cross-sectional survey which included a DCE (see Appendix 9.3). It was part of a larger study which was undertaken in two medical oncology treatment centres in New South Wales, Australia. We recruited cancer patients who had made cancer treatment decisions in the past and were thus able to make informed choices regarding the proposed consultation styles. Recruitment took place from October 2015 to December 2016. The Hunter New England Human Research Ethics Committee has granted full ethics approval for this research (approval number: 14/11/19/4.04, see Appendix 8.3). Participants gave informed consent before taking part in this study. A completed STROBE checklist for this study can be found in Appendix 10.8.

Inclusion criteria

Patients were eligible for this study if they: i) were aged 18 years or over; ii) had a confirmed diagnosis of any type of cancer; iii) were English speaking; and iv) were presenting for their second or subsequent outpatient medical oncology consultation at one of the two treatment centres included in this study.

Recruitment

Eligible patients were identified by clinic staff, using daily clinic lists. On check-in to their appointment clinic staff asked eligible patients if they would be willing to talk to the research team about the study. Informed consent was obtained by a trained research assistant by consecutively approaching patients who indicated they were willing to talk to the research team. Consenting patients completed a pen-and-paper survey via their preferred method (mailed or via email) within one week after recruitment (baseline) and three months later (follow-up, see Appendix 10.7). The DCE assessed in this study was

included as part of the follow-up survey. Non-responders received a reminder telephone call two weeks after receiving a survey and two weeks later. Clinic staff recorded the age and gender of non-consenters who provided permission, to allow for examination of consent bias.

Measures

DCE to examine patients' preferences for consultation type and format of information

The DCE included in this study consisted of two attributes, with two levels each. Attributes and levels were based on a literature review and discussions among the research team, which included experts in the areas of health behaviour, oncology and statistics. The attributes, their levels and the caveat included in the scenarios are described in Table 4.1 and Figure 4.1. To assess the acceptability and feasibility of the approach, the DCE was pilot-tested with experts in health behaviour, oncology and statistics, as well as with breast cancer patients (n = 7) attending a cancer treatment centre in New South Wales, Australia. Each study participant was presented with four scenarios and was asked to indicate their most and least preferred scenario. The scenarios were shown in a randomly selected order. The DCE involved only two attributes with two levels each. This kept patients' choices relatively simple. A "no information" option was not included in the DCE design given clinicians' ethical obligation to provide some information about their treatment options to patients in order to obtain informed consent for the suggested procedure.

Table 4.1 Attributes and levels of the DCE

Attributes	Levels
Number and length of consultations	One 40-minute consultation Two 20-minute consultations
Format of information provided	Written only Written and online

Imagine the following: Your doctor has told you about different treatment options for your cancer. He has asked you to decide which treatment you would like to have.

Importantly:

- There is no difference between the treatment options in terms of how they will affect your length of life.
- However, the treatment options have different pros and cons. Your doctor believes that it is important that the decision is yours. He is happy for you to have either type of treatment. The decision depends on how you feel about the pros and cons of the options.
- Whichever treatment you choose, it will start in two weeks from your first appointment.

We are interested in finding out what you think would help you most in making this decision.

If you were in that situation, which of the scenarios below would you like most? Also, which of the scenarios would you like least? For each question please choose one option only by ticking one of the relevant boxes:

	One 40-minute consultation and written information only	One 40-minute consultation and written and online information	Two 20-minute consultations and written information only	Two 20-minute consultations and written and online information
I would like **MOST** Please tick one box in this row:	☐	☐	☐	☐
LEAST Please tick one box in this row:	☐	☐	☐	☐

Figure 4.1 Scenarios patients could choose from to indicate their most and least preferred consultation type and format of information

Demographic and cancer characteristics

For this study, the following self-reported demographic and disease-related characteristics were evaluated: gender, age and cancer type.

Statistical analysis

All analyses were conducted in Stata 14.2 and R 3.2.3 (2015-12-10). Consent bias with regard to gender and age were assessed using Chi-square tests. The DCE data were analysed using descriptive statistics, Pearson's Chi-square test with Yates' continuity correction and an ordinal regression model (see Appendix 10.9). This enabled us to examine the trade-offs patients made when choosing between the different levels of the attributes.

4.5 Results

Participants

For the larger study, 455 eligible patients were approached. Of these, 379 (83%) consented to participate in the larger study. Two hundred and fourteen patients (47% of all eligible patients approached) were sent a 3-month follow-up survey including the DCE. Of these, 159 (74%) returned a completed survey. Most participants were female (n = 116, 73%) and were receiving treatment for breast cancer (n = 91, 58%). Participants had a mean age of 64 years (see Table 4.2). There were no significant differences between consenters and non-consenters in terms of age and gender ($p > 0.05$).

Table 4.2 Sociodemographic and cancer-related characteristics of participants

Characteristic	Patients n=159 (%)
Age in years, mean (SD)	64 (12)
Gender	
Male	43 (27)
Female	116 (73)
Primary cancer location	
Breast	91 (57)
Colon	16 (10)
Prostate	10 (6.3)
Lung	9 (5.7)
Others	32 (20)
Missing	1 (0.6)

Patients' preferences

Ninety-two percent of study participants (n = 147) completed the DCE. Of the four scenarios presented to patients, the most preferred option was to receive two consultations along with written and online information (n = 65; 44%; see Figure 4.2). The second most preferred scenario chosen by patients was being provided with one consultation and written and online information (n = 38, 26%). The least preferred scenarios included one consultation and written information only (n = 23; 16%) and two consultations with written information only (n = 21, 14%). The ordinal regression analysis showed that statistically significantly more patients preferred being provided with written and online information rather than written information only ($p < 0.01$). Comparatively, there was no main effect for the attribute of consultation length. However, a significant interaction between the two attributes was found, with significantly more patients preferring to receive two 20-minute consultations over one 40-minute consultation, when this was combined with being provided with written and online information ($p < 0.01$).

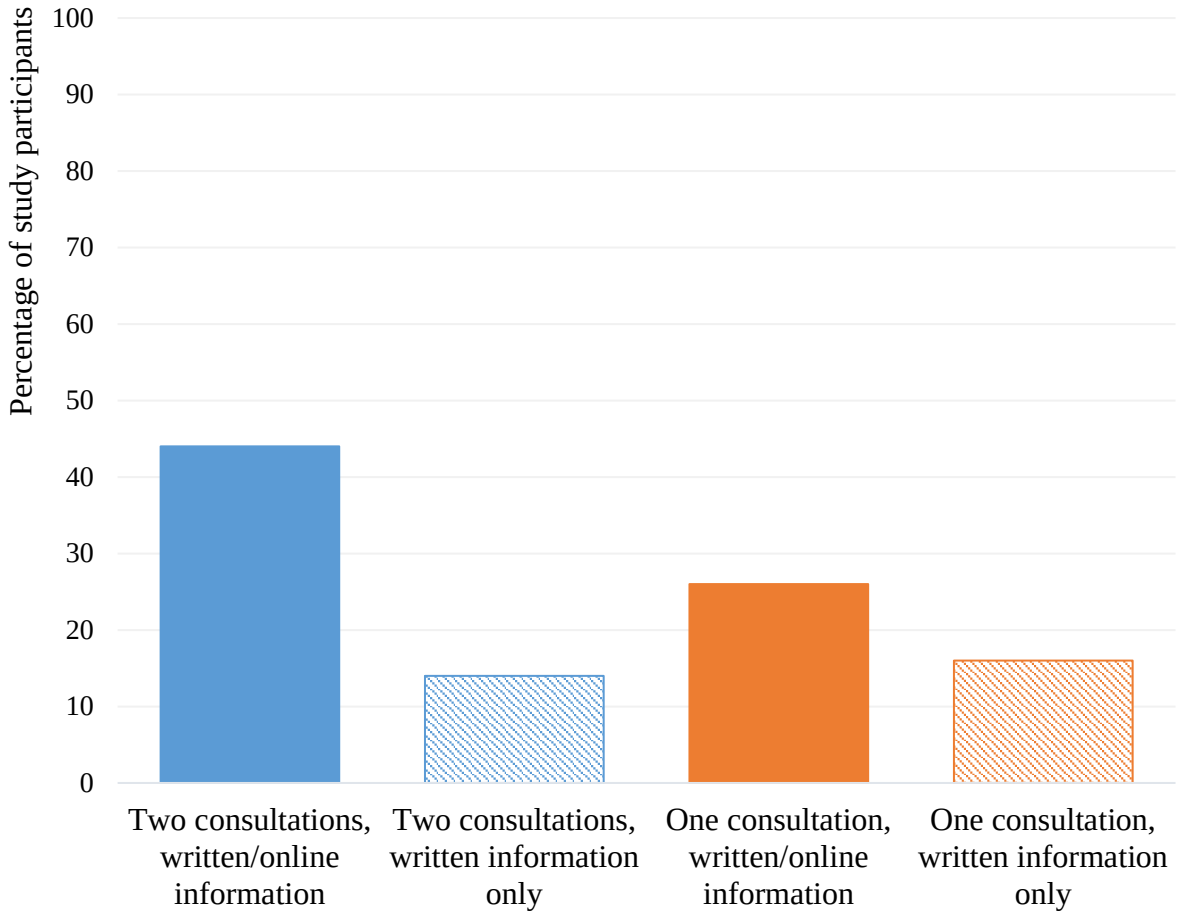

Figure 4.2 Patients' preferences for scenarios

4.6 Discussion

Our findings highlight that some patients would prefer receiving information regarding their treatment options in multiple formats and would like to have time to consider their options in order to make informed decisions. To our knowledge, this is the first study to elicit patients' preferences for the number and length of consultations and the format of information provided when making a cancer treatment decision. Most patients in our study preferred being provided with written and online information regarding their treatment options, combined with two consultations. While we did not directly elicit patients' reasons for their choices, potential reasons may include that this consultation style could allow patients to better "digest" the abundance of information presented

during the consultation and help overcome their feeling of being overwhelmed [12]. Specifically, providing information via multiple formats can help patients access information according to their preferences. This can increase patients' satisfaction with the consultation and help them better cope with their cancer [13]. It may also help overcome poor health literacy and enhance patients' understanding and recall of the information provided [14].

Offering two consultations may facilitate the involvement of patients' support persons by affording them the opportunity to consider the information provided by the doctor and discuss the treatment options with the patient in-between two consultations. This may be valued by patients who feel more certain about their decision after consulting their support persons [15]. However, a number of patients in our study wished to receive one longer consultation rather than two shorter ones. It may be that these patients perceive urgency and prefer to make treatment decisions as soon as possible in order take immediate action and prevent a worsening of their cancer [16]. This preference could also be due to practical constraints, such as support persons' ability to attend multiple consultations and patients' travel time to the clinic.

Clinicians should offer patients the option of presenting information in multiple formats in two consultations

The variation across patients' preferences suggests that a patient-centred approach towards oncology consultations is required whereby care is tailored to patients' preferences for information provision and decision making. This requires clinicians to have a clear understanding of a person's preferences. However, previous research indicates that clinicians do not always have an accurate understanding of when and how patients would prefer to receive information about their treatment options [17]. Clinicians' misperceptions regarding patients' comprehension of information [18] and

preferred involvement in treatment decisions have been reported previously [19]. Asking patients directly about their preferences for information provision and decision making has the potential to reduce the discord between patient and clinician estimates [20]. Wherever possible, patients should also be offered the option of receiving information about their treatment options in multiple formats and having two consultations. Where appropriate, clinicians should emphasise to patients that it is usually safe to take some time to consider their options before making a decision.

How to overcome some of the barriers to providing two consultations when making cancer treatment decisions

Clinicians may question the feasibility of providing two consultations for every patient in routine practice. For example, patients living in rural areas may have difficulties travelling to the clinic twice in order to attend two consultations. In these instances, an alternative option may be to hold the second consultation via telephone or online. Using videoconferencing to conduct oncology consultations allows rural patients to receive consultations closer to their homes and has been shown to minimise healthcare access difficulties [21]. This approach has also been found to be acceptable to patients and clinicians and can result in net savings to the patient and healthcare system compared with usual care [22]. It can be implemented in many geographically distant areas which require lengthy travel to access healthcare [22].

There may also be concerns that providing two shorter consultations would increase clinicians' perceived time pressure. For instance, they may need more time associated with the increased number of consultation letters to write [23]. However, helping patients understand the information provided to them and involving them in treatment discussions occurring at an early stage can lead to more succinct discussions later, which may ultimately save time [24]. It also has the potential to improve a number of patient

outcomes, including decreased anxiety and fear of cancer recurrence, increased satisfaction with the consultation and higher quality of life [25, 26].

Limitations and implications for future research

It has been argued that patients' preferences for choosing hypothetical scenarios may differ from their preferences for making actual treatment decisions. However, a number of studies have compared actual choices with stated preferences and found that parameters from both were similar [27–29]. Telser and Zweifel compared willingness-to-pay values for health-related goods derived from actual choices with ones derived from a DCE and found a close correspondence between the two results [30]. Despite including numerous cancer types, this sample was overrepresented by women diagnosed with breast cancer. Thus, there is a need to investigate patients' preferences for different consultation styles in other cancer populations, including with males. These patients may have different preferences for information provision and decision making. Having such data will help examine the generalisability of our findings.

We also do not know how different consultation styles may affect patient outcomes. It has been suggested that tailoring consultations according to patients' preferences can improve a number of patient outcomes, including increased patient satisfaction and emotional well-being [31]. Intervention trials are needed to assess prospectively the impact of receiving two consultations along with written and online information, rather than one consultation and written information only. Two consultations may increase costs for patients receiving care in those healthcare settings where patients have to pay per consultation. It may also increase patients' waiting times. We did not collect information on how patients would trade-off increased costs and waiting times against receiving their preferred consultation style. More research is needed to assess whether these factors would impact on patients' preferences for different consultation styles.

4.7 Conclusion

Based on our findings, cancer patients seem to prefer the idea of being provided with written and online information combined with two shorter consultations, rather than having one consultation and written information only. Wherever possible, clinicians should offer patients this consultation style to allow for time to "digest" the presented information and support patients with making informed treatment decisions. Given the variation across patients' preferences, it is essential that clinicians ask their patients about their decision-making preferences and tailor care accordingly. This can help ensure that cancer patients receive optimal, patient-centred care.

Acknowledgements

We would like to thank the patients who were involved in this study. We also thank Professor Scott Brown for his contribution to the development and analysis of the DCE. We acknowledge infrastructure funding from the University of Newcastle and Hunter Medical Research Institute.

Funding information

Financial support for this study was provided by a Strategic Research Partnership Grant (CSR 11-02) from the Cancer Council New South Wales to the Newcastle Cancer Control Collaborative (New-3C) and by a Partnership Project (APP1059760) from the National Health & Medical Research Council (NHMRC). Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship and a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship and has received funding support from the Hunter Cancer Research Alliance Implementation Science Flagship Program as part of the 2017 Research Higher Degree Award initiative. Nicholas Zdenkowski is supported by the Hunter New England Local Health District. Amy Waller is funded by an Australian Research Council Discovery Early Career Research Award. The funding agreement ensured the authors' independence in designing the study, interpreting the data, and writing and publishing the report.

Conflicts of interest

The authors declare that they have no competing interests.

Contribution of co-authors

Please see Appendix 4.2.

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PAPER FIVE

Support persons' preferences for the type of consultation and the format of information provided when making a cancer treatment decision

In order to provide evidence-based, patient-centred care, illness needs to be considered as a social process, not just a biological state [1]. As such, optimal cancer care needs to incorporate both patients' and their support persons' wishes. Support persons can play a key role in patients' decision-making process. They often attend clinical encounters, help patients recall and comprehend the information provided by their doctor, offer opinions on the presented treatment options and become involved in deciding on patient care [2, 3]. Support persons can also have an impact on the doctor-patient-relationship and patients' satisfaction with the care they receive [4]. Paper Five examines support persons' preferences for the amount, format and timing of the information provided when making a cancer treatment decision. It also investigates whether support persons' preferences are similar to what patients wish. Having such data will help increase our understanding of how patient-centred treatment decision making can be improved in routine cancer care.

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Support persons' preferences for the type of consultation and the format of information provided when making a cancer treatment decision

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5.1 Abstract

Background: Patient-centred care incorporates patients' and their support persons' wishes.

Aims: We examined, in a sample of cancer patient support persons, their preferences for i) attending one 40-minute consultation or two 20-minute consultations when making a cancer treatment decision and ii) receiving additional information in written form only or in both written and online forms. We also compared support persons' preferences with patients' preferences.

Methods: A cross-sectional survey, using a discrete choice experiment (DCE), of 159 adult medical oncology patients, and 64 of their support persons. Participants were presented with a set of hypothetical scenarios and asked to indicate their most and their least preferred scenario. The scenarios contained a caveat explaining that there would be no difference between the treatment options in terms of when treatment would be initiated, and the impact it would have on participants' life expectancy.

Results: Ninety-two percent of support persons (n=59) completed the DCE. Most support persons preferred to receive two consultations along with written and online information (n=30, 51%). This was the only scenario that was chosen by statistically significantly more support persons ($p = 0.037$). The proportions of patients and support persons choosing each scenario did not differ significantly from each other ($p > 0.05$).

Conclusion: When making a cancer treatment decision, this group of patients and support persons preferred to receive written and online information, combined with two shorter consultations. Clinicians should consider offering this consultation style.

5.2 Background

Support persons are an important influence on patients' treatment decisions

When deciding on their cancer treatment, patients commonly seek help from their partner, family and friends [1, 2]. Support persons are one of the most important information sources for patients [2]. Patients value their support persons' involvement in decision making and often feel more certain about their decision after consulting their support persons [3]. Many patients want their support persons to have a say about their cancer treatment decisions [4]. Support persons' views on how they prefer to make cancer treatment decisions can further impact on the relationship between doctor and patient [5]. For example, research suggests that support persons can convince patients to choose another doctor if they are unhappy with the provided consultation style [5]. Providing care that does not align with patients' and support persons' preferences may increase the probability of conflicts between doctor, patient and support persons [5]. In order to reduce the likelihood of such conflicts, it is important that we examine the decision-making preferences of patients and support persons to find out whether they share the same views.

We need to focus on preferences for consultation style and format of information provided

Support persons' views on how to make cancer treatment decisions are often under-represented when studying healthcare decision making [6]. Accurate, quantitative data are needed to better understand support persons' preferences for different characteristics of oncology consultations. In particular, we need to focus on those characteristics that tend to vary considerably between clinicians, like the format of the information provided and the number and length of consultations offered [7]. To allow patients and support persons to discuss the information provided during the consultation and facilitate support persons' involvement in treatment decision making, it has been suggested that patients

should be provided with two consultations with a short time between each consultation, combined with information presented in multiple formats [8]. However, when making cancer treatment decisions, patients and support persons are commonly provided with one relatively long consultation and written information alone [9, 10]. To our knowledge, this is the first study to examine support persons' preferences for i) the number and length of consultations, and ii) the format of information provided when making a cancer treatment decision for themselves; and to assess whether their preferences align with what cancer patients would prefer. Having such data can help ensure that patients and support persons receive the resources they need to make informed healthcare decisions.

Discrete choice experiments to study patients' and support persons' preferences

Discrete choice experiments (DCEs) are a methodologically robust approach to assessing people's preferences. They have been used across a number of fields, including economics, marketing and healthcare [11]. In a DCE, participants are presented with two or more hypothetical scenarios and asked to indicate their preferred option [12-14]. Compared with other methodologies which have been used to elicit people's preferences, DCEs have a number of advantages, including: reduced participant burden as participants are only required to consider one single survey item, and elimination of yes-response bias as participants are forced to elicit a preference [15, 16]. There is evidence to support the internal validity and consistency of DCE designs [17, 18].

5.3 Aims

To first examine, in a sample of cancer patient support persons, their preferences for:

i. Attending either one 40-minute consultation or two 20-minute consultations when making a cancer treatment decision for themselves; and

ii. The format of information they would receive regarding their treatment options (written vs written and online).

We then aimed to compare support persons' preferences with patients' preferences.

5.4 Methods

Design

This was a cross-sectional study which included a DCE (see Appendix 9.3). Consenting participants completed a paper-and-pen survey via their preferred method (mailed or via email) within one week after recruitment (baseline) and three months later (follow-up). The DCE assessed in this study was included as part of the follow-up survey. Patient recruitment, data collection and patients' preferences have been described in detail in a separate paper (Paper Four of this thesis and Appendix 10.7). Here we are looking at support persons' preferences and whether they differ from patients' preferences. Consenting patients were asked to nominate a support person. If this person accompanied the patient to their appointment, they were approached for consent in the clinic. If the support person was not present in the clinic, the consenting patient was provided with a recruitment package which included a study information letter and a survey to pass on to the eligible person.

Patients were eligible for this study if they: i) were aged 18 years or over; ii) had a confirmed diagnosis of any type of cancer; iii) were English speaking; and iv) were presenting for their second or subsequent outpatient medical oncology consultation at one of the two treatment centres included in this study. Eligible support persons were: i) nominated by the patient as someone helping them cope with their cancer through support, encouragement and communication; ii) aged 18 years or over; and iii) English speaking. Clinic staff recorded the age and gender of non-consenters who provided permission, to allow for examination of consent bias.

Ethics

The Hunter New England Human Research Ethics Committee has granted full ethics approval for this research (approval number: 14/11/19/4.04, see Appendix 8.3). Participants gave informed consent before taking part in this study.

Measures

DCE to examine patients' and support persons' preferences for timing and format of decision support

The DCE included in this study consisted of two attributes, which comprised two levels each. This resulted in participants being presented with four scenarios for which they were asked to indicate their preferences (see Table 5.1 and Figure 5.1). Attributes and levels were based on a literature review and discussions among the research team, which included experts in the areas of health behaviour, oncology and statistics. The scenarios were shown in a randomly selected order. The DCE was pilot-tested with a number of health behaviour researchers, an oncologist and two statisticians. Feedback on the DCE design was also sought from breast cancer patients attending a cancer treatment centre in New South Wales, Australia (n=7). This was to assess the acceptability and feasibility of the design. Support persons were asked to imagine they had just been diagnosed with cancer and that they had to make a cancer treatment decision for themselves. They then followed the same instructions as patients.

Table 5.1 Attributes and levels of the DCE

Attributes	Levels
Number and length of consultations	One 40-minute consultation Two 20-minute consultations
Format of information provided	Written only Written and online

IMAGINE THE FOLLOWING: You have been diagnosed with cancer. Your doctor has told you about different treatment options for your cancer. He has asked you to decide which treatment you would like to have.

IMPORTANTLY:

- There is no difference between the treatment options in terms of how they will affect your length of life.
- However, the treatment options have different pros and cons. Your doctor believes that it is important that the decision is yours. He is happy for you to have either type of treatment. The decision depends on how you feel about the pros and cons of the options.
- Whichever treatment you choose, it will start in two weeks from your first appointment.

We are interested in finding out what you think would help you most in making this decision.
If you were in that situation, which of the scenarios below would you like most? Also, which of the scenarios would you like least?
For each question please choose one option only by ticking one of the relevant boxes.

	One 40-minute consultation and written information only	**One 40-minute consultation and written and online information**	**Two 20-minute consultations and written information only**	**Two 20-minute consultations and written and online information**
I would like MOST Please tick one box in this row:	☐	☐	☐	☐
I would like LEAST Please tick one box in this row:	☐	☐	☐	☐

Figure 5.1 An example of the scenarios support persons could choose from to indicate their most and least preferred consultation type and format of information

Sociodemographic and cancer characteristics

For this study, the following self-reported sociodemographic characteristics of support persons were evaluated from the participant surveys: age, gender, relationship to patient, whether the support person was living with the patient and the time spent with the patient. The following self-reported demographic and disease-related characteristics of patients were included from the participant surveys: gender, age, cancer type (see Paper Four in this thesis).

Statistical analysis

All analyses were conducted in Stata 14.2 and R 3.4.0 (2017-04-21). Consent bias with regard to gender and age were assessed using Chi-square tests. The DCE data were analysed using descriptive statistics, Pearson's Chi-square test with Yates' continuity correction, and an ordinal regression model. This enabled us to examine the trade-offs participants made when choosing between the different levels of the attributes. Chi-square tests were used to examine if the proportions of support persons who chose each scenario were statistically significantly different from the proportions of patients choosing each scenario, using a p-value cut-off of 0.05. Bootstrapping was used to calculate 95% confidence intervals. The data coding manual can be found in Appendix 10.9.

5.5 Results

Participants

One hundred and thirteen support persons filled out the baseline survey. Of these, 74% (n=84) consented to be sent a follow-up survey. Of those consenting to be sent a second survey, 64 (76%) completed the questionnaire. There were no statistically significant differences between consenters and non-consenters in terms of age and gender ($p > 0.05$).

Support persons had a mean age of 61 years. Most support persons were female (n=41, 64%) and reported to be the patient's spouse or partner (n=37, 58%, see Table 5.2).

One hundred fifty nine patients returned a completed survey. Most patients were female (n=116, 73%) and were receiving treatment for breast cancer (n=91, 58%). Patients had a mean age of 64 years. Patients' consent and response rates as well as patient characteristics have been described in detail elsewhere (see Paper Four in this thesis).

Table 5.2 Sociodemographic and cancer-related characteristics of participants

Characteristic	Support persons n=64 (%)
Age in years, mean (SD)	61 (13)
Gender	
Male	23 (36)
Female	41 (64)
Relationship to the patient	
Spouse/partner	37 (58)
Relative	24 (38)
Other	3 (4.6)
Living with the patient	
Yes	42 (66)
No	22 (34)
Time spent caring for patient	
Less than 20 hours	31 (48)
20-40 hours	10 (16)
More than 40 hours	10 (16)
Unsure or do not provide any care	11 (17)
Missing	2 (3.1)

Support persons' preferences

Ninety-two percent of support persons (n=59) completed the DCE. When comparing their preferences for the four scenarios, we found that just over half of support persons (n=30, 51%) preferred to receive two consultations combined with written and online information when making a cancer treatment decision for themselves (see Figure 5.2). The second most preferred scenario included one consultation and written and online information, with 24% of support persons (n=14) preferring this option. The third most

preferred scenario included one consultation and written information only. Fourteen percent of support persons (n=8) chose this scenario. Support persons preferred least to receive two consultations and written information only. This option was chosen by 12% of support persons (n=7). Regression analyses revealed that the only scenario that was chosen by statistically significantly more support persons included two consultations and written and online information (p = 0.037). The percentages of support persons choosing one of the other scenarios did not differ significantly from each other.

Comparing patients' and support persons' preferences

The proportions of support persons choosing each scenario did not differ statistically significantly from patients' preferences (p > 0.05, see Figure 5.2).

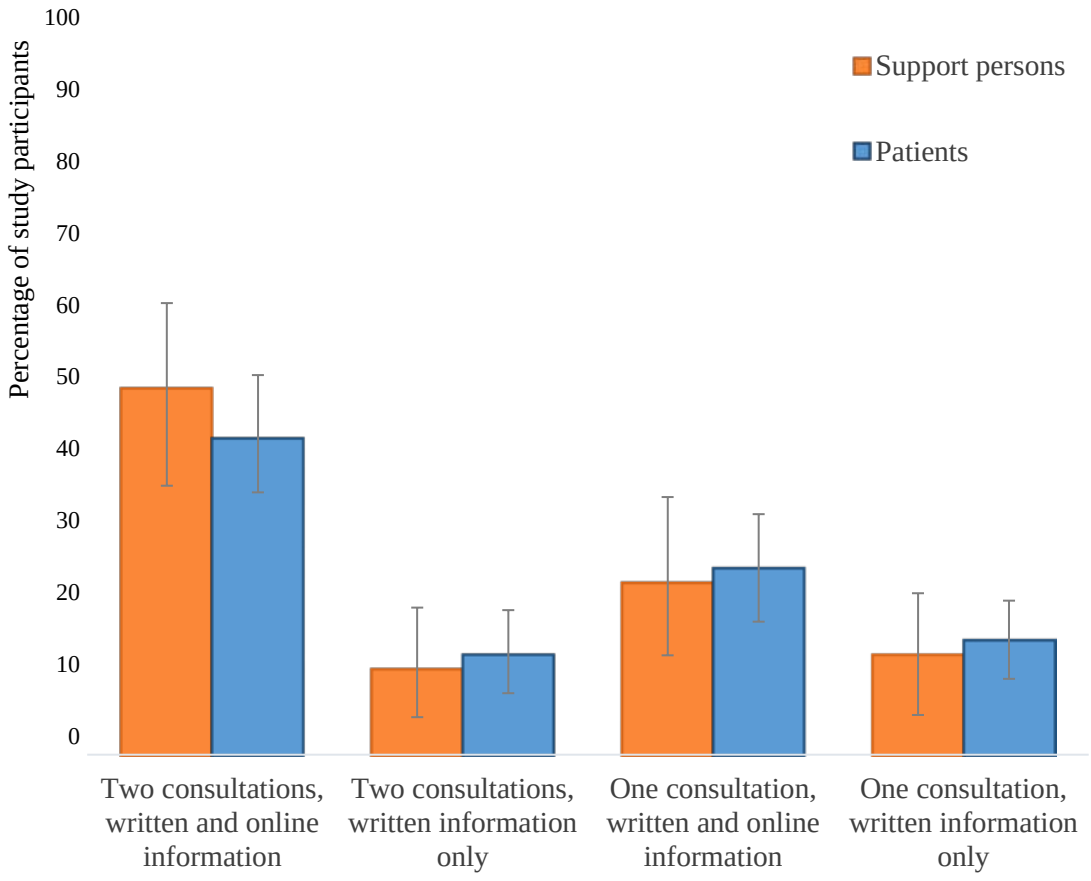

Figure 5.2 Patients' and support persons' preferences for scenarios

5.6 Discussion

Overview of findings

We examined support persons' preferences for different characteristics of oncology consultations when making a cancer treatment decision, and whether these preferences differed from what patients preferred. The data presented in this article indicate that most support persons would prefer to receive two shorter consultations and both written and online information when deciding on their treatment. This was also true for patients. We found no difference in the proportions of support persons' and patients' preferences for the other options. This suggests that both patients and support persons seem to be driven by the same preferences for how to make cancer treatment decisions. They appear to prefer to receive information on the available treatment options in multiple formats and would like to have two consultations to make the decision (see Paper Four in this thesis). When being presented with information on their cancer diagnosis and treatment options, it has been found that patients and support persons often consider themselves as a team and describe the decision-making process as a shared effort [6]. Offering two consultations and thus extending the decisional timeframe may facilitate a shared approach towards decision making between the patient, their support persons and the treating clinicians by allowing patients and support persons to talk about the information provided by the doctors. Also, receiving information via multiple channels may help patients and support persons access information according to their individual preferences, and assist them with comprehending, weighing up and using the information presented to them during the consultation [19, 20].

Why it is important to incorporate patients' and support persons' preferences for how to make treatment decisions

In order to be patient-centred, healthcare needs to align with patients' preferences and incorporate sociocultural influences, such as support persons' needs and wishes [21, 22]. Our data suggest that patients and their support persons may have similar views about how to make cancer treatment decisions. As such, support persons may be a source of information about patients' wishes, which could help doctors identify patients' decision-making preferences and tailor care accordingly. Also, the importance of support persons for patients' decision-making process has been highlighted by a number of health psychology theories, such as the Theory of Reasoned Action and the Theory of Planned Behaviour [23, 24]. These theories suggest that deciding on patient care can be influenced by the so-called "subjective norm" which refers to i) what beliefs the patients think that their support persons hold about the decision at hand, and ii) the extent to which patients are influenced by these others [23, 24]. Clinicians need to be aware of support persons' role in the decision-making process when aiming to support patients with making treatment decisions. Aligning care with patients' and support persons' wishes can improve patient outcomes, for example by reducing conflicts between doctors, patients and support persons [5]. It can further increase patients' satisfaction with the information provided by their doctor, improve patients' emotional well-being and treatment adherence, and ultimately lead to more efficient and effective patient care [6, 25, 26].

Study limitations and directions for future research

It has been argued that people's preferences for making hypothetical scenarios may differ from their preferences for making actual decisions [27, 28]. However, several studies have compared actual choices with stated preferences and found that parameters for both were similar [29]. Also, despite their critical role in the decision-making process, support

persons' views on how to make treatment decisions are often under-represented when studying healthcare decision making [6] . Most studies in this area only focus on the doctor-patient communication and ignore the social context of treatment decision making [2]. More research on support persons' views on making treatment decisions is needed to better understand the social context of medical decision making and improve decision support for patients. It may be worthwhile administering the DCE, which was included in this study to other patient and support person groups in order to investigate the generalisability of our findings.

We examined support persons' preferences with regard to what they would want if they decided on their own cancer treatment. However, they may not have experienced cancer themselves. Thus, their answers may not reflect what they would prefer if they were faced with this decision. Also, support persons' preferences for what they would want for themselves may differ from what they would choose when supporting the patient they care for. However, this study aimed to examine what they would choose if they had to decide on their own treatment. Furthermore, intervention studies are needed to examine how different consultation styles may impact on patients' and support persons' outcomes, such as their understanding of the presented information, their involvement in decision making and their satisfaction with the consultation.

5.7 Conclusion

Patient-centred care needs to align with patients' preferences and incorporate sociocultural influences, such as support persons' needs and wishes. Support persons can play an important role in treatment decision making, and their preferences need to be taken into account in order to achieve optimal, patient-centred cancer care. Based on our findings, patients and support persons seem to prefer the idea of having two shorter consultations supplemented with written and online information, rather than one longer

consultation and written information alone, when making cancer treatment decisions. Offering this consultation style may help patients involve their support persons in the decision-making process and assist patients with making informed decisions regarding their care.

Acknowledgements

We would like to thank our study participants for their time and effort. We thank Professor Scott Brown for his contribution to the development and analysis of the DCE. We acknowledge infrastructure funding from the University of Newcastle and Hunter Medical Research Institute.

Funding

Anne Herrmann is supported by a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship and a University of Newcastle International Postgraduate Research Scholarship, and has received funding support from the Hunter Cancer Research Alliance Implementation Science Flagship Program as part of the 2017 Research Higher Award initiative. Nicholas Zdenkowski is supported by the Hunter New England Local Health District. Amy Waller is funded by an Australian Research Council Discovery Early Career Research Award. Financial support was also provided by a Strategic Research Partnership Grant (CSR 11-02) from the Cancer Council New South Wales to the Newcastle Cancer Control Collaborative (New-3C), and by a Partnership Project (APP1059760) from the National Health & Medical Research Council (NHMRC). The funding bodies were not involved in the study design; in the collection, analysis and interpretation of data; in the manuscript writing; or in the decision to submit this manuscript for publication.

Conflicts of interest

The authors declare that they have no competing interests.

Contribution of co-authors

Please see Appendix 5.1.

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PAPER SIX

Wilfully out of sight? A literature review on the effectiveness of cancer-related decision aids and implementation strategies

The qualitative data presented in this thesis suggest that decisions aids provided in-between two consultations may be a useful strategy to facilitate patient-centred decision making. We know that increasing research effort has been directed towards developing and testing interventions which help patients make difficult healthcare decisions [1], and that decision aids have gained increasing attention by researchers, patient advocates and policy-makers worldwide [2, 3]. There is considerable evidence to suggest that decision aids improve a number of patient outcomes, such as improved patient knowledge of their treatment options and decreased decisional conflict [4, 5]. However, decision aids are not commonly used in clinical practice [6]. Papers Four and Five reported on the quantitative data included in this thesis and concluded that intervention studies are needed to test the effectiveness of different ways of delivering decision support. Little is known about the direction and progression of research effort in this area over time. Paper Six provides a review of the literature to examine where decision aid research has been directed to over the last 15 years and to identify potential gaps in the literature. This will help better understand where the focus of future research should lie to help improve patient-centred decision making in cancer care.

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Wilfully out of sight? A literature review on the effectiveness of cancer-related decision aids and implementation strategies

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Citation: Herrmann A, Mansfield E, Hall AE, Sanson-Fisher R, Zdenkowski N: Wilfully out of sight? A literature review on the effectiveness of cancer-related decision aids and implementation strategies. *BMC Med Inform Decis Mak* 2016, 16(1): 1-9. doi: 10.1186/s12911-016-0273-8

6.1 Abstract

Background: There is evidence to suggest that decision aids improve a number of patient outcomes. However, little is known about the progression of research effort in this area over time.

Aims: This literature review examined the volume of research published in 2000, 2007 and 2014 which tested the effectiveness of decision aids in improving cancer patient outcomes, coded by cancer site and decision type being targeted. These numbers were compared with the volume of research examining the effectiveness of strategies to increase the adoption of decision aids by clinicians.

Methods: A literature review of intervention studies was undertaken. Medline, Embase, PsychInfo and Cochrane Database of Systematic Reviews were searched. The search was limited to human studies published in English, French, or German. Abstracts were assessed against eligibility criteria by one reviewer and a random sample of 20% checked by a second. Eligible intervention studies in the three time periods were categorised by: i) whether they tested the effectiveness of decision aids, coded by cancer site and decision type; and ii) whether they tested strategies to increase clinician adoption of decision aids.

Results: Over the three time points assessed, increasing research effort has been directed towards testing the effectiveness of decision aids in improving patient outcomes ($p < 0.0001$). The number of studies on decision aids for cancer screening or prevention increased statistically significantly ($p < 0.0001$), whereas the number of studies on cancer treatment did not ($p = 1.00$). The majority of studies examined the effectiveness of decision aids for prostate ($n = 10$), breast ($n = 9$) and colon cancer ($n = 7$). Only two studies assessed the effectiveness of implementation strategies to increase clinician adoption of decision aids.

Conclusion: While the number of studies testing the effectiveness of decision aids has increased, the majority of research has focused on screening and prevention decision aids for only a few cancer sites. This neglects a number of cancer populations, as well as other areas of cancer care such as treatment decisions. Also, given the apparent effectiveness of decision aids, more effort needs to be made to implement this evidence into meaningful benefits for patients.

6.2 Background

Patients as key players in their own healthcare

Over the last two decades cancer care has evolved from a paternalistic, clinician-centred model to a patient-centred model [1, 2]. Patient-centred care places great emphasis on involving patients in their own healthcare [3, 4]. Clinical decision making is now largely viewed as a collaborative process in which the clinician, the patient (and their support persons) choose healthcare options together, based on the patient's informed preferences [5, 6]. Involving patients in their healthcare decisions is associated with improved patient outcomes, including decreases in patient unmet information needs and anxiety and increases in patients' satisfaction with the consultation [7, 8]. Shared decision making can improve patients' quality of life [9–12].

Preference-sensitive healthcare decisions are challenging

Patients' willingness to become involved in decisions may be hampered by difficulties in choosing between the various healthcare options available to them [13, 14]. This is especially true for preference-sensitive decisions, where there is little or no difference in the medical effectiveness of the available healthcare options. In these instances the final decision involves weighing up the costs and benefits of the different options according to the values and preferences of the patient [3, 15]. With an increasing variety of treatment and care options, more and more cancer prevention, screening and treatment decisions are becoming preference-sensitive. For example, early-stage breast cancer patients and their clinicians may have a number of different treatment options to choose from, including surgery, cytotoxic or endocrine therapy [16]. Some patients may have the option to decide whether they receive chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant). Each of these treatments shows similar medical effectiveness for these

patients but holds various side-effects and impacts that may be valued differently by different patients [17].

Decision aids to help patients make difficult healthcare decisions

To assist patients in making these difficult decisions, clinicians have been encouraged to use patient decision aids. Decision aids are interventions which provide patients with specific information on their available options and guide patients towards choosing the option that aligns with their values. They intend to encourage patients to become more involved in the decision-making process [18, 19]. Decision aids can be delivered in various formats, such as face-to-face, written booklets and web-based tools [20]. They cover a variety of healthcare options, including cancer screening, prevention and treatment [21].

There is evidence for the effectiveness of decision aids

Numerous reviews have provided considerable evidence of the effectiveness of decision aids in improving patient outcomes [22–25]. The first Cochrane review on the effectiveness of decision aids was published in 2001, and concluded that decision aids improve knowledge, reduce decisional conflict, and stimulate patients to be more active in decision making [26]. Updated versions of this review were published in 2003, 2009, 2011 and 2014, and all supported the original findings [20, 27–29]. To date, over 100 Randomized Controlled Trials (RCTs) exist that demonstrate that decision aids are effective in improving patient outcomes. Despite the evidence for the effectiveness of decision aids, they are not commonly used in practice [30]. Previous research has identified barriers which preclude the implementation of decision aids [31–33]. Little is known about whether the focus of research on the effectiveness of decision aids has changed over time and whether this evidence has translated into the development and testing of strategies to implement decision aids. Once the effectiveness of decision aids

in a certain area has been established, research should move from testing the effectiveness of these interventions to testing the effectiveness of implementing decision aids into routine care.

Research output as measure of research effort

Examining the volume of peer-reviewed research output using bibliometric methods can be used as a proxy indicator of scientific productivity [34–37]. As a result, assessing the volume of research output can provide an indication of the focus of research effort and where future research is needed most. To date, there has been no time sampling of the volume of research examining the effectiveness of decision aids, compared with the volume examining the effectiveness of strategies to increase their adoption by clinicians. We aimed to give an indication of the focus of research efforts, in order to provide an indication of where future research is required.

6.3 Aims

The aim of this review was to provide a snapshot of where research effort focusing on cancer-related decision aids has been directed over the past 15 years. We examined changes in the volume of research that examined the effectiveness of cancer-related decision aids, across three time points. We also categorised eligible articles by cancer type and decision being targeted. Finally, we compared the number of studies that assessed the effectiveness of cancer-related decision aids with the number of studies that assessed strategies to increase the adoption of decision aids by clinicians.

6.4 Methods

Literature search

The electronic databases Medline, Embase, PsychInfo and Cochrane Database of Systematic Reviews were searched using the OVID platform. We selected these databases

due to their focus on biomedicine and health publications in scholarly journals. The search strategy included three categories of search terms and subject headings: cancer, decision making/decision aids and patient participation. We adapted the search strategy to the requirements of each individual database. The full search strategy for each database is available in Additional file 1. Searches were restricted to English, French and German language publications and human studies. Although most scientific research is published in English, the importance of non-English studies is hard to predict [38, 39]. English, French and German belong to the most common alternative languages used in scientific research [40–42]. Studies published in French and German were included in this review to reduce the likelihood of English-language bias. Reference lists of systematic reviews on the effectiveness of decision aids were also searched to ensure that all relevant studies were included in this paper. Where feasible and applicable, the PRISMA guidelines were followed [43].

Inclusion and exclusion criteria

Studies were included if they were intervention studies which examined either the effectiveness of decision aids on patient outcomes, or the effectiveness of strategies to increase clinician adoption of patient decision aids. Eligible papers were those published in any country in 2000, 2007 or 2014. These time periods were chosen prospectively as the patient-centred care model gained popularity after the influential report "*Ensuring Quality Cancer Care*" released by the US National Cancer Board and published in 1999, advocating for patient-centred care [2]. Awareness of the patient-centred model was further heightened by the 2001 Institute of Medicine report "*Crossing the Quality Chasm*" [1]. We excluded case studies, commentaries, conference abstracts, proposed studies, protocol papers and editorials.

Definitions

We based our definition of patient decision aids on that proposed by the International Patient Decision Aid Standards (IPDAS) Collaboration [44–46]. The IPDAS aims to improve the quality and effectiveness of patient decision aids by establishing standards for improving their content, development, implementation, and evaluation [18, 19, 47]. Decision aids were defined as interventions which help patients to participate in making deliberated choices among healthcare options. They explicitly state the decision to be made and provide specific, evidence-based information on the available healthcare options as well as information on the possible risks and benefits of each option. Decision aids aim to help patients to clarify and communicate the value they associate with each option [20, 46]. Strategies to increase clinician adoption of decision aids were defined as any actions taken in order to increase clinician usage of decision aids in clinical practice. Implementation strategies were coded as such if they were targeted at the clinician, and/or if they were targeted at the healthcare system.

Paper coding

After removing the duplicate results, abstracts were screened according to the eligibility criteria by one reviewer (AH). They were rejected if the reviewer determined from the title and abstract that the study did not meet the inclusion criteria. Full-text copies of the remaining publications were retrieved and further assessed against the eligibility criteria by the same reviewer (AH). A random sample of 20% of full-text studies identified as eligible were checked for relevance and double-coded by a second reviewer (EM). Eligible studies in the three time periods were categorised by whether they tested i) the effectiveness of decision aids in improving cancer patient outcomes, or ii) the adoption of decision aids by clinicians. Studies testing the effectiveness of decision aids were also coded by cancer type of the study sample. The type of decision being targeted was coded

as either screening/prevention or treatment. Screening decision aids include those which assist patients to make a decision about whether they want to undergo cancer screening, such as mammography and colonoscopy. Cancer prevention decision aids include those which assist patients to make a decision about whether they will undergo a procedure to lower the risk of getting cancer, such as prophylactic mastectomy and immunisation. Cancer treatment decision aids include those designed to help patients choose between different cancer treatments.

Analysis

One-way trend tests were performed to examine the changes in the proportions of studies on the effectiveness of decision aids, as well as on screening or prevention and treatment decision aids separately across time. Analyses were programmed using Stata v13.0 (StataCorp Ltd, College Station, TX).

6.5 Results

Search results

As shown in Figure 6.1, a total of 2,690 citations were retrieved using the search strategy. Of these, 35 full-text studies met the eligibility criteria and were included in this review. Double-coding of 20% of all full-text articles resulted in 100% agreement between the reviewers (Kappa = 1.000). A list of included citations is provided in Additional file 2.

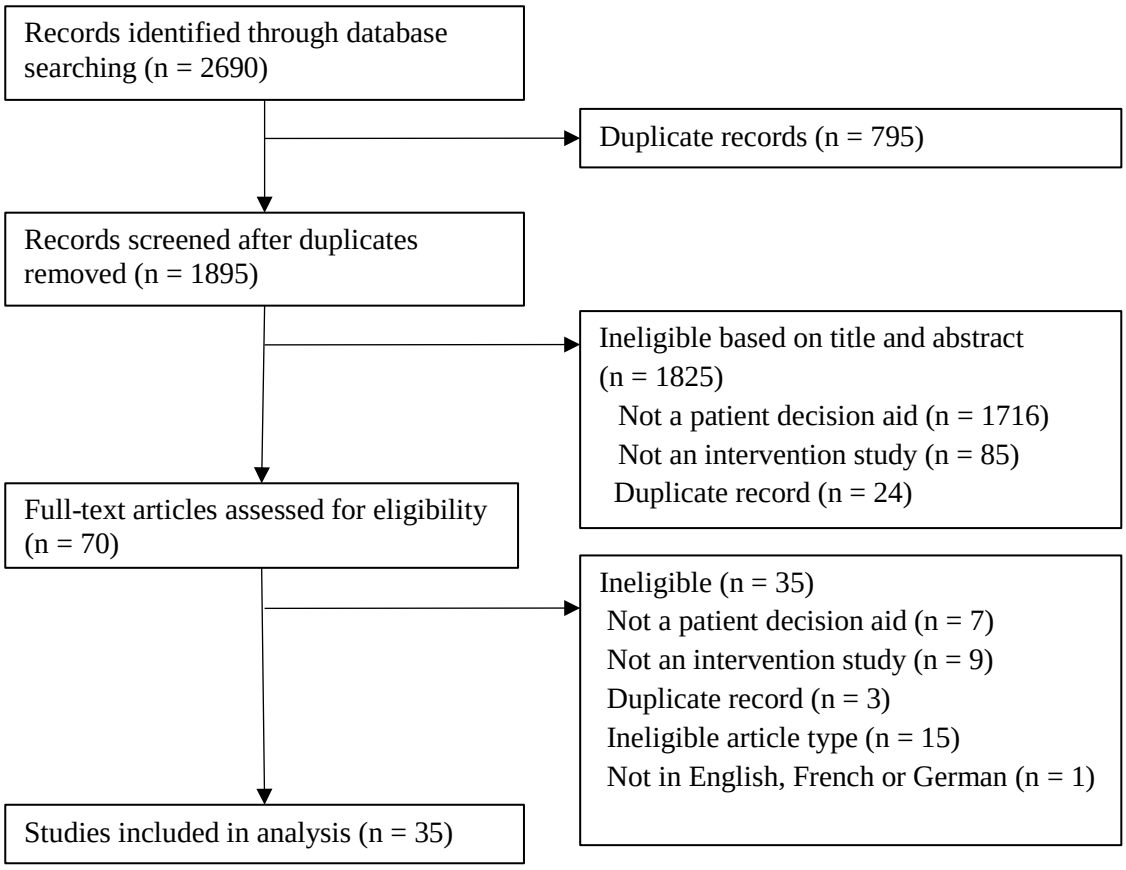

Figure 6.1 Flow chart of search strategy and study selection, according to the PRISMA guidelines ([43], see Appendix 10.10)

Studies reporting on the effectiveness of decision aids

Of the included studies, 33 tested the effectiveness of decision aids in improving cancer patient outcomes. The number of studies examining the effectiveness of decision aids increased significantly across the three time points ($p < 0.0001$), from 8 studies in 2000 (22.8%), to 10 studies in 2007 (28.5%) and 15 studies in 2014 (42.8%). As shown in Figure 6.2, the majority of these papers focused on decision aids for cancer screening and prevention (n = 26), compared with those focused on treatment (n = 7). Across the three time points assessed, the number of studies focusing on cancer screening and prevention decision aids increased significantly ($p < 0.0001$), while the number focused on cancer treatment did not ($p = 1.00$, Figure 6.2). Decision aids were found for breast, prostate,

colon, lung, pancreatic, skin, ovarian and cervical cancer. The majority of studies focused on prostate (n = 10), breast (n = 9) and colon cancer (n = 7). Two studies focused on more than one cancer type, including breast, ovarian, cervical and colon cancer (Figure 6.3).

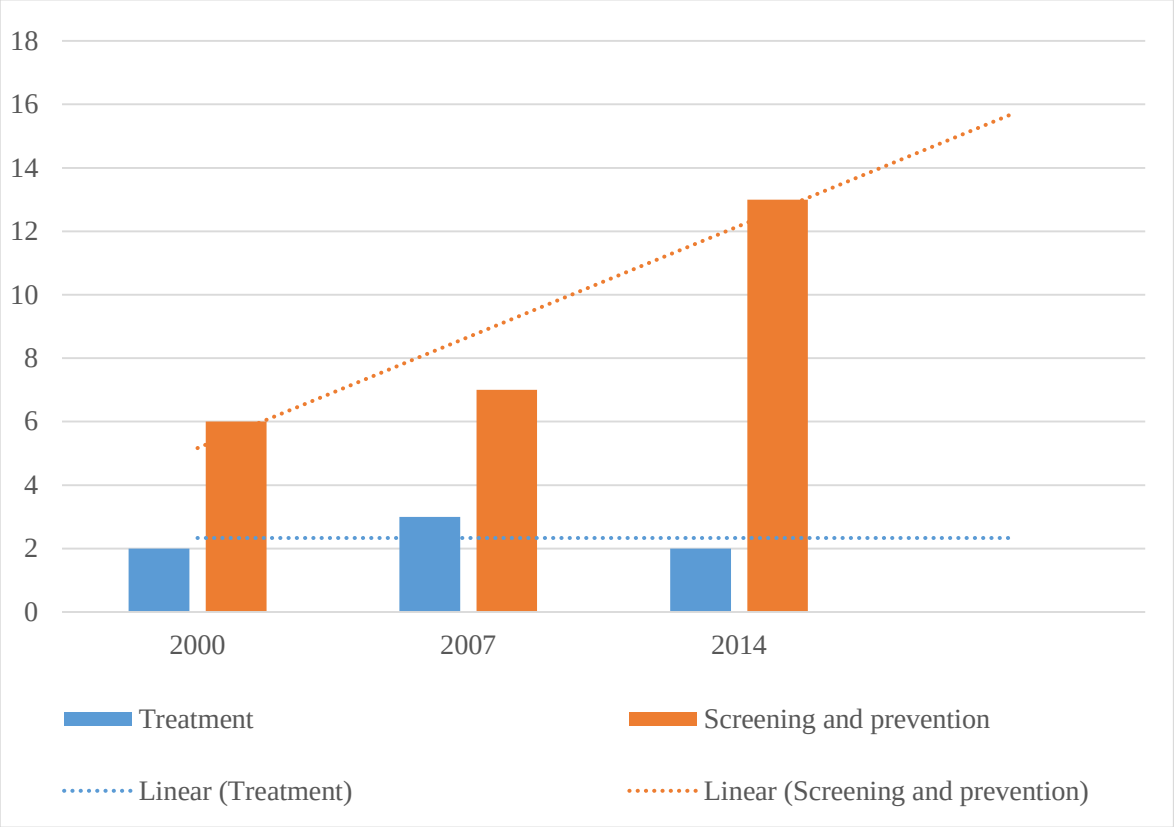

Figure 6.2 Numbers of studies on the effectiveness of decision aids by decision type being targeted

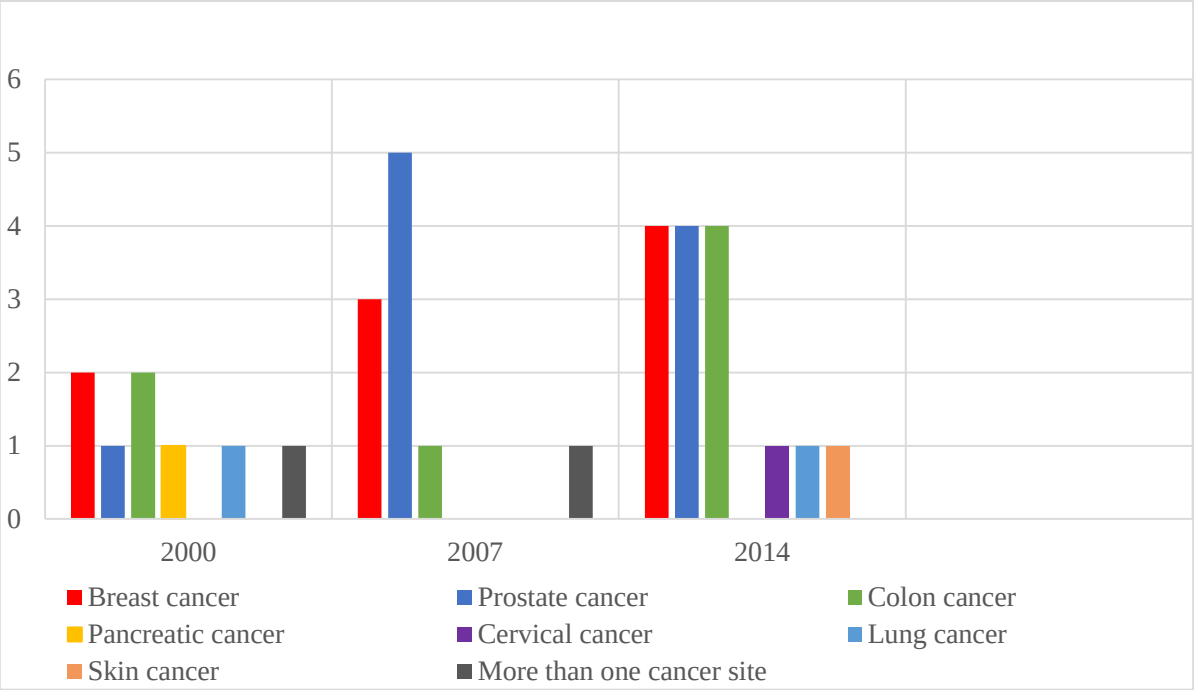

Figure 6.3 Numbers of studies on the effectiveness of decision aids by cancer site

Studies reporting on strategies to implement decision aids

Only the two remaining studies, published in 2000 and 2007, assessed the effectiveness of strategies to increase the implementation of decision aids into clinical practice. Due to the low number of these studies, a statistical comparison was not performed. The number of studies testing the effectiveness of decision aids vs the number of studies examining implementation strategies is reported in Figure 6.4.

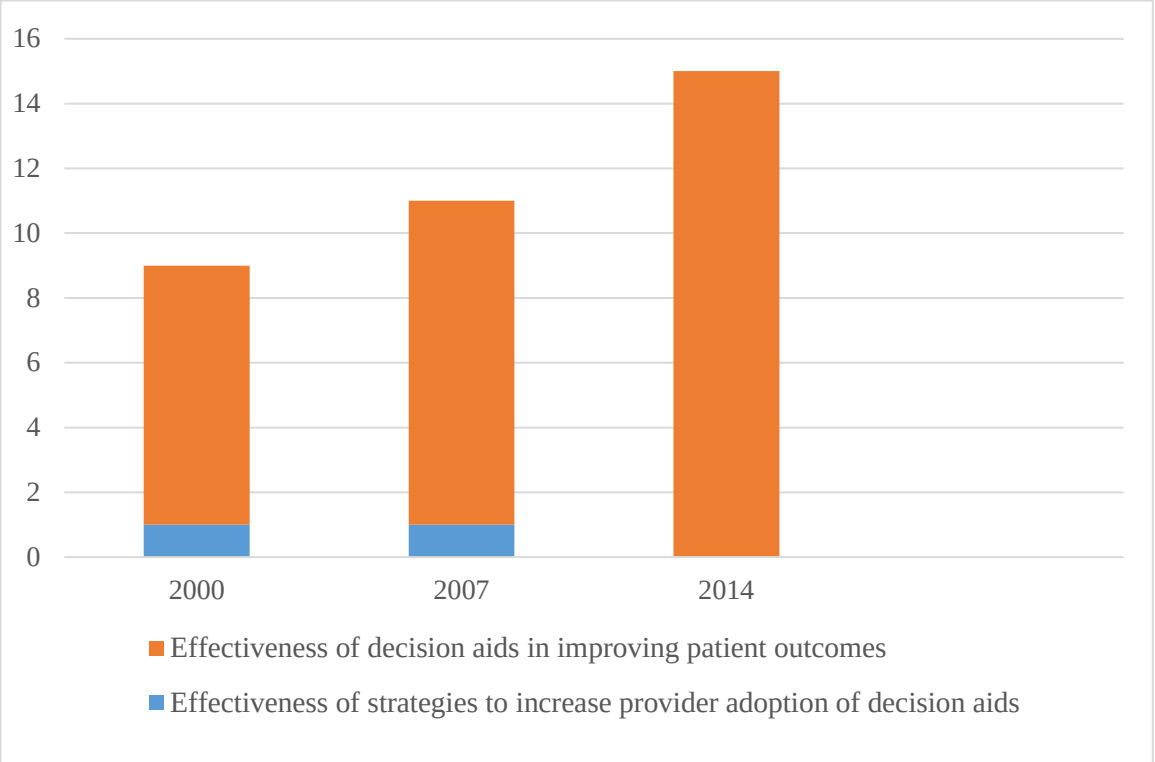

Figure 6.4 Number of studies on the effectiveness of decision aids compared with the number of studies on implementation strategies

6.6 Discussion

Research priorities by relative volume of intervention studies

We examined the progression of research volume which tested the effectiveness of decision aids by cancer site and decision type being targeted, across three time points. Also, we compared these numbers with the volume of research testing the effectiveness of strategies to increase the adoption of decision aids by clinicians. Our data suggest that an increase in research effort has been directed towards assessing the effectiveness of decision aids for cancer screening and prevention. The majority of studies focused on prostate, breast and colon cancer. Only two studies examined the effectiveness of strategies to increase clinician adoption of decision aids, despite evidence illustrating the benefit of decision aids for some patient outcomes [20, 25].

Lack of research on the effectiveness of decision aids for cancer treatment

Although decision aids are available for a number of healthcare decisions, research has been increasingly focusing on screening and prevention decisions as opposed to treatment decisions. One reason for the larger volume of screening and prevention decision aids may be that these interventions are aimed at healthy people, rather than a vulnerable patient group. This can facilitate the research process, for example by easier access to large sample sizes and by the facilitation of the ethical review process. Developing and testing decision aids on treatment options needs considerable clinical input, which relies on strong collaborations between researchers and clinicians [48, 49]. For example, clinicians may vary in their preferences for different treatment options based on their clinical experience [50]. If clinicians disagree with the content of a decision aid, the development of such decision aids may be hindered [32, 51]. However, treatment decisions can be very distressing for patients [13]. Also, as the number of treatment options available to patients has been increasing, particularly in relation to preference-sensitive treatments, opportunities arise to develop and test decision aids for cancer treatment decisions.

Narrow research focus on decision aids for only a few cancer types

Over the past 15 years, increasing research effort has been directed towards examining the effectiveness of decision aids on prostate, breast and colon cancer. This may seem understandable, as according to the latest GLOBOCAN statistics these are amongst the most prevalent cancer types worldwide [52]. Screening recommendations for breast, colon and prostate cancer have been established for decades which could further explain the increased research volume focused on these sites [53]. However, research with other cancer types where decision aids could be beneficial seems to be sparse. For instance, there are guideline recommendations for cervical cancer screening, prevention and

treatment, which could motivate decision aid research in this area [54, 55], but a lack of such research across these three time periods has been shown. Also, lung cancer has high incidence and burden, but little research exists about decision aids for lung cancer screening, prevention and treatment [20, 25]. This might be because there are no nationally standardised screening programmes for lung cancer in many countries as there are for other types of cancer, such as breast and colon [53, 56, 57]. However, many lung cancer patients are faced with difficult healthcare decisions, such as a choice between different treatment modalities. Some of these require the patient to decide between a slightly higher chance of longer survival or fewer treatment-related side-effects [58, 59]. Thus, there is a need for effective decision aids for cancer populations other than prostate, breast or colon.

Lack of research effort towards testing effective implementation strategies

This review has shown that the research volume on decision aids for cancer screening and prevention has increased over the three time points assessed. Given that decision aids are not commonly used in practice [30], it may be expected that we should have started to see the testing of strategies to implement decision aids that have been shown to be effective. However, we found only two studies on the effectiveness of implementation strategies across the three time periods assessed. The little attempt to translate evidence into meaningful benefits for patients may result from various factors, such as methodological difficulties of carrying out well-controlled implementation trials; perception that optimal care is already being delivered; difficulties of addressing further barriers to the adoption of decision aids in practice; and potential further questions to be answered by ongoing research on the effectiveness of decision aids. These factors are discussed below.

Methodological difficulties of carrying out implementation trials

Implementation of decision aids may involve changes in processes of care. This necessitates system-orientated change, which is not always amenable to the "gold-standard" RCT intervention design. Decision aids are complex interventions in a complex field of social interactions. They address various influences on behaviour. Attention should be paid to this complexity and to the context of implementation [24, 60]. It has been argued that RCTs are not suitable for taking into account all relevant contextual factors in which complex interventions are delivered and received [61]. The randomisation and blinding required by RCTs cannot always accommodate the complexity and flexibility needed to test these interventions on a system level [62, 63]. According to the Medical Research Council's guidance for evaluating complex interventions, a range of alternate study designs should be considered, including Stepped Wedge or Multiple Baseline Designs [64, 65]. Future attempts to test implementation strategies should consider these designs. As planning and conducting such complex trials takes an extended period of time, it may be that much of the implementation research is still being carried out [66]. It is possible that we see a surge in such studies in the near future.

Perception that optimal care is already being delivered

There may be an assumption that evidence-based strategies are already being used in practice. For example, O'Brien and colleagues reported that some clinicians have high confidence in their own communication skills and believe that patients understand the information they have conveyed [31]. Clinicians in this study have indicated that decision aids' effects on the decision-making process are not compelling enough to change their practice. Consequently, some have argued that there is no need to conduct research to implement decision aids into routine care [31]. However, given the increasing range and

availability of prevention, screening and treatment options, healthcare decisions have become increasingly difficult. Especially in clinical situations where there is low or conflicting evidence on the medical effectiveness of the available healthcare options, it is crucial to involve patients' preferences in the decision-making process.

Further barriers to the adoption of decision aids in practice

Findings of previous research indicate that clinicians identify numerous barriers that affect their ability to implement patient decision aids [31–33, 67]. Such barriers include: concerns about how comprehensive and current the content of decision aids is; lack of awareness of existing decision aids; time constraints; and concerns about how to integrate decision aids into clinicians' workflow [32, 68]. Designing implementation strategies to overcome these barriers is challenging. There is little evidence that passive dissemination through strategies such as guidelines is effective [69]. Implementation strategies need to actively target clinicians, patients or both [66]. They should be tailored to the specific setting, avoiding "one-fits-all" solutions". Instead of controlling for confounding variables, implementation attempts need to investigate these variables in order to better understand the long-term implementation of decision aids [70]. Practice-based research within the real-world setting of daily cancer care needs to be conducted [71]. Researchers should focus on illuminating processes, rather than "packages", and use the strengths of collaborative research across various contexts in order to systematically study the impact of the individual settings [70].

Open questions regarding the effectiveness of decision aids

Although there is a large body of evidence demonstrating that decision aids are effective in improving a range of patient outcomes, open questions remain with regard to the stated effectiveness. For example, further studies are required which explore the "active ingredients" of decision aids and clinically relevant outcomes, apart from the ones already

assessed [24]. Greater understanding of the mechanisms of action of decision aids and further evidence of their clinical impact may increase their acceptability in clinical practice and motivate more attempts to design and evaluate implementation strategies. Further open questions remain with regard to the "orientation" and "insight" phases of implementing decision aids into practice. Consequently, we need further in-depth investigation of clinicians' understanding and opinions on decision aids before we ask them to implement these tools [23, 51, 72, 73]. However, as the body of work on the effectiveness of decision aids has been growing, we hope that the number of intervention studies which test implementation strategies will develop accordingly.

Limitations

The results of this study should be considered in light of several limitations. First, only three years of publication were included in this study. It is possible that the trends in research output differ in the years which were not assessed. In addition, due to the low numbers of eligible studies, it was not possible to compare statistically the trends in effectiveness and implementation trials over time. This limits the strength of our conclusions about the relative increase in effectiveness compared with implementation trials. However, the inclusion of these three time points provides an indication of research effort over the past 15 years. Grey literature such as policy documents and dissertations were not included as they do not meet the standards associated with peer-reviewed publications. It is possible that the exclusion of such research has biased the results due to the file drawer problem, whereby studies showing null (or negative) findings tend not to be published. The exclusion of conference abstracts may have led to underestimating the number of implementation studies currently underway.

6.7 Conclusion

Although multiple Cochrane reviews provide evidence that decision aids are effective in improving a range of patient outcomes, our review suggests that research testing the effectiveness of decision aids has increased over the three time points assessed. Research effort in this area has focused predominantly on screening and prevention decisions in only a few cancer sites. This neglects a number of cancer populations, as well as other areas of cancer care such as treatment decisions. Further, once the effectiveness of certain decision aids is established, strategies to increase their adoption by clinicians need to be designed and tested. Such research will help to ensure that the benefits of decision aids reach the intended patient populations.

Acknowledgements

We thank Angela Smith for her support to the literature search and Alessandra Bisquera for her advice on the statistical analysis. Furthermore, we would like to acknowledge funding support from a Strategic Research Partnership Grant (CSR 11-02) from Cancer Council NSW to the Newcastle Cancer Control Collaborative (New-3C), and infrastructure funding from the University of Newcastle and Hunter Medical Research Institute.

Funding

Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship and a University of Newcastle/ Hunter Cancer Research Alliance Research Scholarship. Nicholas Zdenkowski is supported by a Sydney Catalyst scholarship.

Conflicts of interest

The authors declare that they have no competing interests.

Contribution of co-authors

Please see Appendix 6.2.

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6.9 Additional files

Additional file 1 – Search strategies for each database

Database: MEDLINE 1946 to Present with Daily Update

Search Strategy:

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1 1 exp neoplasms/ (2746146)

2 decision support techniques/ (13910)

3 decision aid*.tw. (1427)

4 2 or 3 (14668)

5 decision making, computer assisted/ (2561)

6 decision making/ or choice behavior/ (93958)

7 5 or 6 (96449)

8 physician patient relations/ (62989)

9 patient education as topic/ (73272)

10 patient participation/ or patient preference/ (22845)

11 8 or 9 or 10 (148799)

12 7 and 11 (9869)

13 4 or 12 (23918)

14 1 and 13 (3840)

15 limit 14 to (humans and (editorial or letter or news)) (307)

16 14 not 15 (3533)

17 limit 16 to yr="2001" (88)

18 limit 16 to yr="2007" (136)

19 limit 16 to yr="2014" (354)

20 17 or 18 or 19 (578)

Database: Embase Classic+Embase <1947 to 2015 August 05>

Search Strategy:

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1 1 exp neoplasm/ (3787744)

2 decision support system/ (15551)

3 decision aid*.tw. (2142)

4 exp decision making/ (237828)

5 patient/ or cancer patient/ (1717880)

6 patient education/ (91855)

7 patient participation/ (18909)

8 patient satisfaction/ (95412)

9 doctor patient relation/ (84354)

10 5 or 6 or 7 or 8 or 9 (1970972)

11 4 and 10 (36134)

12 2 or 3 (17172)

13 11 or 12 (52281)

14 1 and 13 (9691)

15 limit 14 to (human and (book or book series or editorial or letter or note)) (747)

16 14 not 15 (8944)

17 limit 16 to yr="2001" (118)

18 limit 16 to yr="2007" (232)

19 limit 16 to yr="2014" (1244)

20 17 or 18 or 19 (1594)

Database: PsycINFO <1806 to July Week 3 2015>

Search Strategy:

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1 1 exp neoplasms/ or cancer*.tw. (51282)

2 decision support systems/ (2450)

3 decision aid*.tw. (966)

4 2 or 3 (3298)

5 exp decision making/ (72923)

6 "shared decision making".tw. (1440)

7 client participation/ (1489)

8 5 or 6 (73401)

9 7 and 8 (277)

10 4 or 9 (3552)

11 1 and 10 (296)

12 limit 11 to human (289)

13 limit 12 to yr="2001" (1)

14 limit 12 to yr="2007" (17)

15 limit 12 to yr="2014" (23)

16 13 or 14 or 15 (41)

Search Name: Decision making

Date Run: 10/08/15 04:14:42.540

Description:

ID	Search	Hits
#1	MeSH descriptor: [Neoplasms] explode all trees	54477
#2	MeSH descriptor: [Decision Support Techniques] explode all trees	3251
#3	decision aid*	2974
#4	#2 or #3	5935
#5	MeSH descriptor: [Decision Making, Computer-Assisted] explode all trees	3740
#6	MeSH descriptor: [Decision Making] explode all trees	2767
#7	MeSH descriptor: [Choice Behavior] explode all trees	904
#8	#5 or #6 or #7	6479
#9	MeSH descriptor: [Physician-Patient Relations] explode all trees	1105
#10	MeSH descriptor: [Patient Education as Topic] explode all trees	6735
#11	MeSH descriptor: [Patient Education as Topic] explode all trees	6735
#12	MeSH descriptor: [Patient Participation] explode all trees	902
#13	MeSH descriptor: [Patient Preference] explode all trees	372
#14	#9 or #10 or #11 or #12 or #13	8473
#15	#8 and #14	512
#16	#4 or #15	6305
#17	#1 and #16	810

Additional file 2 – List of included studies

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DISCUSSION

D1. Key findings

This thesis used qualitative and quantitative methods to increase our understanding of patients' experiences and preferences for making cancer treatment decisions. It also investigated factors we need to take into account when designing and implementing decision support strategies for cancer patients. The main findings arising from this body of work are:

1) *Patient-centred decision making is not always delivered to cancer patients.* Although some patients perceived that they received their preferred level of involvement in cancer treatment decisions, others did not, and were more or less involved than they would have liked to be (Paper One). Furthermore, as suggested by the findings of Paper Two, some patients did not perceive they had been offered a choice of cancer treatment, despite the principles of patient-centred care recommending that they should be.
2) *Asking cancer patients about their preferences for involvement in decision making is related to their care experiences.* Patients vary in their preferences for the level of involvement they would like to have when making cancer treatment decisions (Paper One). Clinical judgement of patients' decision-making preferences may not always reflect patients' actual preferences. In order to deliver patient-centred care, clinicians should ask patients about their preferences, rather than assuming what their preferences may be and tailoring care according to these assumptions. The findings of Paper One suggest that not being asked about their decision-making preferences may be associated with discordance between patients' preferred and perceived involvement in decision making.
3) *When making cancer treatment decisions, clinicians should consider offering two shorter consultations combined with written and online information, rather than*

one longer consultation and written information only. Patients are often provided with copious amounts of information regarding their diagnosis, prognosis and treatment options. As a consequence, many patients feel overwhelmed when asked to make a cancer treatment decision (Paper Two). However, most patients and their support persons wish to receive comprehensive information regarding the available treatment options, presented in multiple formats (Papers Three, Four and Five). Also, when making cancer treatment decisions, patients and their support persons seem to prefer receiving two shorter consultations with some time to consider their options in-between these consultations, rather than one longer consultation (Papers Four and Five). Offering take-home written and online information to consider in-between two consultations may help patients and their support persons "digest" the provided information in the comfort of their homes, at their own pace and via their preferred channels. It may assist them with comprehending, weighing up and using the information presented to them during the consultation, and facilitate patients' and their support persons' involvement in treatment decision making, to the extent they desire (Paper Three).

4) *Decision aids may be a valuable tool to help patients understand their treatment options and participate in the decision-making process.* Increasing research effort has been directed towards testing the effectiveness of decision aids in improving patient outcomes (Paper Six). However, research is lacking on how best to use decision aids in routine cancer care. Based on qualitative and quantitative data included in this thesis, it is suggested that providing decision aids in-between two consultations may be a strategy for successfully implementing them into routine cancer care (Papers Three, Four and Five).

D2. Considerations when interpreting the thesis findings, and directions for future research

D2.1 Using the strengths of combining qualitative and quantitative methods

Mixed-methods approaches can provide a more comprehensive picture of patients' experiences and preferences for making complex cancer treatment decisions than either qualitative or quantitative methods alone. Both approaches have their own strengths, and when used in combination they often help compensate for the respective limitations that are associated with each of these methods [1]. Despite these benefits, relatively few studies have used mixed-methods approaches to improve service delivery in healthcare [2]. This body of work makes an important contribution to the field by using a mixed-methods design which utilises both quantitative and qualitative research methods [1].

Quantitative methods were used to assess the prevalence of patients' decision-making preferences and experiences using large samples [3]. This allowed to quantify the relationship between patients' preferences, experiences and characteristics. Using quantitative research methods also helped maximise the generalisability of the research findings [4]. Qualitative methods, on the other hand, were used to provide detailed, in-depth insights into patients' decision-making preferences and experiences. It also helped capture the complexity of patients' care experiences, which is not always possible with quantitative methods [5]. The qualitative studies included in this thesis facilitated the generation of hypotheses on why and how patients decided on their cancer treatment, and how decision support strategies can be used to help patients make difficult decisions (Papers Two and Three) [6]. This allowed the development of a theoretical understanding of the decision-making process and the examination of the generated hypotheses with the help of larger samples. Using qualitative research methods thus informed and extended on the quantitative studies included in this thesis [7].

D2.2 Employing methodologically robust approaches to investigate patients' decision-making preferences and experiences

Numerous approaches have been developed to investigate patients' decision-making preferences and experiences [8, 9]. However, many studies do not employ psychometrically robust measures [10]. For this thesis, an adapted version of the Control Preferences Scale was used to assess the concordance between patients' decision-making preferences and experiences. It is a standardised instrument that has been used extensively in cancer populations and has evidence of reliability and validity [11, 12]. Validity was established through grounded theory analyses of roles in decision making, while reliability was shown using Coombs' criterion [11].

Also, a discrete choice experiment (DCE) was used to examine patients' and support persons' preferences for cancer treatment decision making. Discrete choice designs are an innovative and methodologically robust approach to assess people's preferences for decision making. Discrete choice experiments have been used across a number of fields of study, including economics, marketing and, more recently, healthcare [13]. They are based on the assumptions that i) healthcare interventions, services and policies can be described by a number of attributes, and that ii) an individual's choice depends on the levels of these attributes [14]. Discrete choice experiments provide a means to measure the overall value people place on the different factors which influence the decision-making process, as well as the trade-offs people are willing to make between these factors [15]. Compared with other methodologies, which have been used to elicit patients' preferences, DCEs have a number of advantages, including: reduced patient burden as patients are only required to consider one single survey item, and elimination of yes-response bias as patients are forced to elicit a preference [16, 17]. There is also evidence

to support the internal and external validity, as well as the consistency of DCE methodology [14, 18].

D2.3 Providing data from heterogeneous samples of Australian cancer patients

Many studies in the area of patient-centred decision making have to be considered in the light of the following limitations: they have focused on only one specific type of cancer; they recruited patients from a limited number of clinics; and they were conducted outside Australia [19-21]. The studies included in this thesis help overcome these limitations by examining heterogeneous samples of cancer patients who have been recruited from multiple sites within Australia, including medical and radiation oncology settings. The participating patients constitute a heterogeneous sample, reflecting various sociodemographic backgrounds, cancer types, stages of disease and a range of treatment decisions.

Despite the heterogeneous sample included in this thesis, a large proportion of study participants were diagnosed with breast cancer. The prevalence of this patient group is a result of the site patient recruitment. Consequently, some of the thesis findings reflect the views of this subgroup of cancer patients. Different patient subgroups may have different preferences for decision making [22]. For example, it has been suggested that younger, female patients are more likely to wish to participate in healthcare decision making [19]. This establishes the need to examine patients' decision-making preferences and experiences in other patient populations in the future. There are various other cancer types with high incidence and burden of suffering for patients. For example, testicular cancer is the most common malignancy among young men [23]. Many of these patients are faced with difficult healthcare decisions, such as the choice between different treatment modalities [24, 25]. They may have different preferences for involvement in decision making than patients with other cancer types [22, 26]. Studying patients' decision-making

preferences and experiences in other patient populations in the future will help examine the generalisability of the thesis findings.

Also, the samples included in this thesis are limited to English-speaking respondents. It is possible that patients who speak languages other than English may have different preferences for and experiences with making cancer treatment decisions [27]. This is an important consideration as many societies are ethnically diverse. Patients' cultural backgrounds influence their disease expression, their information needs and their preferences for medical care [28]. Consequently, different cultural groups vary in how they use services provided by the healthcare system [29]. Betsch and colleagues have argued that the way in which doctors take cultural differences into account when communicating with their patients influences patients' understanding and the effectiveness of healthcare communication which can increase disparities in health outcomes [27]. However, previous research in this area lacks guidance for the design and implementation of culturally sensitive decision support for patients [29]. For example, decision aids have been tested predominantly in Western, English-speaking countries [30]. Cross-country comparisons are warranted to assess patients' views and experiences with patient-centred decision making in different healthcare systems, as well as in ethnically diverse communities. This means that we have to keep broadening research on patient-centred decision making beyond individual settings and national borders, using the strengths of multidisciplinary, international collaborations [31].

D2.4 Outcomes and outcome measures of research on decision support strategies should be reconsidered

D2.4.1 Rethinking primary outcomes of decision support strategies

There has been debate surrounding what it is that decision aids are meant to change, and what outcomes should be used to assess the impact of decision support strategies [32].

While most researchers agree that decision support strategies should improve the quality of patient decision making, uncertainty remains regarding how this can be assessed [8]. Consequently, there is still considerable variability in the outcomes used to assess the effectiveness of decision support strategies [33, 34]. For instance, Trikalinos and colleagues reviewed randomised controlled trials assessing the effectiveness of cancer-related decision aids in improving patient outcomes [34]. They found an array of objectives that decision aids were designed to achieve, such as improving knowledge of the patient's health condition and healthcare options, and reduced anxiety and decisional conflict [34]. Most studies differed considerably in how they defined the outcomes they assessed [34].

The findings included in this thesis suggest that other outcomes than the ones already assessed may need to be considered for investigating the effectiveness of decision support strategies. For example, the results of Paper Three suggest that some patients used decision aids to confirm their decision, rather than to assist them with the process of deciding on their treatment. This outcome has been seldom assessed in previous studies [21, 131]. Also, the data included in this thesis indicate that patients were not always aware that they had a treatment choice or that the treatment decision at hand depended on their preferences (Paper Two). Understanding that a treatment decision needs to be made and that the "best" choice should align with patients' preferences is key to adequate patient involvement in decision making. However, this outcome has been widely neglected by previous research in this area [34, 35]. For example, Stacey and colleagues found that none of the 115 trials assessed in the latest Cochrane Review on the effectiveness of decision aids in improving patient outcomes evaluated whether decision aids helped patients recognise that a decision needs to be made, or helped them understand that their values affect the decision [30].

The variability in the outcomes assessed creates confusion as to what specific purposes decision support strategies have in clinical practice, and when and why they should be used. Having such information will help successfully implement decision support strategies into clinical practice [36]. An agreed minimal set of main outcomes to use is required [37, 38]. For example, the International Patient Decision Aid Standards (IPDAS) Collaboration aims to improve the quality and effectiveness of decision aids by establishing standards for their content, development, implementation and evaluation [39, 40]. The IPDAS Collaboration set out key constructs which are specific to the outcomes used in decision aids research [40, 41]. The latest Cochrane review on the effectiveness of decision aids employed these constructs as an organising framework and presented its results around two core dimensions: the quality of the choice made, and the quality of the decision-making process [30]. Also, when considering potential outcomes, it is important to use objectives that are clinically meaningful. For instance, we need to know whether patients' increased knowledge about their options is not only statistically significant but also impacts on the clinical consultation during which the decision is discussed, for instance by changing patients' understanding of their treatment options, their involvement in the decision-making process or their treatment decision [42]. Attempts to standardise the outcomes used in this area, such as those made by IPDAS, can help produce agreement on what it is that decision support strategies are actually trying to affect. This knowledge could be used as a guide when determining clinically relevant outcomes.

D2.4.2 Rethinking outcome measures of decision support strategies

Once we have agreed on what outcomes should be assessed, we can work towards making informed decisions on the most appropriate and rigorous measures to be employed to examine these specific outcomes. Previous reviews suggest that even when studies assessed the same outcomes of the decision-making process, they often used different

measures. For example, Kryworuchko and colleagues conducted a secondary analysis of the studies included in the 2003 Cochrane review on the effectiveness of decision aids in improving patient outcomes in order to examine the primary outcome measures used. Among the 35 trials assessed, they found 35 unique primary outcome measures [32]. Sepucha and colleagues analysed data from the 2011 Cochrane review on the effectiveness of decision aids. Across the 86 studies included in this review, they identified 17 different instruments used to assess constructs of the decision-making process [33].

Some of the instruments used in previous research on patient decision making may only capture some aspects of patients' perceptions of treatment decision making. For instance, the Control Preferences Scale, which has been used widely in the literature on patient decision making, focuses on patients' views about the final decision rather than the process of decision making [149]. However, patients may be unaware that a decision needs to be made (Paper Two), have difficulties focusing on one specific decision in the context of a complex healthcare experience involving multiple decisions, or may not feel that they should have participated in this decision [43]. Also, the findings of this thesis suggest that patients may report that they made the final treatment decision although they did not feel actively involved in the decision-making process (Paper Two). Measures focusing on different aspects of the decision-making process, rather than the final decision, may be the way forward. For example, it has been argued that in order to adequately assess patient involvement in decision making, we should examine how clinicians i) help patients understand the health issues at hand; ii) listen to the things that matter most to patients about their health issues; and iii) include what matters most to patients when choosing what to do next [8, 43, 44]. An agreed set of standardised outcome measures should be developed to enhance meaningful meta-analyses, facilitate the

replication of studies and help researchers conclude confidently what it is that decision support strategies are effective in changing. This will help clinicians know why and how to use decision support strategies in routine cancer care.

D2.5 Longitudinal studies may help assess possible changes in patients' decision-making preferences and experiences

Cancer patients usually follow a specific treatment pathway. Most patients receive their cancer diagnosis, are faced with multiple tests to determine possible treatments and then have to decide on what treatments to receive [45, 46]. While this is the general pathway for most cancer patients, it can be different for each individual person, depending on a range of factors including tumour site, stage of cancer and patient age. It has been suggested that patients' preferences for and experiences with information provision and decision making may change over the course of their treatment pathway, for example, when situational factors change, such as patients' disease status [47].

When interpreting the findings of this thesis, one should consider that all studies were retrospective cross-sectional studies. For each study, patients' preferences and experiences were examined retrospectively at a single point in time. However, patients' decision-making preferences might have changed over time and might have been different at the time of making the decision to the time when patients completed the survey. Also, patients varied in the length of time since the treatment decision they were asked to refer to for each study. Recall bias may have occurred with those patients who had a relatively long period of time since their last important treatment decision, resulting in incomplete or inaccurate responses. Research in this area suggests that patients may not accurately recall the treatment discussions with their clinicians and that they may rate their health-related experiences better or worse than they previously did [48, 49]. For example, patients may rate their involvement in the decision at hand differently at

different points in time. This may be because patients' judgement of what value on a scale reflects excellent or poor levels of involvement in decision making can change over time, depending on various factors, such as changes in patients' disease status [50, 51]. Prospective, longitudinal studies can help overcome these limitations. Repeatedly assessing patients' decision-making preferences and experiences along their treatment pathway may help understand whether and how patients' preferences and experiences change across different treatment decisions, and how this may be impacted by patient characteristics.

D2.6 Observational studies may help examine patients' actual involvement in treatment decision making

When interpreting the findings of this body of work, care should be taken regarding the fact that most studies included in this thesis used self-reported medical, sociodemographic and decision-making variables. This might potentially result in some degree of inaccuracy in the information obtained. For example, the studies included in this thesis examined patients' perceived involvement in treatment decision making, rather than their actual involvement. Examining patients' perceived involvement in treatment decision making is important, as patient-centred care is concerned with how patients feel about the care they received (i.e. it is focused on their perceptions of their care rather than their actual care). Nevertheless, it is possible that patients' perceptions of their involvement in their treatment decision making may differ from their actual involvement [52]. For example, patients may overestimate or underestimate the degree to which they have been involved in deciding on their treatment [53]. Also, we do not know how other factors, such as clinicians' communication skills and styles, may influence the decision-making process. For example, it has been suggested that clinicians' skills in communicating risks to patients or involving their support persons in the decision-making process may have an

impact on patients' recall and understanding of their treatment options and their willingness to engage in decision making regarding their care [54, 55]. It is possible that this has occurred in the studies included in this body of work. Conducting observational studies may help overcome these shortcomings. For example, analysing audiotapes or videotapes of the consultations during which treatment decisions were made could help examine whether patients' perceived involvement in decision making matches their actual involvement. It could also help determine how other factors, such as clinicians' communication skills and styles, may impact on patients' decision-making preferences and experiences.

D2.7 Future research should examine both patients' and clinicians' views of how to successfully implement patient-centred decision making into cancer care

By exploring cancer patients' perspectives on the decision-making process, this thesis provides an important step towards understanding how to best implement patient-centred decision making into cancer care. However, studies indicate that in order to successfully implement decision support strategies into clinical practice, research should address both clinician and patient factors [88]. A number of clinician-related barriers to implementing decision support have been identified. These include clinicians' concerns related to integrating decision support strategies in their daily workflows, clinicians' lack of awareness of decision support strategies, and clinicians' trust in their own communication skills [56-58]. However, Elwyn and colleagues have argued that the underlying issues that hinder the adoption of decision support strategies into clinical practice are still under-investigated [59]. More research is needed to better understand clinicians' perceptions of decision support strategies and patient-centred decision making.

For example, it is recommended by cancer treatment guidelines that patients are provided with a treatment choice and a choice of how they want to be involved in decisions

regarding their care [60, 61]. Previous research in this area indicates that whether or not patients are given a choice regarding their treatment may be of greater relevance to their psychosocial outcomes than the type of treatment performed [62]. However, the data included in this body of work suggest that patients do not always perceive they have been offered a treatment choice, or feel they have not always been asked how involved they would like to be in deciding on their cancer treatment (Papers One and Two). To better support patients with being involved in deciding on their treatment, we need to understand under what circumstances they are offered choices regarding treatment decision making. One way to achieve this is to examine clinicians' perceptions of when and how to offer treatment choices to patients. Having such information could be used to actively target clinicians and patients when trying to implement decision support strategies into clinical practice, as both are key players for the healthcare decisions to be made. Such research will help ensure that decision support strategies are acceptable and feasible to both patients and clinicians, and reach the intended patient populations.

D2.8 Intervention studies are needed to investigate the impact of different consultation styles on patient outcomes

All studies included in this thesis are descriptive. Although informative, such research does not allow the identification of causal relationships [63, 64]. Therefore, we do not know how the decision support strategies discussed in this thesis may impact on patient outcomes. For example, the findings of this body of work indicate that patients may prefer to receive information in multiple formats combined with two shorter consultations, rather than one longer consultation and written information only, when deciding on their cancer treatment (Paper Four). However, we do not know how this consultation style may impact on patient outcomes when compared with usual care. It has been suggested that extending the decisional timeframe may help patients comprehend and consider the

information provided to them, and assist them with overcoming their feeling of being overwhelmed [65, 66]. Providing two shorter consultations and take-home information to consider in-between these consultations may also relieve the pressure of having to provide and receive all required information during one consultation. Having more time to make their treatment decision and being able to involve support persons may help patients identify and communicate their preferences, and this may decrease patients' decisional conflict regarding feeling unclear about their values and preferences [54, 66].

Also, the findings of Paper One suggest that asking patients about how involved they would like to be in treatment decisions is associated with patients not receiving their preferred level of involvement in decision making. This was a descriptive study. Consequently, we cannot draw any conclusions as to whether there is a causal relationship between these two variables. Previous studies in this area suggest that asking patients about their decision-making preferences can improve patient outcomes, such as increases in their confidence in the decision that was made [67]. However, more intervention research is warranted to examine how asking patients about how involved they would like to be in treatment decisions impacts on patient outcomes. A proposed intervention study for addressing this issue is presented below.

D2.9 A cluster randomised controlled trial to assess the impact of different consultation styles on patient outcomes

A cluster randomised controlled trial could be used to test whether asking patients about their decision-making preferences and providing two shorter consultations rather than one longer consultation can improve patients' and support persons' outcomes. This may include increased knowledge of the available treatment options, greater concordance between preferred and perceived involvement in decision making, and reduced decisional regret related to their treatment decision. This proposed trial would focus on the provision

of optimal patient-centred care. It would contribute to gathering level 1 evidence as to whether the suggested consultation style is effective in helping patients decide on their treatment. Such high-quality evidence can help decide which strategies should be implemented into clinical practice in order to improve the delivery of optimal, patient-centred care. The proposed trial design is discussed below.

It has been argued that patients are often overwhelmed when being confronted with information regarding their diagnosis and treatment options [66]. This makes it hard for patients to understand and use the information provided by their clinicians [68-70]. If patients are not adequately informed about their treatment options and are not asked about their decision-making preferences, they may not be able to participate in the decision-making process, to the extent they desire [71]. They may also have less confidence in the decision they made [72]. Further, when making important decisions regarding their care, patients and their support persons often describe themselves as a team [73]. The majority of patients consider their support persons as the most important information source and value their support persons' involvement in decision making [74, 75]. Thus, it is important to examine whether the proposed consultation style may have an impact on the outcomes of both patients and their support persons.

Aims: Primary aim: To examine the effectiveness of a multicomponent intervention designed to improve adult cancer patients' knowledge about their treatment options at diagnosis (baseline) and at one-week follow-up. Secondary aims: To establish at one-week follow-up whether patient and support person dyads receiving the intervention report greater concordance between preferred and perceived involvement in decision making, and lower decisional regret.

Inclusion criteria: Eligible patients would i) have a confirmed diagnosis of cancer; ii) be aged 18 years or older; iii) speak English; and iv) be presenting for an outpatient

consultation to receive their diagnosis and discuss their treatment options. Patients who are judged by clinical staff to be physically or mentally incapable of receiving the intervention and completing the survey, or unable to provide informed consent, would be excluded. Eligible support persons would be determined and nominated by the patients as people who are helping them cope with their cancer through support, encouragement and communication. Support persons would be aged 18 years or over, and able to speak English and provide informed consent.

Recruitment: Eligible patients would be identified from clinic lists prior to their appointment by a clinic nurse and asked if they would be willing to talk to a member of the research team. Willing patients would then be approached by a trained research assistant who would provide study information and seek informed consent. If the nominated support person has accompanied the patient to the appointment, the research assistant would approach the support person for consent. If the support person is not present in the clinic, consenting patients would be provided with a recruitment package to pass on to the eligible support person. Support persons could only participate if patients participate, and vice versa, to allow for the examination of changes in the outcomes of patient and support person dyads. The age and gender of non-consenting dyads would be recorded to examine consent bias.

Data collection: Each consenting patient and support person would complete a baseline survey (no more than 15 minutes) on an iPad or as a paper-and-pen survey while waiting for their clinic appointment. The survey would assess perceptions about illness and treatment options, preferred involvement in decision making, and sociodemographic characteristics. Completion of the questionnaire would not impede clinic functioning. Patients and support persons would be told that they could stop the survey as soon as their doctor is able to see them and resume it after their appointment if desired.

The consultations in both study arms would be audiotaped using a simple recorder which would be placed on a desk or held in the hand. A copy of the recordings would be kept by the research team for analysis of the consultations' content. For each follow-up, participants would complete a face-to-face or phone interview one week after their final decision-making consultation. The interview would include questions regarding perceptions of illness and treatment options, perceived involvement in decision making, and decisional regret.

Intervention: Following completion of the baseline questionnaire, treating clinicians would be randomised, so that their patients and their support persons receive either the intervention or usual care. Randomising clinicians rather than patients would help control for contamination. Participants would be blinded to prevent them from knowing whether they would receive the intervention or usual care. The intervention group would be i) asked during the consultation with their clinician how involved they would like to be in deciding on their treatment; and ii) provided with two 20-minute consultations with their treating clinician, one week apart (if acceptable to the patient), and additional written and audio-visual information to consider in-between these consultations.

Usual care: The usual care group would receive standard care from their clinicians. Details of what constitutes usual care would be recorded as part of the study, and include timing, length of consultation and information provided.

Outcome measures: Questions regarding knowledge of illness and treatment options would be based on the additional written and online information provided as part of the intervention. As suggested by previous research in this area, the proportion of accurate responses would be transformed to a percentage scale ranging from 0% (no correct responses) to 100% (perfectly accurate responses) [30]. Items may assess perceptions

about topics such as diagnosis, prognosis, goals of treatment, and potential risks and benefits of the treatments available.

The concordance between preferred and perceived involvement in decision making would be assessed using CollaboRATE, which is a brief, process-orientated, self-reported measure of shared decision making [43, 44]. CollaboRATE helps overcome some of the limitations of previous measures in this area. Previous instruments often refer to a treatment "decision" or "options". This may be misleading as patients and support persons do not always understand that a decision needs to be made, or may have problems focusing on only one decision in the context of a comprehensive healthcare experience involving a number of decisions [43]. Study participants would be asked how much effort was made, and should be made, to i) help patients understand their cancer and treatments; ii) listen to the things that matter most to them about their treatments; and iii) include what matters most to them in choosing what to do next [43].

Decisional regret (follow-up only) would be measured using the Decisional Regret Scale, which assesses distress or remorse after a healthcare decision [76]. The scale has been shown to have good internal consistency and is strongly correlated with decision satisfaction, decisional conflict and quality of life [76].

Sociodemographic and disease variables obtained from patients would include age, gender, marital status, country of birth, postcode, highest level of education completed, income, perceived health status, and treatments received. Support persons would be asked to self-report on their age, gender, marital status, country of birth, postcode, highest level of education completed, income, perceived health status, relationship to patient, whether the support person is living with the patient, and the time spent with the patient. All sociodemographic and disease variables would be assessed at baseline and follow-up to account for changes in participants' circumstances which may affect their outcomes [47].

Information regarding cancer diagnosis, cancer stage, and treatments received would be obtained from patients' medical records to decrease research-related burden on patients. To examine to what extent the intervention was implemented, qualitative semi-structured interviews would be conducted with a purposeful subsample of patients, support persons and clinicians. This approach has been widely used to assess the intervention process and has been shown to be able to shed light on novel phenomena relevant to interventions [77]. The qualitative data would be analysed using a framework analysis process, which is a systematic and flexible approach for mapping and interpreting qualitative data in health research [78].

D3. Recommendations for clinical practice

D3.1 Clinicians should educate patients on the preference-sensitive nature of some cancer treatment decisions

More and more decisions in cancer care involve options which show similar survival benefits but involve different impacts which each individual patient may value differently [46]. The work included in this thesis suggests that patients do not always understand the preference-sensitive nature of the decisions they have to make (Paper Two). In these instances, there is often no collaborative decision on a mutually acceptable treatment plan as patients do not perceive they have a true treatment choice; rather, they have to come to terms with their cancer and their doctors' treatment recommendation [79]. Consequently, clinicians should explain to patients that their preferences need to be incorporated in the decision-making process in order to determine the "best" treatment choice. Given the complexity of some cancer treatment decisions, it is essential that clinicians offer to explain the available evidence to patients, as well as help patients comprehend the risks and benefits of their options and check for patients' understanding. This could help patients consider what matters most to them and enhance patients' confidence in being involved in their treatment decisions [80].

D3.2 Patients should be asked about their preferences for information provision and decision making

Clinical guidelines suggest that clinicians should elicit patients' views on how they would like to make decisions regarding their care [60]. However, this does not always occur in clinical practice [67, 81, 82]. Also, the findings of this thesis highlight that not asking patients how involved they would like to be in deciding on their treatment might be associated with a negative care experience (Paper One). In order to provide care that is respectful of and responsive to patients' needs and preferences, clinicians should elicit

patients' views on how they would like to make treatment decisions. This includes asking patients how much and what kind of information they wish to receive, how much time they would like to have to consider their options, and how involved they would like to be in decision making regarding their care.

D3.3 The provision of two consultations combined with written and online information for patients to consider at home

Tailoring oncology consultations according to patients' and their support persons' needs and preferences can improve a number of patient outcomes, such as increased patient satisfaction with their consultations, higher quality of life and decreased anxiety [72, 73, 83, 84]. According to the data presented in this thesis, patients and their support persons seem to prefer having two shorter consultations combined with written and online information, rather than one longer consultation and written information only, when making cancer treatment decisions (Papers Four and Five). Once evidence has been established to suggest that this consultation style can improve patient and support person outcomes, clinicians should offer two consultations, along with a variety of information on patients' treatment options. This may increase patients' understanding of their options and help them become adequately involved in complex decisions regarding their care [66]. It may support patients in making informed treatment decisions which might ultimately enable patients to cope better with their cancer and lead to more efficient and effective care [85, 86]. Also, offering two consultations may facilitate the involvement of patients' support persons in decision making. Support persons can help patients recall, understand and use the information provided by their doctors, and further support patients in making difficult treatment decisions [54, 87]. This has been shown to be valued by patients who often feel more certain about their decisions after consulting their support persons [75].

D3.4 Clinicians should adopt decision aids in routine cancer care

There is considerable evidence to suggest that decision aids can improve a number of patient outcomes (Paper Six) [30]. For example, they may increase patients' understanding of their healthcare options and decrease patients' decisional conflict and anxiety related to their cancer and treatment options [30, 34]. Numerous decision aids have been developed to support a variety of healthcare decisions (Paper Six) [39, 88, 89]. However, in order to reach the intended patient populations, decision aids need to be implemented into clinical practice [59]. Using decision aids in clinical practice may facilitate discussions between doctor and patient about the preference-sensitive nature of the treatment decision at hand, and help elicit and respond to patients' preferences for information provision and involvement in decision making. This is an important step towards the delivery of optimal cancer care that should be focused on the patient as a person, not just the disease itself.

D4. Conclusion

This thesis includes using both qualitative and quantitative methods to assessing cancer patients' preferences for and experiences with deciding on their treatment. Methodologically robust and innovative approaches were employed to collect and analyse data from heterogeneous samples of Australian cancer patients and their support persons. The findings of this body of work suggest that patient-centred decision making is not always delivered to cancer patients. Clinicians should consider asking patients about their preferences for involvement in decision making and offer two shorter consultations combined with written and online information, rather than one longer consultation and written information only, when making cancer treatment decisions. Decision aids may be a valuable tool to help patients understand their treatment options and participate in the decision-making process. The limitations of this thesis include the restriction to English-speaking cancer patients, over-representation of female breast cancer patients and the use of a cross-sectional design.

The thesis findings provide valuable insights into cancer patients' preferences for and experiences with deciding on their treatment. Having such data is an important step towards the delivery of optimal patient-centred cancer care. Future research should employ methodologically rigorous intervention studies to investigate the impact of different consultation styles on patient outcomes.

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Working towards patient-centred decision making in cancer care

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Submitted for fulfilment of the award of Doctor of Philosophy

in Behavioural Science in Relation to Medicine

Submitted December 2017

School of Medicine and Public Health, University of Newcastle

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Appendix 1: PAPER ONE

Appendix 1.1: Statements of contribution from co-authors

UON Graduate Research

Co-authorship declaration

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

I attest that the Research Higher Degree Candidate **Anne Herrmann** contributed significantly to the manuscript conceptualisation, data analysis and manuscript preparation for the paper/publication entitled:

Not asking cancer patients about their preferences does make a difference. A cross-sectional study examining cancer patients' preferred and perceived role in decision making regarding their last important cancer treatment

FULL NAME OF CO-AUTHOR	SIGNATURE OF CO-AUTHOR	DATE
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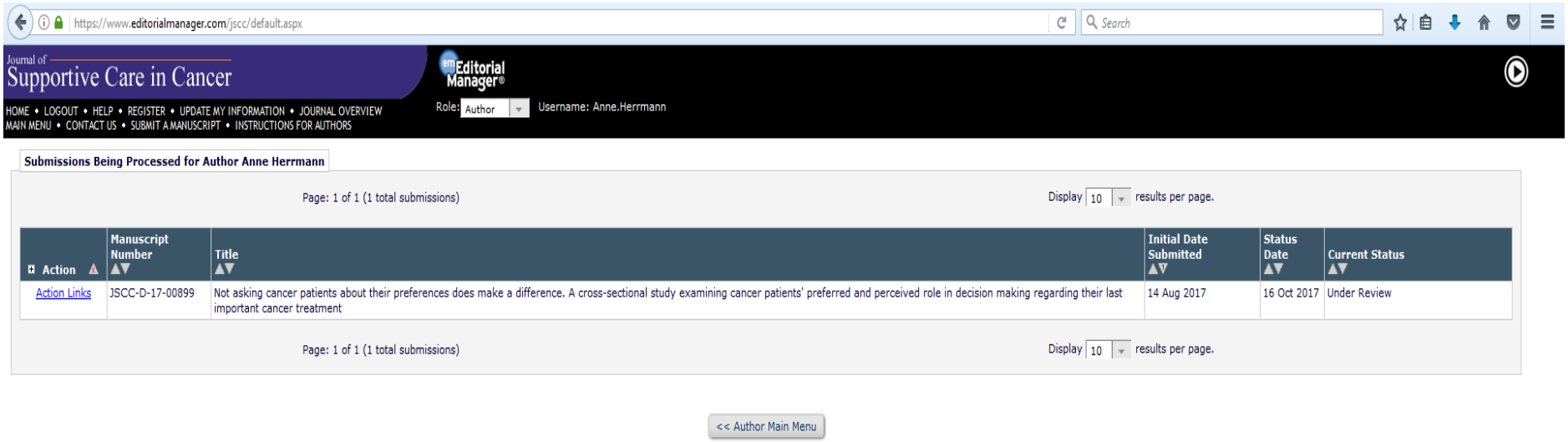
Date: 17/11/2017

Appendix 1.2: Evidence of paper submitted to peer reviewed journal



Appendix 1.3: Sociodemographic and cancer-related characteristics of participants

Characteristic	Respondents n=423 (%)[a]
Gender	
Male	189 (45)
Female	234 (55)
Age	
≤49	50 (12)
50-54	39 (9.5)
55-59	49 (12)
60-64	64 (16)
65-69	77 (19)
70-74	55 (13)
≥75	77 (19)
Education	
High school or below	237 (58)
Trade or vocational training	115 (28)
University degree	50 (12)
Other	6 (1.5)
Employment	
Currently employed	115 (28)
Currently not employed	298 (72)
Treatment centre	
Treatment Centre A	84 (20)
Treatment Centre B	105 (25)
Treatment Centre C	117 (28)
Treatment Centre D	82 (19)
Treatment Centre E	35 (8.2)
Cancer type	
Breast cancer	133 (31)
Colon cancer	53 (13)
Prostate cancer	56 (13)
Lung cancer	38 (9)
Other	108 (26)
Unknown	35 (8)
Time since diagnosis	
0-3 months	44 (11)
4-6 months	82 (20)
7-12 months	79 (19)
1-2 years	66 (16)
More than 2 years	141 (34)

Stage of cancer at diagnosis	
Early	208 (51)
Advanced and/or incurable	135 (33)
Don't' know	62 (15)
Treatments received	
Have received surgery	12 (2.8)
Have received chemotherapy	29 (6.9)
Have received radiation therapy (radiotherapy)	44 (10)
Have received other treatment only	12 (2.4)
Have received no treatment	8 (1.9)
Have received more than one cancer treatment	318 (75)
Time point in the cancer journey	
"Watch and wait"	9 (2.2)
Treatment to cure cancer	170 (41)
Treatment completed, follow-up	124 (30)
Palliative treatment	96 (23)
No treatment for incurable cancer	13 (3.2)
Number of visits at treatment centre to receive treatment in the last 6 months	
None	13 (3.2)
1-2	73 (18)
3-5	85 (21)
6-10	95 (24)
More than 10	138 (34)
Travel time to clinic	
Less than 1 hour	339 (83)
1-2 hours	59 (14)
More than 2 hours	12 (2.9)
Private health insurance coverage	
Yes	189 (46)
No	223 (54)
Concession cards	
Yes	259 (63)
No	154 (37)

[a] not all columns sum to 423 due to missing data

Appendix 2: PAPER TWO

Permission to copy and communicate this work, *"Women's experiences with deciding on neoadjuvant systemic therapy for operable breast cancer: A qualitative study"*, has been kindly granted by Wolters Kluwer Medknow Publications.

Appendix 2.1: Published paper

Original Article

Women's Experiences with Deciding on Neoadjuvant Systemic Therapy for Operable Breast Cancer: A Qualitative Study

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Received: July 20, 2017; Accepted: August 27, 2017

ABSTRACT

Objective: We explored, qualitatively, in a sample of Australian early-stage breast cancer patients eligible for neoadjuvant systemic therapy (NAST): (i) their understanding of the choice of having NAST; (ii) when and with whom the decision on NAST was made; and (iii) strategies used by patients to facilitate their decision on NAST. Methods: A sub-sample of patients participating in a larger intervention trial took part in this study. A total of 24 semi-structured phone interviews were analyzed using framework analysis. Results: A number of women perceived they were not offered a treatment choice. Most patients reported that the decision on NAST was made during or shortly after the initial consultation with their doctor. Women facilitated decision-making by reducing deciding factors and "claiming" the decision. Most women reported that they made the final decision, although they did not feel actively involved in the decision-making process. Conclusions: When deciding on NAST, patient-centered care is not always delivered to patients. Clinicians should emphasize to patients that they have a treatment choice, explain the preference-sensitive nature of deciding on NAST and highlight that patients should be involved in this treatment decision. Providing patients with appropriate time and tailored take-home information might facilitate patient decision-making. Process-orientated research is needed to adequately examine patient involvement in complex treatment decisions.

Key words: Breast cancer, doctor–patient-communication, neoadjuvant systemic therapy, neoplasm, patient decision-making, qualitative research, treatment choice

Introduction

Patient-centered decision-making implies that patients are offered a treatment choice, are enabled to participate in the decision-making process and that patients have the final say regarding their treatment decisions.[1,2] This has

Access this article online

Quick Response Code:

Website: www.apjon.org

DOI: 10.4103/apjon.apjon_60_17

Cite this article as: Herrmann A, Hall A, Zdenkowski N. Women's experiences with deciding on neoadjuvant systemic therapy for operable breast cancer: A qualitative study. Asia Pac J Oncol Nurs 0;0:0.

been shown to increase patients' understanding of their treatment options, improve patients' satisfaction with their care and their overall quality of life.[7-9] Clinicians have been encouraged to help patients become involved in deciding on their treatment, to the extent they desire.[6] However, treatment decision-making can be challenging. Treatment choices are increasingly involving differing outcomes, such as efficacy and toxicity, which may be valued differently by different patients.[7,8] Such "preference-sensitive" decisions often add complexity and uncertainty at a time when patients are likely to be distressed from the initial cancer diagnosis.

A potentially difficult "preference-sensitive" decision is the choice as to whether to receive neoadjuvant systemic therapy (NAST) or not. Early-stage breast cancer patients with larger operable or highly proliferative disease may be offered this option. It involves the receipt of chemotherapy or endocrine therapy before cancer-removing surgery. Based on the current prospective randomized data of 3,946 patients with operable breast cancer, survival rates and disease progression are equivalent for NAST compared to upfront surgery, regardless of cancer type.[9] However, the impacts of the two options are different. Some patients may value NAST due to a higher chance of breast conserving surgery rather than mastectomy.[10] NAST also allows a better understanding of tumor response and biology. This can facilitate prognostication,[9,11] and might decrease patients' anxiety associated with their cancer.[12,13] However, some patients may prefer having upfront surgery as they fear that their cancer could get worse while receiving NAST, and thus wish to have the tumor surgically removed as soon as possible.[14]

Adequate patient involvement in such difficult treatment decisions it is not always applied in clinical practice.[15,16] Elwyn *et al.*, have argued that the specific underlying issues that militate against the adoption of adequate patient involvement, are still under-investigated.[17] To guide the development and implementation of appropriate decision support for cancer patients, we need to better understand how patients make difficult treatment decisions and what we can do to adequately support them when deciding on their treatment.[18]

This paper reports a qualitative analysis of phone interviews conducted as part of a prospective, single-arm pre- and post-trial. The trial aimed at evaluating a decision aid which has been designed to help women decide on NAST. We explored, qualitatively, in a sample of early-stage breast cancer patients eligible for NAST: (i) their understanding of their treatment choice; (ii) when and with whom their decision on NAST was made; and (iii) strategies used by patients to facilitate this decision. Another analysis focusing on women's use and perceived benefit of the decision aid is currently in press.

Methods

Setting and sample

A purposeful sample of 24 patients attending breast cancer treatment centers in New South Wales and Victoria, Australia. Recruitment continued until data saturation (no new themes in three consecutive interviews) was achieved.

Inclusion and exclusion criteria

Patients were eligible for this study if, at the time of enrolment, they (i) were female; (ii) were aged ≥18 years; (iii) had a histological diagnosis of operable invasive breast cancer, (iv) were considered for NAST as a treatment option with curative intent; (vi) were willing and able to access the trial information through the internet and complete a phone interview. Patients were excluded if: (i) <3 months duration of NAST was planned; (ii) they had a hearing or another impairment or insufficient English language skills for participation in a phone interview; (iii) they had inflammatory, metastatic, or inoperable breast cancer; (iv) they were considered by the treating investigator to have a medical or psychiatric condition precluding informed consent; and (vi) they were unable to be contacted via telephone.

Ethics approval and consent to participate

This study was developed and conducted in accordance with the tenets of the Declaration of Helsinki and principles of Good Clinical Practice. All participants provided voluntary informed consent to join the study, which had been approved by the regional research ethics committee (approval number: 14/12/10/4.05) and conducted according to local site governance processes.

Recruitment

The treating clinician identified all eligible patients attending their clinic for a consultation, introduced the larger intervention trial and obtained written consent to be contacted by the Australia and New Zealand Breast Cancer Trials Group for study registration. Consenting patients were emailed a link with access to the trial information letter and online consent form for the larger intervention trial, which gave participants the option to opt out of a follow-up telephone interview. Patients who consented to a telephone interview were contacted via phone by a researcher to schedule the interview.

Data collection

All interviews were conducted by one researcher who has been trained extensively in qualitative research methods.

Participants were informed that the interviews would be audiorecorded and transcribed but that their information would remain de-identified. They were asked to tell how they made their decision on NAST, in the way they preferred, without interruption from the interviewer. This narrative was followed by semi-structured questions about the information provided to patients, their information seeking behavior, the decision-making process and psychological concerns (for questions in each domain of the question guideline please see Appendix 1). At the end of the interview, patients were given the option to provide additional comments. The questions were informed by a previous study and discussions among the research team.[14] Participants were asked as many questions as needed to gain the required information, with prompting used to elicit topics not spontaneously spoken about by patients.

Statistical analysis

Interviews were transcribed verbatim. Transcripts were checked for accuracy by one researcher and analyzed using framework analysis.[20] According to Gale *et al.*, the framework analysis approach belongs to a broad family of qualitative data analysis methods often related to as "thematic analysis" or "qualitative content analysis." As suggested by these approaches, we aimed to draw both descriptive and explanatory conclusions from the data which were clustered around themes.[15] Conclusions drawn from the data were double checked by another researcher. Disagreement was resolved by discussions between all members of the research team. The transcripts were read line by line, and their content was examined, compared, and categorized to apply a paraphrase or label (a "code") that describes what was interpreted in the passage as important. "Open coding" took place, i.e. anything was coded that could have been relevant from as many different perspectives as possible.[15] Codes were then grouped to start the development of more complex categories. An analytical framework was developed based on key categories and data were assigned to the codes and categories in the framework.[20] An iterative approach was followed with newly developed and existing codes and categories constantly being compared with each other and revised if necessary.[21] This enabled us to develop interpretive concepts that describe or explain aspects of the data (i.e. themes).[15]

The coding process was accompanied by writing analytical memos to help document the research process and preliminary findings. This approach to qualitative data analysis provided a systematic model for mapping and interpreting the data and was thus considered appropriate to develop a profound understanding of patients' decision-making experiences.[15] Demographics are presented using appropriate summary statistics.

Results

Patients were interviewed between February 2016 and February 2017. Fifty-nine patients consented to participate in the trial, 30 (51%) consented to be interviewed and 24 (41%) were available for an interview, by which time saturation was achieved. The median time since diagnosis was 91 days (interquartile range = 49,169). Participants' median age was 51 (standard deviation [SD] = 7.3), [Table 1]. The results are organized around three themes: (1) patients' perceptions of being provided with a treatment choice; (2) decision-making in a situation of perceived emergency; and (3) strategies used to facilitate decision-making.

Patients' perceptions of being provided with a treatment choice

Many patients did not feel that they had a choice of whether or not to receive NAST. This was for three main reasons. First, some women perceived that they were not offered a treatment choice at all. They felt that their doctor provided them with a treatment plan without discussing alternative options. This did not allow women to participate in the decision-making process. However, due to the power imbalance between doctor and patient, women accepted their doctor's treatment choice.

> *"She (=the surgeon) said, you're going to have chemo anyway, so let's have it first. Shrink the tumour, and yeah – that was very simple. We didn't even discuss other options at all. She made the decision. (…) I heard that it usually goes, surgery first, then chemo. When I told her I want to*

Table 1: Patient characteristics (*n*=24)

Characteristics	Patients, *n* (%)
Age (years), mean (SD)	51 (7.3)
Marital status	
De facto	4 (17)
Married	17 (71)
Single	3 (13)
Education	
Secondary school	4 (17)
Vocational	3 (13)
University	17 (71)
Lymph nodes involved	
Yes	10 (42)
No	14 (58)
Treatment decision	
Neoadjuvant	21 (88)
Adjuvant	3 (13)
Surgery	
Mastectomy only	10 (42)
Breast conserving surgery only	13 (54)
Both	1 (4.1)

SD: Standard deviation

have surgery first, then chemo, she said, that's not going to happen, and then I said, okay, you know best; and that was all." (P8)

Second, even when perceived to be offered a treatment choice, many women did not feel that they had a say in the treatment decision. They reported that the decision was strongly guided by their doctors. Doctors were seen to have a preference for the "best" treatment choice and were perceived to have guided the decision-making process both in an explicit way (i.e. providing a treatment recommendation) and in an implicit way (i.e. implying a preferred treatment option through the way in which options were presented to patients). All women followed their doctors' treatment advice. Some women felt that they were *"in their doctors' hands" (P2)* and that they could only participate in the decision-making process if they were agreeing with their doctors' treatment recommendation. In these instances, decision-making on NAST was predominantly characterized by clinicians' disclosure and explanation of information, rather than being a patient-centered process which involves joint participation between doctor and patient.

"Ultimately they both (=the surgeon and the oncologist) heavily heavily heavily recommended that I make this decision that favours what they decided. So whether it's – they gave me the information which was pretty hard to say no to. Whether they made the decision and then decided to convince me that it was the best option, or whether I was just – you know I go with the experts. (…) I suppose I did make the decision, but it was after some pretty heavy pressuring." (P 16)

"It was pretty much this is what we recommend. He (=the oncologist) did present it as you have a choice but all of the advice led down that path (=to have NAST)." (P 21)

Third, some women struggled with comprehending and accepting the preference-sensitive nature of the decision on NAST. Although survival outcomes are equivalent for NAST and upfront surgery, women found it hard to understand that their preferences needed to be involved in the decision-making process to determine the "best" treatment choice. These women perceived the decision on NAST as a no-win-situation. They felt that no matter which option they chose, it would not lead to a perceived gain, given that survival benefits are similar for NAST or upfront surgery, and given that they would have chemotherapy anyway. Some women experienced the decision-making process as a burden, rather than a chance to make a treatment decision in line with their individual preferences.

"Either way wasn't really going to make any difference. I guess I felt by doing it beforehand (=chemotherapy before surgery), I'm not disadvantaging myself (.) It seems that the results and so on are the same, or there doesn't seem to be much in difference." (P 12)

"Unfortunately it's such a grey area that there are pros and cons to both sides. So you're like shit, there's no obvious answer at the end." (P 22)

Decision-making in a situation of perceived emergency

Many women felt that the decision on NAST needed to be made quickly and perceived to be in an emergency situation which required urgent action to prevent a worsening of their cancer. The majority of patients reported that the decision was made during or shortly after the initial consultation with their doctor. A mean of 5 days (SD = 4.6) elapsed between study consent and treatment decision. A number of women reported having little time between the consultations with their medical specialists during which their treatment options were discussed. Some women noted the limited amount of time they had with their doctors during these consultations. Many women felt rushed when deciding on NAST which did not allow them to comprehend and weigh-up the information provided to them and make a considerate treatment decision.

"It was all really quite quick for me. I only found out in the morning and (was) then at the doctor's the same day, both the breast surgeon and the oncologist. So there wasn't very much down time for me. (…) So I was straight into, okay, you've been diagnosed, and straight into acting on it straight away."(P 5)

"Because when you are in a surgeon appointment, it's only a limited amount of time. Like it's specific to, boom, boom, boom, the things that have to be dealt with." (P 17)

A number of women felt a loss of control over the situation in which the decision was made. They were overwhelmed by the fear associated with their diagnosis and the potential treatment outcomes. Many patients reported a lack of medical expertise and did not feel capable of taking an active role in the decision-making process. A number of women perceived the lack of information as a "vicious circle" as it did not allow them to ask further questions which might have helped overcome their perceived lack of understanding. Some women felt that it was their responsibility to escape this "vicious circle" by seeking additional decision support.

"Obviously it was overwhelming because it's not something that you obviously hope on anybody." (P 5)

"Maybe I would have wanted to know more about prognosis and survival rates, but, if I wanted to know more, I should have asked more."(P 8)

Most women made the decision with their doctors and their support persons and perceived them to be the most important information sources for deciding on NAST. Some women reported to have appreciated if their doctor

suggested a treatment plan and offered to change the course of treatment at any time. These women perceived that the "right" treatment choice was determined by treatment success. Having the option to change the treatment plan if NAST was considered unsuccessful seemed to help women feel more satisfied with their decision.

> *"Yeah, like I really didn't know either way, so – but I was happy with the decision that was made knowing that at any time we could stop the chemo and have surgery if they felt the cancer was progressing or wasn't reacting or – yeah, if there were any other signs going on."* (P 2)

Strategies used to facilitate decision-making

Women used a number of strategies to facilitate decision-making on NAST. The most commonly used strategies included: (i) reducing deciding factors; (ii) "claiming" the decision; and (iii) using additional information. These strategies are described below.

Most women did not contemplate over the variety of potential reasons for or against having NAST. They seemed to base their decision on one or two key factors which they perceived as most important to them, at the time when the decision was made, such as having breast conserving surgery, rather than a mastectomy, or having a treatment that would affect the whole body, not just the breast. The reasons why women decided for or against NAST did not only relate to the medical effectiveness of the treatment options available to them. Some women decided on NAST based on their personal circumstances or on what they considered emotionally "bearable." For example, some women made the decision on NAST based on their family commitments or the fear associated with their cancer. This highlights that when deciding on NAST, the "right" treatment choice depends heavily on patients' individual preferences and needs.

> *"So if it doesn't affect the prognosis and / or the percentages of survival, and it does help you in other words in a few ways, in that the cancer can be reduced in size which means that the operation is not such a major one. Number one (1). Number two (2), if the cancer does reduce in size, they know that the chemo actually works."* (P 16)
>
> *"I suppose in the back of your mind you're thinking because as it's (=the chemotherapy) blasting the whole body and even if it is somewhere in my body, you can only hope that it has been blasted by this chemotherapy."* (P 4)
>
> *"I think the main clincher with me was finally feeling the size of the lump after the dressing's come down and everything. Then just thinking that I couldn't cope with that (=not getting the tumour removed immediately) and not knowing if it was going to get bigger or spread."* (P 9)
>
> *"I thought, well, I would rather get the chemo out of the way first because we've also got something coming up later in the year and I didn't want to be going through chemo when that happened. Our daughter's wedding is in the middle of the year, so that's why I was happy to do the chemo first."* (P 7)

Most women described the decision-making process in the passive voice. Although they did not seem to play an active role in deciding on NAST, most women reported that they made the final decision and thus "claimed" the decision. In these instances, patients' perceived involvement in the decision-making process differed from their perceived involvement in the final decision.

> *"I guess it was my decision at the end of the day but I was really just guided by what the doctors were saying."* (P 2)
>
> *"I guess you sign the paper and you say I'm making the decision but I do think that definitely the surgeon and the oncologist had both said this is what we would recommend."* (P 21)

Women used additional written information, such as the decision aid that was part of the larger trial, to confirm their decisions on NAST, rather than changing them. (An in-depth qualitative analysis of the use and perceived benefit of the decision aid is presented in another article which is currently in press). Using additional information helped women supplement the information provided by their doctors and reassure that their treatment choice was not solely determined by their doctors' opinion, but based on women's individual circumstances and preferences. Some women reported that using additional information helped them comprehend that they had a treatment choice and thus enabled them to better understand the preference-sensitive nature of the decision on NAST.

> *"Then she (=the breast surgeon) said, we've got this trial which is a decision tool. Would you be interested in being part of that? I said, yes that would be good, because I'd like to make sure that the decision that I am making is not being influenced by my healthcare practitioners who were telling me what they thought was better. So this helped me confirm that the decision that we were making together was the right decision."* (P 13)
>
> *"As I went away and started reading the literature in between sessions, it suddenly dawned on me that this is actually a choice. I could choose."* (P 23)

Women who used additional information in between the consultation with their surgeon and their medical oncologist appreciated having sufficient time to make sense of the information provided by their doctors. It helped them better cope with the perceived emergency of the situation and feel more involved in deciding on NAST.

> *"I think it was important to speak to the surgeon and get his view on it all, but I think it was also very helpful to have the written information that was in the decision aid so I could sit and read that at my own pace."* (P 17)

Discussion

Our data suggest that preference-sensitive decision-making in the context of NAST can be difficult for patients. Some did not feel that they were offered a treatment choice or received a strong treatment recommendation. This is in line with previous studies. Ziebland *et al.*, analyzed pancreatic cancer patients' perceptions of treatment decision making and found that doctors were often perceived to have presented surgery as the obvious course of action, rather than offering a treatment choice patients could have been involved in.[22] It is possible that the treatment recommendations of some clinicians may be at odds with patients' values.[23,24] Clinicians should emphasize that patients have a treatment choice and make it clear that patients can be involved in decision-making. This could be done by offering to explain the available evidence to patients, help patients comprehend the risks and benefits of their options, check for patients' understanding, and ask patients about their preferences for information provision and decision-making.[25] A patient-centered approach towards medical decision-making could help patients consider "what matters most to them" and facilitate their involvement in treatment decisions.[26,27] This is important as there is evidence to suggest that patients make decisions regarding their cancer care not only based on statistical risk assessment but based on a broad range of experiential factors, including family history of cancer or information sought from their personal network of family and friends.[28,29]

The patients in our study felt that the decision on NAST needed to be made quickly. Many felt overwhelmed by their diagnosis and treatment options which is in line with previous studies on other cancer treatment decisions.[27,30,31] It is vital to provide patients with appropriate time to consider their options and make sense of the information presented to them. Where possible, clinicians should emphasise to patients that it is usually safe to consider their options for a few days before making a decision. Offering the second consultation may be a strategy worthy of investigation to help improve patients' understanding of their options and their participation in decision-making.[32] Furthermore, providing additional written information for patients to review at home could take the pressure off having to provide and receive all required information within the consultation. This could counteract patients' feeling of being overwhelmed and allow for considered decision-making which might reduce patients' decisional regret.[32,33]

A patient-centered approach towards medical decision-making might also reduce costs to the healthcare system as there is evidence to suggest that patient-centered communication might be associated with better recovery from discomfort, better emotional health, and fewer diagnostic tests and referrals.[34,35] A recent Cochrane review on interventions to support patient involvement in decision-making indicated that consultations that involved such interventions were on average only 2.5 min longer (median: 2.55 min).[36] Patient-centered communication about treatment decisions patients have to make soon after their diagnosis might also lead to more succinct treatment discussions later in patients' care trajectory.[37] As a consequence, emphasizing that patients have a treatment choice and involving patients in treatment decision-making could ultimately lead to more efficient and effective patient care.

"Claiming" the decision to maintain cognitive consonance and the need for process-orientated research.

Many women reported having made the final decision on NAST, although they did not feel that they had been actively involved in the decision-making process. Festinger's Theory of Cognitive Dissonance may help explain why this occurred. This theory suggests that people strive to achieve a state of harmony by maintaining consistency between their beliefs, values and behaviors, to avoid psychological discomfort.[38] It might be that patients perceived to have made the final decision, although they did not feel that they played an active role in the decision-making process to align their behavior with their understanding of the situation. It is likely that women perceived an obligation for being involved in their own healthcare decisions, as it is the patients who have to manage the consequences of treatment decisions.[2] In line with the premise of cognitive dissonance theory, it might be that this strategy of "claiming" the final decision helps patients maintain cognitive consonance and thus psychological comfort by protecting themselves from any distress they may experience as a result of their views not aligning with their behavior.

Decision-making is a dynamic process where patients' preferences and needs might change.[39] When measuring patients' decision-making preferences and experiences, researchers should focus on the decision-making process rather than patients' perceptions of the final decision. However, many instruments in this area, including the widely used Control Preferences Scale, focus on patients' views about the final decision rather than the process of decision-making.[40] Such measures can be misleading as patients are often unaware that decisions need to be made and do not feel that they should have participated in them.[41] Process-orientated measures might help better understand patient involvement in treatment decisions by examining different components of the decision-making process.[28,41,42]

This is likely to increase the progress in the research and the implementation of patient-centered care.

Limitations

The study findings are not intended to be numerically representative. They rather provide in-depth insights into how women decided on NAST. As such, we avoided a potentially misleading numerical description of our results. We conducted phone interviews which might be a less productive mode of data collection than face-to-face interviews.[43,44] However, evidence is lacking on whether phone interviews produce lower quality data.[45-47] Also, patients might feel more relaxed and able to disclose sensitive information when being interviewed on the phone, in the comfort of their homes and without having to face the interviewer.[48] Furthermore, there is evidence to suggest that rearranging a phone interview by calling back at a more convenient time for the interviewee might cause study participants less embarrassment and difficulty than rearranging a face-to-face interview.[47] This was considered to be of particular importance for this study as many women asked to rearrange the interview because they felt too unwell to do the interview, or because they had to attend the clinic. As a consequence, it was assumed that conducting phone interviews, rather than face-to-face interviews would reduce research-related burden on patients. Some women participated in the interview months after deciding on NAST (median time between study consent and interview: 102 days). This introduces the possibility of recall bias that could lead to inaccurate narratives.[49] Also, most study participants were well-educated and younger. Older women and those with lower levels of education might have different experiences with deciding on NAST.[50] Clinicians' communication skills and styles may have influenced how women decided on NAST. For example, clinicians' skills in communicating risks might have had an impact on patients' understanding of their options.[9,15] As we do not have recordings of the consultations where the decision on NAST was discussed, we do not know how clinicians' communication skills and styles may have influenced patient decision-making.

Conclusion

Although the patients in this study presumably had a choice between two equally effective treatment regimes, a number of women felt overwhelmed and believed that they were not offered a treatment choice. Clinicians should emphasize to patients that they have a treatment choice, explain the preference-sensitive nature of NAST and highlight that patients should be involved in this decision, to the extent they desire. Strategies to support patient involvement in deciding on NAST might include providing patients with appropriate time and further written information to consider at home. Where possible and reasonable, clinicians should emphasize to patients that it is usually safe to take a few days to consider their options before a decision is made. Also, many of the study participants "claimed" the decision and reported having made the final decision, although they did not feel actively involved in deciding on NAST. Process-orientated research is warranted to examine changes in patients' preferences and experiences with making cancer treatment decisions.

Acknowledgments

We would like to acknowledge funding support from a Strategic Research Partnership Grant (CSR 11-02) from Cancer Council New South Wales to the Newcastle Cancer Control Collaborative (New-3C) and infrastructure funding from the University of Newcastle and Hunter Medical Research Institute. The ANZ1301 DOMINO study is funded by an HCF Research Foundation grant and by the Breast Cancer Institute of Australia.

Financial support and sponsorship

Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship, a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship and has received funding support from the Hunter Cancer Research Alliance Implementation Science Flagship Program as part of the 2017 Research Higher Degree Student Award initiative. Nicholas Zdenkowski is supported by the Hunter New England Local Health District.

Conflicts of interest

There are no conflicts of interest.

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SUPPORTING INFORMATION

Appendix 1 – Questions in each domain of the question guideline

Questions on information provided to patients included asking patients i) where they got information to help them make a decision about whether to have chemotherapy before surgery; ii) which of these information sources they found most useful; (iii) what exactly the information was that helped them make the decision; (iv) whether they felt they were given enough information to allow them to make a decision; (v) if they felt they were not given enough information, what other information they would like to have received; and (vi) how they would like information presented to them (written, face-to-face, online).

Questions regarding the decision-making process and psychological concerns included asking patients i) who made the decision in the end; (ii) what was difficult about making the decision; (iii) how certain they were about the decision at the time when they made the decision; (iv) how certain they were now that they made the right decision; and (v) if their certainty has changed, why it has changed. Patients were further asked whether vi) they do or did worry that their cancer would get worse whilst having chemotherapy; (vii) what period during chemotherapy and surgery they found most difficult, mentally and physically; and (viii) whether they worried that their cancer would come back.

Questions regarding other factors which might have influenced patients' decisions included asking patients whether and if so, how the following factors influenced their decision: i) having breast conserving surgery (lumpectomy); (ii) being able to know whether the cancer responded to chemotherapy; (iii) having treatment sooner for the whole body, not just for the breast; (iv) being involved in a clinical trial (and whether their doctor talked to them about this); (v) their ability to have children in the future. Patients were further asked whether (vi) they were aware that breast cancer can be inherited in the family and whether that was relevant to their decision; (vii) what other issues they considered when making the decision, such as financial or logistic issues; and (viii) whether they have considered having a breast reconstruction.

Appendix 2.2: Statements of contribution from co-authors

UON Graduate Research

Co-authorship declaration

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

I attest that the Research Higher Degree Candidate **Anne Herrmann** contributed significantly to the manuscript conceptualisation, study design, data collection, data analysis and manuscript preparation for the paper/publication entitled:

Women's experiences with deciding on neoadjuvant systemic therapy for operable breast cancer: A qualitative study

FULL NAME OF CO-AUTHOR	SIGNATURE OF CO-AUTHOR	DATE
Alix Hall		15/11/2017
Nicholas Zdenkowski		15/11/2017

Anne Herrmann

Date: 15/11/201

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Appendix 3: PAPER THREE

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Appendix 3.1: Published paper

Received: 4 May 2017 | Revised: 19 June 2017 | Accepted: 30 June 2017

DOI: 10.1002/HSR2.13

WILEY Health Science Reports

ORIGINAL PAPER

Exploring women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer

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Funding Information
University of Newcastle International Postgraduate Research Scholarship; University of Newcastle/Hunter Cancer Research Alliance Research Scholarship; Hunter Cancer Research Alliance Implementation Science Flagship Program; Hunter New England Local Health District; Cancer Council New South Wales, Grant/Award Number: CSR 11-02; Hunter Medical Research Institute; HCF Research Foundation; Breast Cancer Institute of Australia

Abstract

Background: Some women with operable breast cancer have a choice between receiving upfront surgery followed by chemotherapy or neoadjuvant systemic therapy (NAST) prior to receiving surgery. While survival outcomes are equivalent for both options, the decision about treatment sequence can be difficult due to its complexity and perceived urgency. A decision aid has been developed to help patients decide on whether to receive NAST.

Aims: To explore, qualitatively, women's use and perceived benefit of a decision aid to help with their decision on NAST.

Methods: A framework analysis process was conducted on a purposeful sample of 20, one-on-one, semistructured phone interviews with early-stage breast cancer patients eligible for NAST. Participants had recently decided on whether or not to have NAST.

Results: Patients perceived the decision aid as useful to becoming more informed and involved in making a decision as to whether they receive NAST. They described the information provided in the decision aid as reliable, relevant, sufficient in terms of amount, and tailored to their needs. Reading and rereading the decision aid at home in-between the consultations with their surgeon and their medical oncologist allowed women to better understand their treatment options and easily integrate the decision aid into their care. The decision aid seemed to confirm but not change women's decisions on NAST.

Conclusion: The decision aid appears to help breast cancer patients support their decision about whether to receive NAST. Patients' ability to review the decision aid in-between two consultations seems to be an acceptable and feasible way of integrating the decision aid into patients' care.

KEY WORDS

breast cancer, decision aid, decision making, qualitative research

1 | INTRODUCTION

1.1 | Breast cancer treatment decisions can be challenging

To maximise their outcomes, patients should be involved in their treatment decisions, to the extent they desire.[1] This can decrease patients' distress and anxiety, and increase their satisfaction with the consultation and overall quality of life.[2] However, breast cancer patients can be overwhelmed by the number of treatment options available to them.[3] In addition to the large number of treatment options available, the complexity of each treatment choice can further complicate the decision-making process. For instance, treatment choices are increasingly involving differing outcomes, such as efficacy and toxicity, which may be valued differently by different patients. Such decisions are called "preference-sensitive."[4,5] They can be very difficult for patients, as the "best choice" cannot be predefined; it depends on patients' preferences and involves each individual patient weighing up the risks against benefits of the

options available to them. It is essential that patients are adequately supported by the health care system when deciding on their treatment.[6]

1.2 | Deciding on neoadjuvant systemic therapy can be particularly difficult for patients

Some early-stage breast cancer patients with larger operable or highly proliferative disease may be offered a choice about whether to have neoadjuvant systemic therapy (NAST), ie. chemotherapy or endocrine therapy before surgery. This is a particularly difficult decision to make, as the concept of NAST adds complexity and uncertainty at a time when patients are likely to be distressed from the initial diagnosis of cancer. However, patients may value the neoadjuvant approach due to a higher chance of breast conserving surgery rather than mastectomy.[7] Neoadjuvant systemic therapy also allows a better understanding of tumour response and biology, which can facilitate prognostication.[8] Improved prognostication can decrease patients' anxiety and depression associated with their cancer and potential treatment outcomes.[9,10] Survival and recurrence rates are equivalent for NAST followed by surgery compared to receiving surgery first.[8] However, some patients fear that their cancer could get worse while receiving NAST and thus prefer to have the tumour surgically removed as soon as possible.[11] Therefore, for women with operable breast cancer, the decision for or against NAST relies heavily on patients' preferences.[12] To allow these patients to make informed treatment decisions, they need to be provided with adequate, evidence-based information.

1.3 | Decision aids can improve patient outcomes

Decision aids provide patients with evidence-based information regarding the health care options available to them. Decision aids aim to assist patients with clarifying and communicating the value they associate with each option.[13] They are designed to engage patients in the decision-making process and to guide them towards making deliberated decisions that align with their preferences.[14] A number of Cochrane reviews have shown that decision aids are effective in improving certain patient outcomes, including increased knowledge and understanding of the options available, and reduced decisional conflict, when compared to usual care.[15] Although decision aids have been developed for numerous health conditions, one was not available for the decision on NAST before this study commenced.[16] To fill this current gap, our group designed a decision aid to help women become more informed and more involved in decisions about NAST. The decision aid is being evaluated in a prospective, single-arm pre-post trial. Here, we report on the qualitative analysis of phone interviews included in the larger trial to assess women's use of, and perceived benefit from, the decision aid. This substudy aims to provide in-depth insights into women's perspective on the effectiveness of the decision aid and helps explore whether it might be a valuable tool to facilitate decision making on NAST in clinical practice.

1.4 | AIMS

The aim of this study was to explore, qualitatively, in a sample of early-stage breast cancer patients eligible for NAST, the use and perceived benefit of a decision aid that was designed to provide women with relevant information to assist their decision on NAST.

2 | METHODS

2.1 | Development and testing of a decision aid on NAST

The development of the decision aid was informed by (1) a qualitative study conducted to examine the information needs of patients receiving NAST;[11] (2) a literature review to define treatment options and the positive and negative outcomes associated with those options; and (3) identification of relevant issues important to the decision on NAST by an expert consensus panel. The structure of the decision aid was based on the International Patient Decision Aid Standards Collaboration (IPDAS) statement to include a balanced description of adjuvant and neoadjuvant therapy. The decision aid includes an introduction that helps newly diagnosed breast cancer patients understand basic concepts about their treatment modalities. This was important, as these patients may not have received other written general information at the time when NAST was discussed. The decision aid further includes brief general information about breast cancer and the treatments commonly used, an explanation of the options for the timing of chemotherapy and surgery, the advantages and disadvantages of neoadjuvant and adjuvant therapy, a values clarification exercise (ie. a worksheet to help patients consider how they value key aspects of the decision on NAST), a page for notes, a glossary, and information about where to find additional resources. To improve patients' risk perception and lead to better informed decision making, key components of risk are presented in visual, numeric, and narrative formats using appropriate labelling. The decision aid is designed to be compatible with online and paper delivery. The IPDAS criteria for judging the quality of decision aids have been adhered to (please see Appendix S1 for a completed IPDAS checklist).[17-19] Consumers and members of a breast cancer support organisation (Breast Cancer Network Australia) reviewed and helped refine the content and comprehensibility of the decision aid. Care was taken to make use of the shortest word and simplest sentence structure possible. Word and sentence length had to be balanced against the overall length of the decision aid. An excessively long decision aid was not considered likely to be approachable by those with low literacy. To avoid duplication of information, the decision aid refers to other information sources, which are routinely made available by breast care nurses to women who have been examined with breast cancer.

2.2 | Setting and sample

A purposeful sample of 20 patients attending breast cancer treatment centres in New South Wales and Victoria were interviewed one-on-one via telephone. Recruitment continued until data saturation (no new themes in 3 consecutive interviews) was achieved.

2.3 | Inclusion and exclusion criteria

Patients were eligible for this study if, at the time of enrolment, they (1) were female; (2) were aged ≥18 years; (3) had a histological diagnosis

of operable invasive breast cancer; (4) were considered for neoadjuvant systemic (chemo or endocrine) therapy (NAST) as a treatment option with curative intent; and (5) were willing and able to access the trial information and the decision aid via the Internet and complete the telephone interview. Patients were excluded if (1) < 3-month duration of NAST was planned; (2) they had hearing or other impairment that would preclude a phone interview; (3) they had insufficient English language skills for participation in a phone interview; (4) they had inflammatory, metastatic, or inoperable breast cancer; (5) they were considered by the treating investigator to have a medical or psychiatric condition precluding informed consent; and (6) they were unable to be contacted via telephone. We excluded those patients who were going to receive less than three months of chemotherapy because the outcome probabilities presented do not apply to those patients. The intent was to include patients who were going to receive a full course of neoadjuvant chemotherapy, which is typically three months or more. This duration is required for maximal benefit from neoadjuvant chemotherapy.

2.4 | Recruitment

The treating clinician identified eligible patients attending their clinic for a consultation, introduced the trial, and obtained written consent to be contacted by the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) for study registration. The clinician then completed a screening form and faxed it to ANZBCTG. The screening form contained an eligibility checklist, investigator assessment of information needs and distress at that time, consent for release of information to the ANZBCTG, and patient email address and phone number for further contact. Patients who consented to further study contact were emailed a link with access to the trial information letter and online consent form, which patients could access after the consultation with their treating clinician. The consent form asked patients to provide consent to take part in the larger intervention trial and gave participants the option to opt out of a follow-up telephone interview. Once patients had consented to participate in the trial they entered their demographic details and completed a series of patient reported outcome measures in an online survey. Patients were then provided with access to the decision aid, which they could read online or print out. Patients who consented to a telephone interview were contacted via phone by a member of the research team (AH) to schedule the interview. Most interviews took place two to three months after study consent (median time between study consent and interview: 93 d). Women were not asked to have the decision aid on hand during the interview.

2.5 | Data collection

All interviews were conducted by a single researcher (AH) who has been trained in qualitative research methods. Participants were informed that the interviews would be audio-recorded and transcribed but that their information would remain confidential and de-identified. They were then asked to tell the interviewer how they made their decision to have chemotherapy before or after surgery. Participants were encouraged to tell their story in the way they preferred, without interruption from the interviewer. This narrative was followed by semistructured open-ended questions that included asking patients about the information provided to them, their information seeking behaviour, the decision-making process, psychological concerns, and experiences with the decision aid. The question guide is described in Appendix S2. At the end of the interview, patients were given the option to provide additional comments. The questions were informed by a previous study and discussions amongst the research team.[11,19] Participants were asked as many questions as needed to gain the required information, with prompting used to elicit topics not spontaneously spoken about by patients.

2.6 | Data analysis

Interviews were transcribed verbatim. Transcripts were checked for accuracy by one researcher (AH) and analysed using a framework analysis process. Transcripts and conclusions drawn from the data were double-checked by another member of the research team (NZ). Disagreement was resolved by discussions between AH and NZ. The framework method was considered appropriate to develop a profound understanding of patients' experiences with the decision aid, as it provides a systematic model for managing and mapping the interview data and for generating themes by making comparisons within and between cases.[20] After familiarising ourselves with the data, AH examined, compared, and categorised segments of content to assign codes and to start the development of categories. A category in this sense was a group of codes that share a commonality.[21] After identifying initial codes and categories, AH developed a coding matrix and assigned data to the codes and categories in the coding matrix.[22] This coding matrix was then discussed and refined with one member of the research team (NZ). Throughout the coding process, an iterative approach was applied. Newly developed categories and existing ones were constantly compared with each other and revised if necessary. To do this, the interviews were analysed individually and then compared with each other.[23,24] The coding process was accompanied by writing analytical memos. This helped document the research process and preliminary findings. These techniques contributed to the intersubjectivity of the procedure and allow to reconstruct or repeat the analysis.[25] Demographics are presented using appropriate summary statistics.

3 | ETHICS

This study was developed and conducted in accordance with the tenets of the Declaration of Helsinki and principles of Good Clinical Practice. All participants provided voluntary informed consent. The study was approved by a recognised Human Research Ethics Committee and conducted according to local site governance processes. The parent intervention trial was prospectively registered on the Australia and New Zealand Clinical Trials Registry (www.anzctr.org.au, ACTRN12614001267640).

4 | RESULTS

4.1 | Demographics

Patients were interviewed via phone between February and September 2016 by one researcher (AH). Of 59 patients who consented to the larger trial, 42 consented to be interviewed and 20 were interviewed, by which time saturation was achieved. Interviews lasted between 15 and 37 minutes. Participants' median age was 52 (SD = 6.9); median time since diagnosis was 82 days (IQR = 49 141). The majority of patients decided for NAST (85%), while the remaining 15% underwent upfront surgery. Most patients were married or living with a partner (85%) and had a university-level degree (75%, see Table 1).

4.2 | The use and perceived benefit of the decision aid

The following themes emerged from the data: (1) integration of the decision aid into care, (2) improved knowledge and understanding of treatment options, (3) providing customised, reliable information, and (4) facilitating involvement in decision making. Our data suggest that by providing customised and reliable information to patients, the decision aid helped women better understand their options and thus facilitated the decision-making process. Most women used the decision aid in-between the consultations with their doctors. As such, the decision aid could be easily integrated into women's care pathway. The themes are described in detail below.

4.3 | Integration of the decision aid into care

Most women used the decision aid just after the initial consultation with their surgeon about their treatment options, prior to their consultation with the medical oncologist, and perceived this as the right timing. A mean of 5 days (SD = 2.3) elapsed between study consent and treatment decision. Reading and rereading the decision aid at home in-between the two consultations allowed women to easily integrate the decision aid into their care. They appreciated the opportunity to reconsider their options at their own pace after consulting their surgeon. This was particularly important for those women who thought that the initial consultation with their surgeon did not provide sufficient time to answer all the questions they had. Many women felt that the decision on NAST needed to be made quickly and welcomed using the time in-between the consultation with their surgeon and their medical oncologist to think about their options with the help of the decision aid.

> *I think it was important to speak to the surgeon and get his view on it all, but I think it was also very helpful to have the written information that was in the decision aid so I could sit and read that at my own pace. [...] When you are in a surgeon appointment, it's only a limited amount of time. Like it's specific to, boom, boom, boom, the things that have to be dealt with. It felt like it [=the decision aid] was more information than what I'd had from him [=the surgeon]. It was also that I was able to absorb it better because I could sit down and take the time to read it. [patient ID: 13010041]*

While most women received the decision aid after the initial consultation with their surgeon, many women made the decision during or just after this initial discussion and some wished they had the decision aid "right from the start" [patient ID: 13010035], ie. just after their diagnosis. Although using the decision aid in-between two consultations seemed appropriate, some patients reported they would have liked to receive the decision aid during rather than after the initial consultation with their surgeon.

> *The book that I was sent after I did that survey, I would have loved to have had access to that book from the get go. [patient ID: 13010034]*

Some patients did not use the decision aid as they felt that they (or their doctors) had already made the decision. However, most women read the entire decision aid at least once and then reread the passages they perceived to be most relevant to them. The amount of information provided was seen to be appropriate. Patients appreciated that they could read the decision aid from beginning to end or only focus on those parts they were most interested in.

> *You could read more into it if you wanted, but for me, I read bits and pieces of the bits that weren't relevant to me – and all of what was relevant to me but I think it was enough information that if you weren't quite sure you could always go and get more if you wanted [...] for me it was the right amount of information. [patient ID: 13010033]*

4.4 | Improved knowledge and understanding of treatment options

The decision aid enhanced patients' knowledge and understanding of the treatment options available to them by summarising and extending

TABLE 1 Patient characteristics

	Patients (n = 20)
Age in years, mean (SD)	52 (6.9)
Marital status	
De facto	15% (3)
Married	70% (14)
Single	15% (3)
Education	
Secondary school	15% (3)
Vocational	10% (2)
University	75% (15)
Lymph nodes involved	
Yes	45% (9)
No	55% (11)
Treatment decision	
Neoadjuvant	85% (17)
Adjuvant	15% (3)
Surgery	
Mastectomy only	45% (9)
Breast conserving surgery only	50% (10)
Both	5% (1)

the information provided by their doctors. It helped women comprehend and make sense of their cancer and treatment options. Many women reported that the decision aid made up for their perceived lack of medical expertise by providing structured, objective information and by answering questions patients had after the consultation with their doctor.

> *Sometimes you just need it clearly laid out in front of you, this is your options, without having different people who had their own agendas telling you what is right and what is wrong, or what you should do. [patient ID: 13010033]*

> *It enhanced what my surgeon had told me and allowed me to process it and understand it at a greater depth than I would have been able to if I hadn't had the decision aid. [patient ID: 13010034]*

> *It was very simply written and also to-the-point. I suppose there were some questions that I might have been asking myself and they were being answered in that booklet. [patient ID: 13010035]*

Some women indicated that the included graphs and statistics were particularly helpful to understand the potential risks and benefits of their treatment options. Others found that the explanation of different types of breast cancer helped them better understand why different patients received different treatments. Some participants with a medical background felt that the decision aid could have provided them with more detailed information, for example, on potentials risks and benefits of NAST and upfront surgery according to different age groups. However, they thought that the decision aid provided the right depth and breadth of information to suit the needs of the heterogeneous group of breast cancer patients, which includes patients with very different educational backgrounds and literacy levels.

> *It did give figures for chances of it [=the cancer] disappearing altogether and chances of it coming back, the different types of cancer and yeah, I became a bit more of an expert about breast cancers and the different types that I had been before. [patient ID: 13010048]*

> *I found it interesting to read a little bit about the other cancers and make the decision on me and my situation rather than everyone's situation. [patient ID: 13010033]*

> *I think that the particularly relevant bit was understanding the different types of cancer and the explanation of the HER2 and the other types of cancer, and how they are all slightly different, because I didn't know any of that before I got cancer. [...] so yes the relevant thing, I think, was understanding all the different types of cancer and how one size doesn't fit all. Not everyone should have the same approach. [patient ID: 13010041]*

The decision aid also helped women deal with the fears associated with their treatment options and assisted them in making an informed, rational decision based on their individual circumstances and preferences.

> *I felt after reading it [=the decision aid] that my fears about the tumour remaining there were abated really. [...] my cancer was triple negative and I understood that it had potentially grown quite fast. Once I understood the rationale for why I might have chemotherapy first, I actually felt it was a better option for me to start the chemotherapy sooner rather than later, given that it also had spread to my lymph nodes. [patient ID: 13010033]*

4.5 | Providing customised, reliable information

Women appreciated that information was provided in both face-to-face and written format. Many women preferred the printed decision aid over the online version due to ease of access, viewing, portability, and ability to make notations. Also, patients preferred using the decision aid instead of information they found by searching online. They perceived the information provided in the decision aid to be more trustworthy and targeted to their needs, compared with sources that they identified on the Internet.

> *I just found that the information that I was Googling on the internet, it was too much, it was too airy fairy. Whereas this [=the decision aid] was just straight to the point, it was just in great user friendly language and that's what I really loved about the book. [patient ID: 13010035]*

> *I was a little bit overwhelmed and I wanted reliable information, so I chose not to Google, not to do a Google doctor. [patient ID: 13010034]*

All patients who used the decision aid described the information provided in the decision aid as reliable and tailored to their needs. They liked how the decision aid was organised, including the use of graphics, tables, and sufficient white space that reduced the crowding of text. Most patients found the decision aid easy to understand and balanced (not in favour of NAST or upfront surgery). Some patients perceived it to be in favour of NAST and wished it contained more information on upfront surgery.

> *The way it's laid out, it's quite spacious on the pages and there are lots of diagrams and stuff. So it's not, you know, it's quite intimidating if it was all heavy text closely together. [patient ID: 13010015]*

> *I think it was more slightly biased in terms of chemotherapy first but it could have just been my reading of it because I was already in that frame of mind. [patient ID: 13010041]*

4.6 | Facilitating involvement in decision making

The decision aid not only enabled patients to make an informed decision on NAST but also helped them become more involved in the decision-making process, for example, by prompting additional questions to ask their doctors during the consultation. Some women took parts of the decision aid to the next consultation with their

specialist. This served as a platform for further discussion about their preferences and concerns and helped women remember the questions they wanted to ask their doctor. One patient found the step-by-step approach for how to arrive at a treatment decision particularly helpful. This section of the decision aid included guidance to patients to understand, review, prioritise, and discuss the information provided (see Appendix S3).

> *I felt like I was more involved in the decision and I was making the decision in a more informed way that I maybe would have been able to if I'd just relied on the surgeon's information, if that makes sense. [patient ID: 13010033]*

> *It [=the decision aid] was opening up other questions for me to think about, to help me think about. [patient ID: 13010024]*

> *I actually then just pulled out pages that I thought were more towards what I was thinking. [...] I took that with me to the oncologist appointment. Just so I had things that reminded me of what I wanted to ask. [patient ID: 13010026]*

Some women reported that their family members used the decision aid as well and thus became more informed and involved in the decision-making process. This saved patients from spending time and effort educating their support persons about the risks and benefits of the different treatment options available to them.

> *My husband went through the decision aid as well, and also my two adult daughters. I think it was quite helpful for them. I saved my breath, if you know what I mean, in terms of having to explain and justify why one option might be a better choice than another. [patient ID: 13010034]*

All patients received a treatment recommendation from their doctor and chose the recommended option. The decision-making process was guided by their doctors' opinion and based on patients' trust in their doctors' medical expertise and experience. Although the decision aid helped patients understand their options, confirm their decision, and increase their involvement in the decision-making process, it did not change women's decisions on NAST. Women who felt they made an informed decision on NAST and were involved in the decision-making process seemed to be more satisfied and certain about their decision.

> *It [=the decision aid] just kind of clarified and confirmed to me what I was doing and the decision I made. [patient ID: 13010032]*

> *I felt that having chemo first was the right decision – and the information in there [=the decision aid] helped me confirm that that was the right decision. I just think it's something that should be out there for all women in this situation [...] It's such an important tool to have to make sure that you're making the decision that's right for you. [patient ID: 13010033]*

5 | DISCUSSION

5.1 | Fitting decision aids into the clinic workflow: a feasible prospect

These results suggest that the decision aid was a useful tool to support breast cancer patients in deciding on whether to have NAST. The themes that emerged from the data were of integration of the decision aid into care, increased knowledge and understanding of treatment options, providing customised, reliable information, and involvement in the decision-making process. The decision aid supported women's comprehension of their cancer and the treatment options available to them. It facilitated their participation in deciding on NAST and helped women confirm that they made the right decision. This is in line with current evidence supporting the effectiveness of decision aids in improving patient outcomes.[15,26] The degree of patients' engagement with this decision aid demonstrates the feasibility of patient involvement in decision making in the context of a confronting diagnosis accompanied by a variety of decisions, rather than expecting clinician-led decision making.

Although decision aids have been shown to be effective in improving patient outcomes, widespread clinical use is not yet commonplace.[27] More efforts need to be made to explore how to best integrate decision aids into routine doctor-patient communication. Depending on the format and the decision being made, individual decision aids may be better suited to use either during the consultation or afterwards.[15] The breast cancer patients in our sample appreciated reading the decision aid in-between having a consultation with their surgeon and their follow-up consultation with their medical oncologist. Patients received the decision aid after the initial consultation with their surgeon, while waiting to see their medical oncologist. This allowed the decision aid to be easily integrated into their care pathway. It also gave women the opportunity to reconsider their options and feel more certain about choosing a treatment. This is in line with previous studies reporting reduces in patients' decisional conflict, decisional regret, and depression after the use of decision aids, which had been delivered as a post consultation supplement.[15,28,29] Further studies have suggested that using a decision aid prior to the consultation during which a health care decision is made might increase patients' feeling of being informed about their options, as well as patients' ability and willingness to participate in the decision-making process at hand.[30-32]

Although using the decision aid in between patients' consultation with their surgeon and their consultation with their medical oncologist seems to be appropriate, some women said that the intervention should be introduced and endorsed during the initial consultation with their surgeon. Such an approach may be possible with sufficient resources, however might be difficult to broadly incorporate into routine practice given many clinicians' reluctance regarding the provision of decision aids during the consultation.[33,34] For example, it has been suggested that clinicians might fear that the use of decisions aids could increase their time pressure.[35,36] Further barriers include clinicians' lack of awareness of decision aids or their belief that decisions aids are not applicable to the circumstances of each individual patient.[37] The study processes precluded investigators from

providing participants with the decision aid at the initial consultation with their surgeon, because pre-decision aid questionnaires were required for the larger intervention trial in which this qualitative study was embedded. However, investigators were given a card showing key images and graphs from the decision aid to demonstrate within the consultation. In routine clinical practice, the decision aid could be briefly introduced during the initial consultation with the surgeon. Face-to-face communication between doctor and patient might be best suited to introduce and explain the preference-sensitive nature of the decision on NAST and the potential benefits of the decision aid.[38] This is in line with previous studies that suggest that patients might value having important treatment decisions discussed with their clinician first and having decision aids delivered during the consultation.[39,40] Patients could then use and engage with the decision aid after the consultation to broaden and deepen their understanding of the conveyed information and prior to making a final treatment decision.

5.2 | Exploring the benefits of the decision aid on NAST

The women included in our sample were well educated and had high health literacy levels, which may have contributed to positive feedback about comprehensibility. We do not know whether women with lower health literacy levels would perceive the same benefits from using the decision aid. However, there is evidence to suggest that if patients with lower literacy levels are provided with appropriate decision support, they participate equally well and benefit by becoming more aware of their health care options.[41] It would be beneficial to administer the decision aid to a more representative sample of breast cancer patients to investigate whether our findings are generalisable.

The decision aid reassured women that they made the right decision on NAST but did not change their decision. Other decision aid studies have demonstrated a variable effect on treatment choice[15]; however, the intent is to inform and involve rather than to change people's mind. All women trusted and followed their doctors' treatment recommendation. Many patients felt that their treatment decision needed to be made quickly and felt overwhelmed by their cancer diagnosis and treatment options. Decision aids, such as the one provided within this study, might be an opportunity to counteract this "rushed" decision making by allowing patients to reconsider and confirm their treatment decision.[42,43] Because all patients in our study received a treatment recommendation, this decision aid could be used to educate women on the preference-sensitive nature of the decision on NAST and to highlight the benefits of involving patients' preferences in this decision.[44,45] As such, the endorsement by clinicians influenced the decision aid's success. Also, the decision aid gave patients' support persons specific information about the options available and enabled their participation in the decision-making process. This mirrors previous studies that reported that decision aids can increase families' knowledge of the options available to patients and their involvement in decision making.[46,47]

5.3 | The influence of the decision aid on the decision about NAST

Although most women felt that the decision aid provided unbiased, balanced information, some women perceived that the decision aid was in favour of NAST. When probed to explain why they felt this way, women reported that they decided for NAST and felt that they might have read the decision aid according to what they had already decided. One could assume that to obtain or maintain cognitive consonance, women who chose NAST read the decision aid to confirm their decision and thus got the impression that NAST was recommended by the decision aid.[48] However, it might be that the decision aid is in fact biased. Further examination is needed to answer this question.

A number of women indicated a preference for more detailed information. Although the decision aid includes links to further information sources, it might be worthwhile to provide an optional supplement to the decision aid for those patients who would like to receive more information on the decision on NAST. Such a supplement could include potential risks and benefits of NAST and upfront surgery according to different age groups. This would be more amenable to an online format, which incorporates links and additional pages for those who want more information. Similar approaches have been shown to be valued by patients.[49,50]

6 | LIMITATIONS

Our findings are not intended to be numerically representative. They rather provide much needed in-depth insights into patients' use and perceived benefit of this decision aid, and decision aids in general. As such, we avoided potentially misleading numerical description of our results. A quantitative analysis of the decision aid that includes a larger sample size will be reported elsewhere. Most study participants (85%) chose NAST over upfront surgery. Thus, women's perceptions of the decision aid may have been influenced by their treatment decision. Also, some women used the decision aid months prior to the interview, introducing the possibility of recall bias that could potentially lead to inaccurate narratives.[51] Some patients noted that the shock over their cancer diagnosis and the plethora of information to consider added further difficulty with remembering the decision aid's content.

> *That is a really, really shady period of my life. I can't remember much. You probably know that people do not remember much when they first hear the diagnosis. [patient ID: 13010023]*

We do not have recordings of the consultations during which the decision aid was introduced. As such, we do not know how the communication skills and styles of the doctors who were involved in the delivery of the decision aid might have influenced patients' use and perceived benefit of the decision aid.

7 | CONCLUSIONS

Our results suggest that the decision aid is a valuable tool for supporting women with their decision on NAST. It seemed to increase

women's knowledge and understanding of the options available to them and helped them feel more involved in the decision-making process. The decision aid assisted women with confirming that they made the right decision. For most women, using the decision aid in-between the consultation with their surgeon and the consultation with their medical oncologist appeared to be an acceptable and feasible way of integrating the decision aid into patient care.

COMPETING INTERESTS

The authors declare that they have no competing interests.

FUNDING

AH is supported by a University of Newcastle International Postgraduate Research Scholarship, a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship and has received funding support from the Hunter Cancer Research Alliance Implementation Science Flagship Program as part of the 2017 Research Higher Degree Student Award initiative. NZ is supported by the Hunter New England Local Health District. FB is supported by the Friends of the Mater Foundation.

AUTHORS' CONTRIBUTIONS

AH and NZ conceived of this paper together. AH conducted data collection and analysis. The results of the data analysis were double-checked by NZ. All authors reviewed and approved the final manuscript.

ACKNOWLEDGEMENTS

We would like to acknowledge funding support from a Strategic Research Partnership Grant (CSR 11-02) from Cancer Council New South Wales to the Newcastle Cancer Control Collaborative (New-3C) and infrastructure funding from the University of Newcastle and Hunter Medical Research Institute. The ANZ1301 DOMINO study is funded by an HCF Research Foundation grant and by the Breast Cancer Institute of Australia.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

How to cite this article: Herrmann A, Boyle F, Butow P, Hall AE, Zdenkowski N. Exploring women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer. *Health Sci Rep*. 2017;e213. https://doi.org/10.1002/HSR2.13

Appendix 3.2: Statements of contribution from co-authors

UON Graduate Research

Co-authorship declaration

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

I attest that the Research Higher Degree Candidate **Anne Herrmann** contributed significantly to the manuscript conceptualisation, study design, data collection, data analysis and manuscript preparation for the paper/publication entitled:

Exploring women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer

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Publication: Health Science Reports

Publisher: John Wiley and Sons

Date: Aug 22, 2017

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Herrmann, A., Sanson-Fisher, R., Hall, A. et al. "A discrete choice experiment to assess cancer patients' preferences for when and how to make treatment decisions" Support Care Cancer (2018) 26: 1215. https://doi.org/10.1007/s00520-017-3944-9

Appendix 4.2: Statements of contribution from co-authors

UON Graduate Research

Co-authorship declaration

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

I attest that the Research Higher Degree Candidate **Anne Herrmann** contributed significantly to the manuscript conceptualisation, study design, data collection, data analysis and manuscript preparation for the paper/publication entitled:

A discrete choice experiment to assess cancer patients' preferences for when and how to make treatment decisions

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I attest that the Research Higher Degree Candidate **Anne Herrmann** contributed significantly to the manuscript conceptualisation, study design, data collection, data analysis and manuscript preparation for the paper/publication entitled:

Support persons' preferences for the type of consultation and the format of information provided when making a cancer treatment decision

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Wilfully out of sight? A literature review on the effectiveness of cancer-related decision aids and implementation strategies

Anne Herrmann[1*], Elise Mansfield[1], Alix E. Hall[1], Rob Sanson-Fisher[1] and Nicholas Zdenkowski[2]

Abstract

Background: There is evidence to suggest that decision aids improve a number of patient outcomes. However, little is known about the progression of research effort in this area over time. This literature review examined the volume of research published in 2000, 2007 and 2014 which tested the effectiveness of decision aids in improving cancer patient outcomes, coded by cancer site and decision type being targeted. These numbers were compared with the volume of research examining the effectiveness of strategies to increase the adoption of decision aids by healthcare providers.

Methods: A literature review of intervention studies was undertaken. Medline, Embase, PsychInfo and Cochrane Database of Systematic Reviews were searched. The search was limited to human studies published in English, French, or German. Abstracts were assessed against eligibility criteria by one reviewer and a random sample of 20 % checked by a second. Eligible intervention studies in the three time periods were categorised by: i) whether they tested the effectiveness of decision aids, coded by cancer site and decision type, and ii) whether they tested strategies to increase healthcare provider adoption of decision aids.

Results: Over the three time points assessed, increasing research effort has been directed towards testing the effectiveness of decision aids in improving patient outcomes ($p < 0.0001$). The number of studies on decision aids for cancer screening or prevention increased statistically significantly ($p < 0.0001$) whereas the number of studies on cancer treatment did not ($p = 1.00$). The majority of studies examined the effectiveness of decision aids for prostate ($n = 10$), breast ($n = 9$) or colon cancer ($n = 7$). Only two studies assessed the effectiveness of implementation strategies to increase healthcare provider adoption of decision aids.

Conclusions: While the number of studies testing the effectiveness of decision aids has increased, the majority of research has focused on screening and prevention decision aids for only a few cancer sites. This neglects a number of cancer populations, as well as other areas of cancer care such as treatment decisions. Also, given the apparent effectiveness of decision aids, more effort needs to be made to implement this evidence into meaningful benefits for patients.

Keywords: Decision aids, Implementation, Neoplasm

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Background

Patients as key players in their own healthcare

Over the last two decades cancer care has evolved from a paternalistic, clinician-centred model to a patient-centred model [1, 2]. Patient-centred care places great emphasis on involving patients in their own healthcare [3, 4]. Clinical decision making is now largely viewed as a collaborative process in which the clinician, the patient (and their support persons) choose healthcare options together, based on the patient's informed preferences [5, 6]. Involving patients in their healthcare decisions is associated with improved patient outcomes, including decreases in patient unmet information needs and anxiety and increases in patients' satisfaction with the consultation [7, 8]. Shared decision making can improve patients' quality of life [9–12].

Preference-sensitive healthcare decisions are challenging

Patients' willingness to become involved in decisions may be hampered by difficulties in choosing between the various healthcare options available to them [13, 14]. This is especially true for "preference-sensitive" decisions, where there is little or no difference in the medical effectiveness of the available healthcare options. In these instances the final decision involves weighing up the costs and benefits of the different options according to the values and preferences of the patient [3, 15]. With an increasing variety of treatment and care options, more and more cancer prevention, screening and treatment decisions are becoming "preference sensitive." For example, early-stage breast cancer patients and their clinicians may have a number of different treatment options to choose from, including surgery, cytotoxic or endocrine therapy [16]. Some patients may have the option to decide whether they receive chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant). Each of these treatments shows similar medical effectiveness for these patients but holds various side effects and impacts that may be valued differently by different patients [17].

Decision aids to help patients make difficult healthcare decisions

To assist patients in making these difficult decisions, healthcare providers have been encouraged to use patient decision aids. Decision aids are interventions which provide patients with specific information on their available options and guide patients towards choosing the option that aligns with their values. They intend to encourage patients to become more involved in the decision making process [18, 19]. Decision aids can be delivered in various formats, such as face-to-face, as written booklets or web-based tools [20]. They cover a variety of healthcare options, including cancer screening, prevention and treatment [21].

There is evidence for the effectiveness of decision aids

Numerous reviews have provided considerable evidence of the effectiveness of decision aids in improving patient outcomes [22–25]. The first Cochrane review on the effectiveness of decision aids was published in 2001, and concluded that decision aids improve knowledge, reduce decisional conflict, and stimulate patients to be more active in decision making [26]. Updated versions of this review were published in 2003, 2009, 2011 and 2014, which all supported the original findings [20, 27–29]. To date, over 100 Randomized Controlled Trials (RCTs) exist that demonstrate that decision aids are effective in improving patient outcomes. Despite the evidence for the effectiveness of decision aids, they are not commonly used in practice [30]. Previous research has identified barriers and enablers which preclude the implementation of decision aids [31–33]. Little is known about whether the focus of research on the effectiveness of decision aids has changed over time and whether this evidence has translated into the development and testing of strategies to implement decision aids. Once the effectiveness of decision aids in a certain area has been established, research should move from testing the effectiveness of these interventions to testing the effectiveness of implementing decision aids into routine care.

Research output as measure of research effort

Examining the volume of peer-reviewed research output using bibliometric methods can be used as a proxy indicator of scientific productivity [34–37]. As a result, assessing the volume of research output can provide an indication of the focus of research effort and where future research is needed most. To date, there has been no time sampling of the volume of research examining the effectiveness of decision aids compared to the volume examining the effectiveness of strategies to increase their adoption by healthcare providers. We aimed to give an indication of the focus of research efforts, in order to provide an indication of where future research is required.

Aims

The aim of this review was to provide a snapshot of where research effort focusing on cancer-related decision aids has been directed to over the last 15 years. We examined changes in the volume of research that examined the effectiveness of cancer-related decision aids, across three time points. We also categorised eligible articles by cancer type and decision being targeted. Finally, we compared the number of studies that assessed the effectiveness of cancer-related decision aids to the number of studies that assessed strategies to increase the adoption of decision aids by healthcare providers.

Methods

Literature search

The electronic databases Medline, Embase, PsychInfo and Cochrane Database of Systematic Reviews were searched using the OVID platform. We selected these databases due to their focus on biomedicine and health publications in scholarly journals. The search strategy included three categories of search terms and subject headings: cancer, decision making/decision aids and patient participation. We adapted the search strategy to the requirements of each individual database. The full search strategy for each database is available in Additional file 1. Searches were restricted to English, French and German language publications and human studies. Although most scientific research is published in English, the importance of non-English studies is hard to predict [38, 39]. English, French and German belong to the most common alternative languages used in scientific research [40–42]. Studies published in French or German were included in this review to reduce the likelihood of English language bias. Reference lists of systematic reviews on the effectiveness of decision aids were also searched to ensure that all relevant studies were included in this paper. Where feasible and applicable the PRISMA guidelines were followed [43].

Inclusion and exclusion criteria

Studies were included if they were intervention studies which examined either: the effectiveness of decision aids on patient outcomes or the effectiveness of strategies to increase provider adoption of patient decision aids. Eligible papers were those published in any country in 2000, 2007 or 2014. These time periods were chosen prospectively as the patient-centred care model gained popularity after the influential report 'Ensuring Quality Cancer Care' released by the US National Cancer Board published in 1999, advocating for patient-centred care [2]. Awareness of the patient-centred model was further heightened by the 2001 Institute of Medicine report 'Crossing the Quality Chasm' [1]. We excluded case studies, commentaries, conference abstracts, proposed studies, protocol papers and editorials.

Definitions

We based our definition of patient decision aids on that proposed by the International Patient Decision Aid Standards (IPDAS) Collaboration [44–46]. IPDAS aims to improve the quality and effectiveness of patient decision aids by establishing standards for improving their content, development, implementation, and evaluation [18, 19, 47]. Decision aids were defined as interventions which help patients to participate in making deliberated choices among healthcare options. They explicitly state the decision to be made and provide specific, evidence-based information on the available healthcare options as well as information on the possible risks and benefits of each option. Decision aids aim to help patients to clarify and communicate the value they associate with each option [20, 46]. Strategies to increase healthcare provider adoption of decision aids were defined as any actions taken in order to increase provider usage of decision aids in clinical practice. Implementation strategies were coded as such if they were targeted at the healthcare provider, and/or if they were targeted at the healthcare system.

Paper coding

After removing the duplicate results, abstracts were screened according to the eligibility criteria by one reviewer (AH). They were rejected if the reviewer determined from the title and abstract that the study did not meet the inclusion criteria. Full text copies of the remaining publications were retrieved and further assessed against the eligibility criteria by the same reviewer (AH). A random sample of 20 % of full text studies identified as eligible were checked for relevance and double-coded by a second reviewer (EM). Eligible studies in the three time periods were categorised by whether they tested: i) the effectiveness of decision aids in improving cancer patients' outcomes, or ii) the adoption of decision aids by healthcare providers. Studies testing the effectiveness of decision aids were also coded by cancer type of the study sample. The type of decision being targeted was coded as either screening/prevention or treatment. Screening decisions aids include those which assist patients to make a decision about whether they want to undergo cancer screening, such as mammography and colonoscopy. Cancer prevention decision aids include those which assist patients to make a decision about whether they will undergo a procedure to lower the risk of getting cancer, such as prophylactic mastectomy or immunisation. Cancer treatment decision aids include those designed to help patients choose between different cancer treatments.

Analysis

One way trend tests were performed to examine the changes in the proportions of studies on the effectiveness of decision aids as well as on screening or prevention and treatment decision aids separately across time. Analyses were programmed using Stata v13.0 (StataCorp Ltd, College Station, TX).

Results

Search results

As shown in Fig. 1, a total of 2,690 citations were retrieved using the search strategy. Of these, 35 full-text studies met the eligibility criteria and were included in

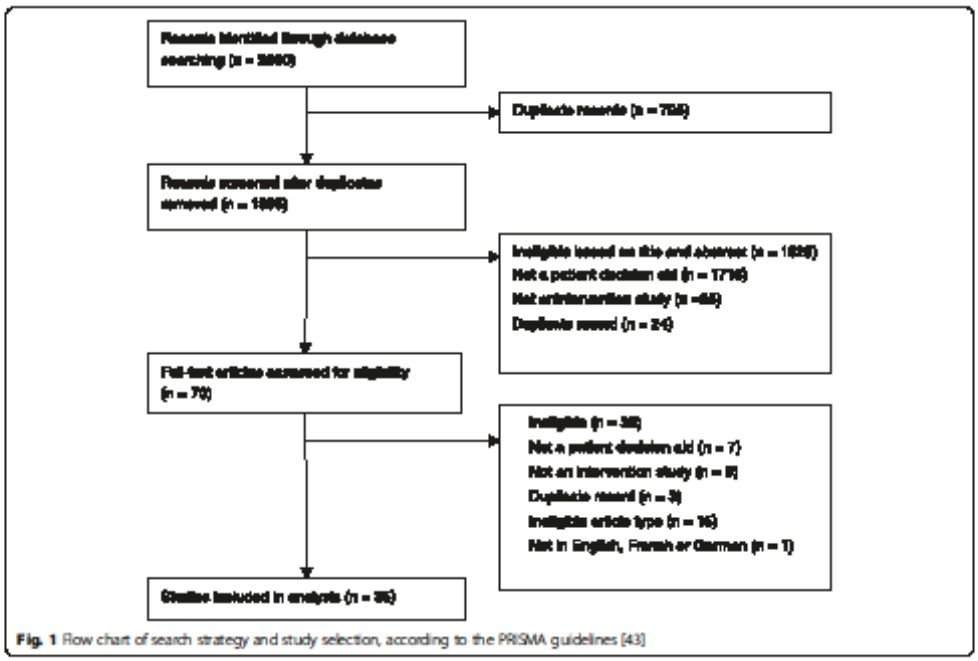

Fig. 1 Flow chart of search strategy and study selection, according to the PRISMA guidelines [43]

this review. Double coding of 20 % of all full-text articles resulted in 100 % agreement between the reviewers (Kappa = 1.000). A list of included citations is provided in Additional file 2.

Studies reporting on the effectiveness of decision aids

Of the included studies, 33 tested the effectiveness of decision aids in improving cancer patient outcomes. The number of studies examining the effectiveness of decision aids increased significantly across the three time points ($p < 0.0001$), from 8 studies in 2000 (22.8 %), to 10 studies in 2007 (28.5 %) and 15 studies in 2014 (42.8 %). As shown in Fig. 2, the majority of these papers focused on decision aids for cancer screening and prevention ($n = 26$), compared to those focused on treatment ($n = 7$). Across the three time points assessed, the number of studies focusing on cancer screening and prevention decision aids increased significantly ($p < 0.0001$), while the number focused on cancer treatment did not ($p = 1.00$, Fig. 2). Decision aids were found for breast, prostate, colon, lung, pancreatic, skin, ovarian and cervical cancer. The majority of studies focused on prostate ($n = 10$), breast ($n = 9$) and colon cancer ($n = 7$). Two studies focused on more than one cancer type, including breast, ovarian, cervical and colon cancer (Fig. 3).

Studies reporting on strategies to implement decision aids

Only the two remaining studies, published in 2000 and 2007, assessed the effectiveness of strategies to increase the implementation of decision aids into clinical practice. Due to the low number of these studies, a statistical comparison was not performed. The number of studies testing the effectiveness of decision aids vs the number of studies examining implementation strategies are reported in Fig. 4.

Discussion

Research priorities by relative volume of intervention studies

We examined the progression of research volume which tested the effectiveness of decision aids by cancer site and decision type being targeted, across three time points. Also, we compared these numbers with the volume of research testing the effectiveness of strategies to increase the adoption of decision aids by healthcare providers. Our data suggests that an increase in research effort has been directed towards assessing the effectiveness of decision aids for cancer screening and prevention. The majority of studies focused on prostate, breast and colon cancer. Only two studies examined the effectiveness of strategies to

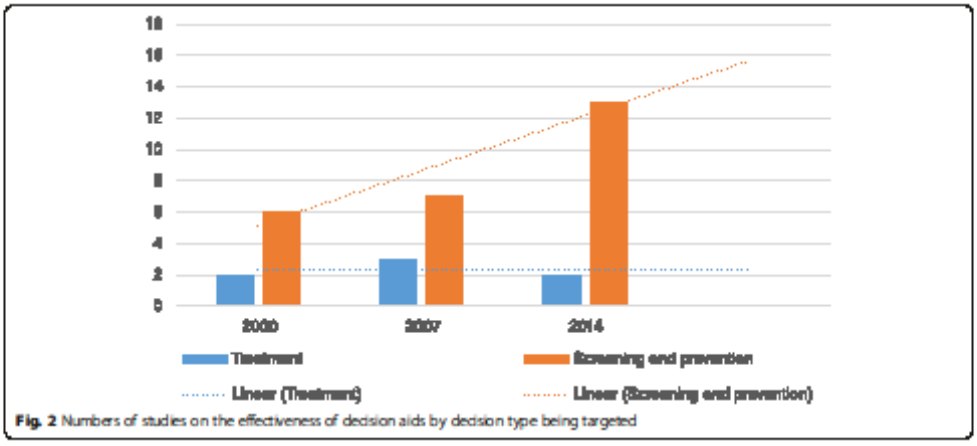

Fig. 2 Numbers of studies on the effectiveness of decision aids by decision type being targeted

increase provider adoption of decision aids, despite evidence illustrating the benefit of decision aids' for some patient outcomes [20, 25].

Lack of research on the effectiveness of decision aids for cancer treatment

Although decision aids are available for a number of healthcare decisions, research has been increasingly focusing on screening and prevention decisions as opposed to treatment decisions. One reason for the larger volume of screening and prevention decision aids may be that these interventions are aimed at healthy people, rather than a vulnerable patient group. This can facilitate the research process, for example by easier access to large sample sizes and by the facilitation of the ethical review process. Developing and testing decision aids on treatment options needs considerable clinical input, which relies on strong collaborations between researchers and clinicians [48, 49]. For example, clinicians may vary in their preferences for different treatment options based on their clinical experience [50]. If clinicians disagree in the content of a decision aid, the development of such decision aids might be hindered [32, 51]. However, treatment decisions can be very distressing for patients [13]. Also, as the number of treatment options available to patients has been increasing, particularly in relation to "preference sensitive" treatments, opportunities arise to develop and test decision aids for cancer treatment decisions.

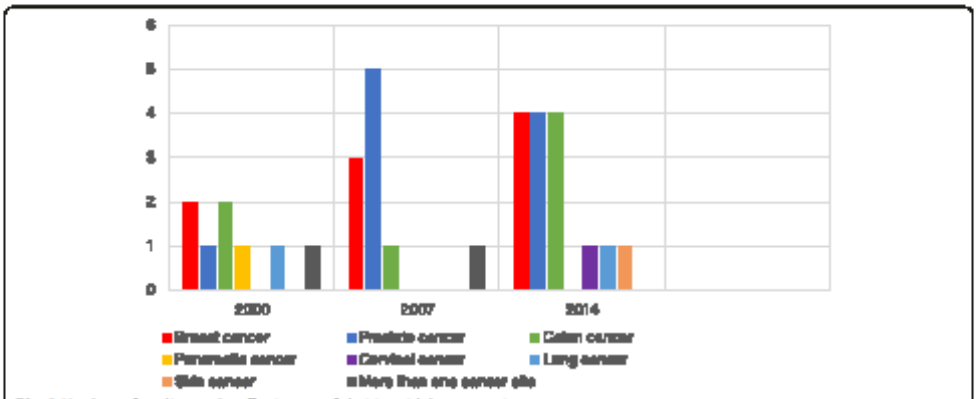

Fig. 3 Numbers of studies on the effectiveness of decision aids by cancer site

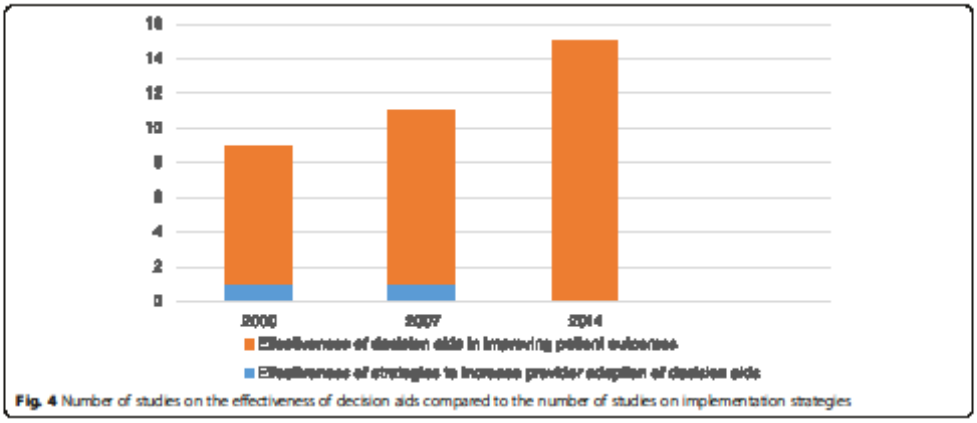

Fig. 4 Number of studies on the effectiveness of decision aids compared to the number of studies on implementation strategies

Narrow research focus on decision aids for only a few cancer types

Over the last 15 years, increasing research effort has been directed towards examining the effectiveness of decision aids on prostate, breast and colon cancer. This may seem understandable as according to the latest GLOBOCAN statistics these are amongst the most prevalent cancer types worldwide [52]. Screening recommendations for breast, colon and prostate cancer have been established for decades which could further explain the increased research volume focused on these sites [53]. However, research with other cancer types where decision aids could be beneficial seems to be sparse. For instance, there are guideline recommendations for cervical cancer screening, prevention and treatment, which could motivate decision aid research in this area [54, 55]. But a lack of such research across these three time periods has been shown. Also, lung cancer has high incidence and burden, but little research exists about decision aids for lung cancer screening, prevention and treatment [20, 25]. This might be because there are no nationally standardised screening programmes for lung cancer in many countries as there are for other types of cancer, such as breast or colon [53, 56, 57]. However, many lung cancer patients are faced with difficult healthcare decisions, such as a choice between different treatment modalities. Some of these require the patient to decide between a slightly higher chance of longer survival or fewer treatment related side-effects [58, 59]. Thus there is a need for effective decision aids for cancer populations other than prostate, breast or colon.

Lack of research effort towards testing effective implementation strategies

This review has shown that the research volume on decision aids for cancer screening and prevention has increased over the three time points assessed. Given that decision aids are not commonly used in practice [30], it may be expected that we should have started to see the testing of strategies to implement decision aids that have been shown to be effective. However, we found only two studies on the effectiveness of implementation strategies across the three time periods assessed. The little attempt to translate evidence into meaningful benefits for patients may result from various factors, such as methodological difficulties of carrying out well-controlled implementation trials; perception that optimal care is already being delivered; difficulties of addressing further barriers to the adoption of decision aids in practice; and potential further questions to be answered by ongoing research on the effectiveness of decision aids. These factors are discussed below.

Methodological difficulties of carrying out implementation trials

Implementation of decision aids may involve changes in processes of care. This necessitates system-orientated change, which is not always amenable to the "gold-standard" RCT intervention design. Decision aids are complex interventions in a complex field of social interactions. They address various influences on behaviour. Attention should be paid to this complexity and to the context of implementation [24, 60]. It has been argued that RCTs are not suitable for taking into account all relevant contextual factors in which complex interventions are delivered and received [61]. The randomization and blinding required by RCTs cannot always accommodate the complexity and flexibility needed to test these interventions on a system level [62, 63]. According to the Medical Research Council's guidance for evaluating complex interventions, a range of alternate study designs

should be considered, including Stepped Wedge or Multiple Baseline Designs [64, 65]. Future attempts to test implementation strategies should consider these designs. As planning and conducting such complex trials takes an extended period of time it may be that much of the implementation research is still being carried out [66]. It is possible that we see a surge in such studies in the near future.

Perception that optimal care is already being delivered

There may be an assumption that evidence-based strategies are already being used in practice. For example, O'Brien and colleagues reported that some clinicians have high confidence in their own communication skills and believe that patients understand the information they have conveyed [31]. Clinicians in this study have indicated that decision aids' effects on the decision making process are not compelling enough to change their practice. Consequently, some have argued that there is no need to conduct research to implement decision aids into routine care [31]. However, given the increasing range and availability of prevention, screening and treatment options, healthcare decisions have become increasingly difficult. Especially in clinical situations where there is low or conflicting evidence on the medical effectiveness of the available healthcare options it is crucial to involve patients' preferences in the decision making process.

Further barriers to the adoption of decision aids in practice

Findings of previous research indicate that clinicians identify numerous barriers that affect their ability to implement patient decision aids [31–33, 67]. Such barriers include: concerns about how comprehensive and current the content of decision aids is, lack of awareness of existing decision aids, time constraints, and concerns about how to integrate decision aids into clinicians' workflow [32, 68]. Designing implementation strategies to overcome these barriers is challenging. There is little evidence that passive dissemination through strategies such as guidelines is effective [69]. Implementation strategies need to actively target healthcare providers, patients or both [66]. They should be tailored to the specific setting avoiding "one-fits-all-solutions". Instead of controlling for confounding variables, implementation attempts need to investigate these variables in order to better understand the long-term implementation of decision aids [70]. Practice-based research within the real world setting of daily cancer care needs to be conducted [71]. Researchers should focus on illuminating processes, rather than "package" and use the strengths of collaborative research across various contexts in order to systematically study the impact of the individual settings [70].

Open questions regarding the effectiveness of decision aids

Although there is a large body of evidence demonstrating that decision aids are effective in improving a range of patient outcomes, open questions remain in regards to the stated effectiveness. For example, further studies are required which explore the "active ingredients" of decision aids and clinically relevant outcomes apart from the ones already assessed [24]. Greater understanding of the mechanisms of action of decision aids and further evidence for their clinical impact may increase their acceptability in clinical practice and motivate more attempts to design and evaluate implementation strategies. Further open questions remain in regards to the "orientation" and "insight" phase of implementing decision aids into practice. Consequently, we need further in-depth investigation of clinicians' understanding and opinion on decision aids before we ask them to implement these tools [23, 51, 72, 73]. However, as the body of work on the effectiveness of decision aids has been growing, we hope that the number of intervention studies which test implementation strategies will develop accordingly.

Limitations

The results of this study should be considered in light of several limitations. First, only three years of publication were included in this study. It is possible that the trends in research output differ in the years which were not assessed. In addition, due to the low numbers of eligible studies, it was not possible to compare statistically the trends in effectiveness and implementation trials over time. This limits the strength of our conclusions about the relative increase in effectiveness compared with implementation trials. However, the inclusion of these three time points provides an indication of research effort over the past 15 years. Grey literature such as policy documents and dissertations were not included as they do not meet the standards associated with peer-reviewed publications. It is possible that the exclusion of such research has biased the results due to the file drawer problem, whereby studies showing null (or negative) findings tend not to be published. The exclusion of conference abstracts may have led to underestimating the number of implementation studies currently underway.

Conclusions

Although multiple Cochrane reviews provide evidence that decision aids are effective in improving a range of patient outcomes, our review suggests that research testing the effectiveness of decision aids has increased over the three time points assessed. Research effort in this area has focused predominantly on screening and prevention decisions in only a few cancer sites. This neglects a number of cancer populations, as well as other

areas of cancer care such as treatment decisions. Further, once the effectiveness of certain decision aids is established, strategies to increase their adoption by healthcare providers need to be designed and tested. Such research will help to ensure that the benefits of decision aids reach the intended patient populations.

Additional files

Additional file 1: Search strategies for each database. (DOCX 13 kb)
Additional file 2: List of citations for included studies. (DOCX 16 kb)

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
All authors designed the review. AH executed the search and undertook data extraction. BM designed the search strategy and carried out the double-coding. AH and AEH drafted the manuscript. All authors read and approved the final manuscript.

Acknowledgements
Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship (UNIPRS), a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship. Nicholas Zdenkowski is supported by a Sydney Catalyst scholarship. We also thank Angela Smith for her support to the literature search and Alessandra Bisquera for her advice on the statistical analysis. Furthermore, we would like to acknowledge funding support from a Strategic Research Partnership Grant (CSR 11-02) from Cancer Council NSW to the Newcastle Cancer Control Collaborative (New-3C), and Infrastructure funding from the University of Newcastle and Hunter Medical Research Institute.

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Received: 8 December 2015 Accepted: 9 March 2016
Published online: 15 March 2016

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Appendix 6.2: Statements of contribution from co-authors

UON Graduate Research

Co-authorship declaration

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

I attest that the Research Higher Degree Candidate **Anne Herrmann** contributed significantly to the manuscript conceptualisation, study design, data collection, data analysis and manuscript preparation for the paper/publication entitled:

Wilfully out of sight? A literature review on the effectiveness of cancer-related decision aids and implementation strategies

FULL NAME OF CO-AUTHOR	SIGNATURE OF CO-AUTHOR	DATE
Elise Mansfield		15/11/2017
Alix Hall		15/11/2017
Rob Sanson-Fisher		15/11/2017
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Date: 15/11/2017

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Appendix 7: ADDITIONAL RELEVANT PUBLICATIONS

Appendix 7.1: Published conference abstracts

- Zdenkowski N, **Herrmann A**, Hall A, Boyle FM, Butow P: Abstract P3-11-02: Women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer." Cancer Research. 2017, 77, Supplement 4: P3-11-02-P13-11-02

  [poster citation: Herrmann A, Zdenkowski N, Hall A, Boyle FM, Butow P: Women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer. 39th Annual San Antonio Breast Cancer Symposium, 6/12 – 10/12 2016, iPoster URL: http://sabcs16.posterview.com/nosl/i/P3-11-02]

2016 San Antonio Breast Cancer Symposium

Publication Number: P3-11-02

Title: Women's experiences with a decision aid for neoadjuvant systemic therapy for operable breast cancer

Zdenkowski N, Herrmann A, Hall A, Boyle FM M and Butow P. Calvary Mater Newcastle, Newcastle, NSW, Australia; University of Newcastle, Newcastle, NSW, Australia and University of Sydney, Sydney, NSW, Australia.

Body: Background: Neoadjuvant systemic therapy (NAST) is a treatment option for selected patients with highly proliferative and/or large operable breast cancer. Whilst survival outcomes are equivalent between up-front surgery and NAST, the decision about treatment sequence can be difficult due to complexity and perceived urgency of the decision. Patients may value the outcomes of these options, such as down staging and prognostication, differently. Involving patients in decisions about their healthcare reduces anxiety, increases quality of life and satisfaction with care. Decision aids can improve patient involvement in health care decisions, but one is not available for the decision about NAST.
Aims/Methods: We conducted a prospective, single-arm pre-post study to evaluate a custom-designed decision aid developed for women who have been offered NAST. Eligible patients were: female; aged ≥18 years; diagnosed with an operable invasive breast cancer; considered for NAST with curative intent. Here, we report on the grounded theory qualitative analysis of a convenience sample of 16 semi-structured phone interviews to explore patient experience with this decision aid.
Results: Participants' median age was 52 (IQR=41-63), median time since breast cancer diagnosis was 5 months (IQR=2-8). Most were married or living with a partner (81.3%) and had a University level degree (68.8%). Patients perceived the decision aid to be useful for becoming more informed and involved in deciding on NAST. Specifically, the decision aid enhanced patients' understanding of their type of breast cancer and the treatment options available to them by summarising and extending the information they received during the consultation with their doctor. Some women perceived the included graphs and statistics to be particularly helpful to understand potential risks and benefits of their treatment options. All patients described the provided information as reliable, relevant and tailored to their needs. They found the decision aid easy to understand and balanced (not in favour of NAST or surgery). The amount of the information provided was seen to be just right. Most women received the decision aid after the initial consultation with their surgeon and perceived this as the right delivery timing. Reading and rereading the decision aid at home in between two consultations allowed women to easily integrate the decision aid into their care. They appreciated the opportunity to reconsider their options after consulting their doctor. A number of women reported that their family members used the decision aid as well and thus became more informed and involved in the decision making process. Some women took the decision aid to the next consultation with their doctor to discuss their preferences and concerns further. All patients followed their doctors' treatment recommendation. The decision aid seemed to confirm but not change women's decisions on NAST.
Discussion: These initial results suggest that this decision aid is a useful tool to assist breast cancer patients' involvement in the decision about NAST. A quantitative analysis of the decision aid's acceptability, feasibility and efficacy will be reported subsequently.

- **Herrmann A**, Hall A, Zdenkowski N: Exploring how women make decisions on neoadjuvant systemic therapy (NAST) for operable breast cancer. The Breast. 2016, 29, Supplement 1, S27. doi: 10.1016/S0960-9776(16)30223-5

This could lead to an optimal decision making process, through a more active and aware patient participation and an increased physician's ability to adapt therapeutic choices to the real patient's needs.
Methods: We have organized a series of training sessions for seven patients, coordinated by a writer and the psychotherapist dedicated to psycho-oncologic support, with the supervision of the centre director. For six months there have been periodic group meetings aimed at sharing and processing individual experiences; at the same time, through a creative writing course, professionals and patients have been encouraged to tell their own experiences in a narrative form.
Result: The final product is a little book that will be distributed in all the points of the Tuscany breast centers network, under the patronage of Istituto Toscano Tumori.
Discussion: This project could improve the quality standards of the Regional Health Service expanding and comparing the spectrum of experience of the various players, declined in the different stages of treatment; it could moreover provide support to patients, family members and professionals, and finally disclose a greater awareness of the care pathway to a wider audience and in general the experience of this very common disease.

PO86
Young breast cancer patients: contraceptive methods used at diagnosis and frequency of unintended pregnancy during the first year after diagnosis

U. Güth[1], D.J. Huang[3], J. Bitzer[3], R. Moffat[2,3]. [1]Brustzentrum Zürich, DTO, Zürich, [2]Fertisuisse, Centre for Reproductive Medicine, Olten, [3]Dept. of Gynecology and Obstetrics, University Hospital Basel, Basel, Switzerland

Objectives: Today, oncologists are increasingly offering counseling for fertility preservation to their young breast cancer (BC) patients. However, this newly developed attitude might eclipse the fact that pregnancy must be effectively prevented after diagnosis and during adjuvant therapy. Pregnancy during cancer treatment is strongly discouraged, as radiotherapy and chemotherapy administered during the first trimester of pregnancy result in increased congenital malformations. Young women experience high levels of anxiety and distress during cancer diagnosis and therapy, and it can be devastating to become pregnant in this vulnerable state.
In this study, we analyzed an unselected, consecutive cohort of young BC patients with regard to the contraceptive methods used at the time of diagnosis. Based on this data, we identified which young BC patients were at risk of unintended pregnancy and report the actual frequency of unintended pregnancy during the first year after BC diagnosis.
Methods: According to data from the Basel Breast Cancer Database, we analyzed all patients who were ≤40 years of age at initial BC diagnosis (n = 100, mean age at diagnosis 35.9 years). We had information for all patients on the contraceptive method used at the time of diagnosis. Contraceptive methods were classified according to tiers defined by the US Centers for Disease Control and Prevention and the World Health Organization.
Results: 42% of the cohort (mean age 36.5 years) were identified as not at risk of unintended pregnancy. However, 58% of the cohort (mean age 35.6 years) had to stop hormonal contraception at time of BC diagnosis or were using no or an ineffective contraceptive method (tier III/IV) and thus were at risk of unintended pregnancy. The rate of unintended pregnancy was 3.5% in this group (two patients).
Conclusions: The majority of young BC patients are in their late reproductive years. At least from the perspective of reproductive medicine, the median age of 36–37 years is comparatively high. Contraceptive methods utilized by this population are very heterogeneous and tend to be insufficient, resulting in a substantially increased risk for unintended pregnancy. To make matters worse, hormonal contraception is usually contraindicated and therefore discontinued in women afflicted with BC.
Oncologists should be aware that the use of reliable contraception should be discussed before starting, and also during adjuvant therapy. They should consider actively referring young BC patients to a gynecologist to ensure proper contraceptive counseling.

PO87
Exploring how women make decisions on neoadjuvant systemic therapy (NAST) for operable breast cancer

A. Herrmann[2], A. Hall[2], N. Zdenkowski[1,2]. [1]Calvary Mater Newcastle, Medical Oncology, [2]University of Newcastle, School of Medicine and Public Health, Newcastle, Australia

Background: NAST may be a suitable treatment option for selected patients with highly proliferative and/or large operable breast cancer. Younger patients may have greater potential benefit from down-staging, time to plan genetic testing and surgical approach, and are likely to value the associated improvement in prognostic accuracy. Whilst survival outcomes are equivalent between up-front surgery and NAST, the decision about treatment sequence can be difficult due to its complexity and perceived urgency. Research is lacking on how patients make decisions on NAST and how a decision aid, developed for NAST, can be integrated.
Aims/methods: A prospective, single-arm pre-post study was conducted to evaluate a decision aid developed for women who have been offered NAST. Eligible patients were: female; aged ≥18 years; diagnosed with an operable invasive breast cancer; considered for NAST with curative intent. Here, we report on the grounded theory qualitative analysis of a convenience sample of 16 women, who completed in-depth semi-structured phone interviews exploring how they decided on NAST.
Results: Participants' median time since diagnosis was 5 months (IQR: 4–7), 44% were aged under 50. Most were married or living with a partner (81.25%) and had a University level degree (68.75%). Patients' main source of information were their clinicians. Younger women tended to seek additional information, for instance by asking for their support persons' advice or reviewing information they received from their healthcare providers. Patients preferred face-to-face or written information over online information. All women reported making the decision during or shortly after the initial consultation with their doctor. They intuitively followed their doctor's treatment recommendation. Most women did not seem to contemplate the plethora of reasons for or against NAST, but based their decision on one or two key factors which they perceived as most important to them. However, women appreciated the opportunity to reconsider their options at home and come back to a second appointment. Some women took the decision aid to the next consultation with their doctor to discuss their concerns further. The decision aid seemed to confirm their decisions on NAST. Women who felt that they made an informed decision seemed to be more satisfied and certain about their decision.
Discussion: When designing and implementing decision support for patients it is important to consider the apparent intuitive nature of patients' decision making process. A quantitative analysis of patients' experiences and preferences for making breast cancer treatment decisions is currently underway.

PO88
Quality of life in long-term breast cancer survivors – evidence from South India

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Background: Women with breast cancer are the largest group of female survivors of cancer. There is limited information about the long-term quality of life (QOL) in disease-free breast cancer survivors.

- **Herrmann A**, Mansfield E, Hall A, Sanson-Fisher R, Zdenkowski N: Examining where research efforts on cancer-related decision aids have been made. Asia-Pacific Journal of Clinical Oncology. 2016, 12, 23. doi: 10.1111/ajco.12618

standardization of ADC values across different magnets. Standardization of ADC values improve the prediction of cancer aggressiveness.

Translational research aspect: This study falls into the T1 translation pipeline.

P28

DESIGNING *INDIGENOUS COUNSELING AND NICOTINE (ICAN) QUIT IN PREGNANCY* PROGRAM WITH THE BEHAVIOR CHANGE WHEEL: IMPROVING HEALTH PROVIDER SMOKING CESSATION CARE FOR INDIGENOUS PREGNANT WOMEN

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[2]*Behaviour Change Centre, University College London, London, United Kingdom*

Background: In Australia, smoking rates among pregnant Indigenous women are 47%, and slow to decline. Previous strategies in this population suffered from design challenges.

Aims: To develop an intervention to meet the needs of the target population, and improve culturally-competent smoking cessation care (SCC) for pregnant Indigenous smokers, by training providers at Aboriginal Medical Services. The behavior change wheel (BCW) – a parsimonious model governing capability, opportunity and motivation for behavioral interventions – provided a theoretical framework for the Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy development.

Methods: We identified evidence-practice gaps through: two systematic literature reviews on provider attitudes and interventions for SCC in pregnancy; a national survey of clinicians; and gathering stories of smoking and quitting from Aboriginal mothers. These studies facilitated the development of this targeted intervention.

Results: Areas identified for performance improvement included: capability (psychological skills), motivation (optimism), and opportunity (resources/time). Using the BCW, we targeted: capability by training clinicians in pharmacotherapy to assist women to quit; opportunity by structuring the consultation using a flipchart and prompts, and using a whole-of-service approach; and optimism for success by presenting recent evidence, and positive testimonials from patients and clinicians. Webinar brings the training to the services to accommodate time and location constraints, and diversify responsibilities to providers other than clinicians. A Stakeholder and Consumer Aboriginal Advisory Panel was consulted on developing intervention materials.

Conclusions: The formative development of ICAN QUIT in Pregnancy demonstrates how it is uniquely designed to improve the implementation of SCC for expectant mothers attending Aboriginal Medical Services. Training was designed to improve gaps identified from several robust studies, and includes improved counseling skills and pharmacotherapy management. The intervention has implications for reducing the risk of cancer from tobacco exposures to mother and child.

Translational research aspect: This T2/3 research translates evidence-based approaches through a theoretical framework, to the context of Australian Indigenous maternal smoking cessation.

P29

DECISION-MAKING PREFERENCES AND SATISFACTION OF STAGE ONE TESTICULAR CANCER PATIENTS

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[5]*Centre for Oncology Education and Research Translation (CONCERT), Ingham Institute for Applied Medical Research and South Western Sydney Clinical School, UNSW, Liverpool, NSW, Australia*

Background: Involving patients in the treatment decision making process is an important aspect of patient-centered care. However, patient's preferences for involvement are not always met.

Aims: This was a retrospective survey study, which assessed a range of factors concerning the treatment decision making process of testicular cancer patients. This abstract reports the following outcomes:

1. The percentage of patients who achieved their preferred level of involvement in treatment decision making.
2. Patient's level of satisfaction with their treatment decision.

Methods: A retrospective, self-report survey of stage 1 testicular cancer patients, who had attended a NSW-based treatment center in the preceding 12 months. Eligible patients were identified from clinical records and sent a questionnaire pack. Participants completed the survey via pen-and-paper or online. Involvement in treatment decision-making and decisional satisfaction were assessed using an adapted version of the control preference scale (CPS) and the satisfaction with decision scale (SWD), respectively.

Results: Fourteen of 51 eligible patients (27%) completed the survey. Half (50%) of patients indicated an exact match on the CPS scale, between their preferred and perceived role in treatment decision making. 29% were less involved, and 21% were more involved than they preferred. The median level of satisfaction with their treatment decision was 4.7 (range: 3–5), out of a possible score of 5.

Conclusions: Involvement of testicular cancer patients in treatment decision making could be improved to better align with their preferences. However, patient satisfaction with their treatment decision was high. Because of the small sample size the results of this study should be interpreted with caution.

Translational research impact: This is part of a descriptive study that will inform the development of a decision aid to support testicular cancer patients (T2/T3).

P30

EXAMINING WHERE RESEARCH EFFORTS ON CANCER-RELATED DECISION AIDS HAVE BEEN MADE

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Background: Decision aids are designed to help patients make difficult healthcare decisions. There is substantial evidence to support decision aids' effectiveness in improving patient outcomes. Despite their apparent effectiveness, decision aids are not commonly used in clinical practice.

Aims

I. To examine the number of studies published in 2000, 2007, and 2014, which tested the effectiveness of decision aids in improving cancer patient outcomes, coded by type of cancer and decision type being targeted.
II. To compare these numbers with the number of studies examining, the effectiveness of implementation strategies to increase the adoption of decision aids by healthcare providers.

Methods: We undertook a literature review of intervention studies and searched Medline, Embase, PsychInfo and Cochrane Database of Systematic Reviews. The search was limited to human studies published in English,

- Smits, R, Bryant J, Sanson-Fisher R, Turon H, **Herrmann A**, Richards L: Do hematological cancer patients get the information they need about their cancer and its treatment? Asia-Pacific Journal of Clinical Oncology. 2016, 12, 32. doi: 10.1111/ajco.12618

P52

THE POTENTIAL OF ORGANIZATIONAL CHANGE INTERVENTIONS TO INCREASE THE DELIVERY OF SMOKING CESSATION CARE IN THE ALCOHOL AND OTHER DRUG TREATMENT SETTING: A SYSTEMATIC REVIEW

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Background: Smoking rates of clients in alcohol and other drug (AOD) treatment is high, an estimated 84% yet the assessment of smoking status is variable and provision of smoking cessation care (SCC) is low. Organizational change interventions aim to build the capacity of services by modifying current processes to ensure routine assessment and treatment of tobacco smoking. There is a developing body of research detailing organizational change interventions to increase the provision of SCC. This study aims to consolidate and examine the evidence of organizational change interventions in the AOD setting on: the provision of SCC practices and client smoking cessation.

Aims: This study aims to consolidate and examine the evidence of organizational change interventions in the AOD setting on: the provision of SCC practices and client smoking cessation.

Methods: MEDLINE, PsycINFO, CINAHL, EMBASE and Scopus were searched using keywords and MeSH terms from each database's inception to July 2016. Studies employing an organizational change intervention with the aim of increasing the delivery of SCC in the AOD setting were included. Two authors independently assessed studies for inclusion and extracted data.

Results: Of the 4625 identified studies, seven publications were included describing five unique studies. The study methodology of included studies was generally of poor quality and low level evidence (IV). Only one study reported changes to staff provision of SCC practices though staff self-reported provision was found to be non-significant, clients reported receiving more SCC and this was found to be highly significant ($P < 0.00001$). Client smoking cessation ranged from 7.5% to 41%, however only one study validated client self-reported abstinence.

Conclusions: Organizational change interventions have the potential to increase the provision of SCC and assist client smoking cessation though further research that employs more rigorous study methodology and validated measures are warranted.

Translational research aspect: This is T3 research.

P53

DO HEMATOLOGICAL CANCER PATIENTS GET THE INFORMATION THEY NEED ABOUT THEIR CANCER AND ITS TREATMENT?

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Background: Effective information provision can have a significant impact on psychosocial outcomes for cancer patients. In addition to legal and ethical imperatives for informed consent, appropriate information can influence patients' role and choices in decision-making regarding treatment. Information provision has been found to reduce psychological distress prior to cancer treatment, and improve anxiety, depression and quality of life when self-managing the symptoms and side-effects of cancer.

Aims: This study aimed to explore the experiences of hematological outpatients in obtaining information about their cancer and its treatment.

Methods: A cross-sectional questionnaire of adult hematological cancer outpatients was conducted in three metropolitan hospitals. Research assistants recruited eligible patients in outpatient clinic waiting rooms. Consenting participants completed two pen-and-paper questionnaires: the first examined demographics and disease characteristics and was completed at the time of consent; the second was completed by mail 4 weeks later. Participants indicated whether they received the information they needed about preparation for potentially threatening medical procedures and self-management, experiences regarding doctor-patient communication, and self-efficacy in seeking information and support. Items were derived from clinical practice guidelines where available.

Results: A total of 293 (84%) patients consented to take part in the study, with 171 (58%) completing both questionnaires. Overall, information experiences were largely positive and in accordance with guidelines. Areas identified as requiring improvement included: insufficient information regarding strategies for managing stress and anxiety related to medical procedures (20%); difficulty recalling information provided by their doctor (28%); information overload (26%); and insufficient opportunity to ask questions (23%).

Conclusions: There is room for improvement in the provision of guideline-recommended psychosocial care for hematological cancer patients. Findings emphasize the need for implementation of evidence-based strategies to aid recall of information post-consultation and minimize information overload.

Translational research aspect: This T3 research explored the experiences of patients in receiving guideline-recommended psychosocial care.

P54

RARE IMMUNE SUBSETS AS BIOMARKERS FOR IMMUNOTHERAPY TREATMENT RESPONSE IN METASTATIC MELANOMA PATIENTS

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Background: Until recently, the survival rate for metastatic melanoma was very low. With the advent of new immunotherapies and targeted therapies, some patients now have enduring disease free period. But for a large portion of patients, there is no response to these therapies and for some that do respond, the disease free time is short-lived. The current method of monitoring patients on immunotherapies is RECIST scores modified for immunotherapy. We propose a blood immune biomarker panel to ascertain patient response to immunotherapy in real-time. This would involve blood collected with the patients' usual monitoring bloods samples to investigate subsets of T cells, B cells and monomyeloid series. During tumor progression, circulating monocytes and macrophages are actively recruited into tumours. By monitoring the passage of these immune cells and the patients T cell and B cell response, a definitive visualization of the patients' response is identified.

Aims: To validate a panel of immune cell surface markers reflecting a patient's response to immunotherapy. These will include but not limited to T_{reg}, activated and naive T cells, and tracking chemokines at three time points. To correlate clinical indicators of response with an immune cell surface panel.

Methods: Metastatic melanoma patients about to commence immunotherapy will be asked for permission to enroll in the study. Blood will be collected before treatment commencement, 21 and 42 days after initial drug dosage. A minimum of 30 patients will be enrolled in the study. Fluorescent bound antibodies to immune cell surface markers will be added to the whole blood

Appendix 7.2: Published poster listings

- **Herrmann A**, Sanson-Fisher R, Hall A, Wall L, Zdenkowski N, Waller A: "A discrete choice experiment to assess cancer patients' preferences for when and how to make treatment decisions", proceedings of the 13th Behavioural Research in Cancer Control Conference, Melbourne, Australia

Abstract Number: 18.01

A discrete choice experiment to assess cancer patients' preferences for when and how to make treatment decisions

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Background: Many cancer patients have to make complex treatment decisions but have difficulty becoming fully informed about their treatment options. Questions remain regarding when and how to provide patients with information to help them make treatment decisions.

Aims: To examine cancer patients' preferences for i) receiving one 40 minute consultation or two 20 minute consultations when deciding on their cancer treatment; ii) receiving written only information regarding their treatment options or written and online information.

Methods: This is an ongoing cross-sectional survey of cancer patients, using a discrete choice experiment. Patients are eligible if they are: aged 18 years or older; have had a confirmed diagnosis of any type of cancer; are English speaking; and are presenting for an outpatient medical oncology consultation in one of two treatment centres in New South Wales. Patients are presented with different scenarios and are asked to choose their most preferred and least preferred option. The scenarios indicate that there is no difference between the presented consultation options in relation to patients' length of life and when treatment will be initiated. The data will be reported using descriptive statistics and link function analysis.

Results: So far, 138 out of a planned 150 surveys have been completed. The results of the data analysis will be presented at the conference.

Conclusions: This study examines whether cancer patients would prefer to make treatment decisions over one long consultation or two shorter ones, and whether they would prefer written only or written and online information when deciding on their treatment. This will help understand what type of support may best assist cancer patients with making treatment decisions.

Abstract Number: 18.02

Enhancing patient-centred communication during cancer treatment

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Background: Experience of a cancer diagnosis involves radical changes in a person's life. During the course of their cancer journey supporting the cancer patient and cancer affected families has become crucial in the minds of health professionals and supportive organizations. The concept of PCC has evolved in the health care system to allow service users a 'voice' in their care and to enhance quality care for patients and their loved ones. Recent studies have shown that cancer patients, carers and health professionals report dissatisfaction and difficulty in their communication. The stigma of Cancer still prevails in Australia and this compounds difficulties with clear communication. During the trajectory of the cancer journey the most traumatizing and stressful stage is often when people are receiving cancer treatment. This highlights the importance of providing supportive care and ensuring optimal communication so that patients are able to make informed treatment choices that enhance their quality-of-life.

Aim: To identify the forms and characteristics of effective communication recognized by cancer patient, health professional and carer during the course of the cancer treatment to enhance patient-centred communication in cancer care.

Methods: Qualitative semi-structured interviews will be conducted with 15 cancer patients, 15 carers and 15 health professionals recruited with the support from Cancer Council ACT and Canberra Hospital. Health professionals in NSW will also be invited to participate. The interviews will investigate the communication experiences during cancer treatment stage and what they consider as 'effective communication'.

Results: Results will be analyzed by using reflexivity and thematic analysis. Results will be available in October 2017.

Conclusions: Available in January 2018.

Implications: This research will develop an appropriate cancer communication pathway to guide continuous support improvement, engagement, research, data infrastructure for cancer care and health care behaviour. The research will also provide successful delivery of information on self-care for cancer patients, carers and health professionals.

Appendix 7.3: Additional journal articles

- **Herrmann A**, Horn R: Overcoming some of the barriers to implementing advance directives and decision aids into clinical practice. Do we have to dig deeper? [submitted *to BMC Health Services Research, in revision*]

Title: Overcoming some of the barriers to implementing advance directives and decision aids into clinical practice. Do we have to dig deeper?

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Abstract

Background: An increasing number of healthcare decisions have become preference-sensitive. This means that patients' goals, concerns and wishes need to be incorporated with the best available evidence regarding different healthcare options to provide optimal patient-centred care. Making preference-sensitive healthcare decisions can be challenging for doctors and patients. Numerous tools have been developed to facilitate decision-making on the healthcare options available to patients, such as decision aids and advance directives. Decision support tools have been shown to be effective in improving patient outcomes, such as patients' knowledge of the healthcare options available to them and their satisfaction with the consultation. However, decision support tools are not commonly used in clinical practice. Numerous barriers have been identified which hinder the implementation of such tools. Most studies have focused on only one decision support tool when investigating aspects which prevent their use in clinical practice.

Discussion: Given that both advance directives and decision aids aim to facilitate healthcare decision-making for patients, we reviewed the literature in both areas to find common implementation barriers. In this paper, we will make suggestions for how to overcome some of the main barriers we have found. We will discuss the following aspects: lack of specific communication trainings, lack of awareness, structural barriers and lack of applicability of decision support tools. Future research needs to go beyond focusing on specific tools. It should further investigate the underlying communication mechanisms which hinder their implementation.

Summary: Both advance directives and decision aids can only be implemented if they are embedded in an empathic, balanced doctor-patient-communication that ensures patients' understanding of the options available to them, clarifies patient preferences and enables patients to be involved in decisions regarding their healthcare. This will help patients make

rational, considerate rather than rushed, emotive decisions and assist doctors in providing the care that mirrors patients' wishes.

Keywords

Decision-making, decision support, doctor-patient-communication, advance directives, decision aids, implementation

Background

Medical decision making is challenging

Medical progress has resulted in a growing number of healthcare options available to patients [1, 2]. Many of these decisions are "preference-sensitive" which means that the options available to patients show similar medical effectiveness but involve impacts or side effects which might be valued differently by different patients. The "best choice" cannot be pre-defined. It depends on patients' preferences [3]. To make the "right" decision for a particular patient, doctor and patient have to weigh-up the consequences of each healthcare option, including its benefits, risks, and costs. They have to assess the probability of each consequence occurring, find the best alternative, and then make and implement the decision [4]. As such, medical decision-making involves very complex communication processes and can be challenging for both patients and doctors [5]. Various tools have been developed to help patients and doctors make healthcare decisions, including patient decision aids[a] and advance directives [6, 7].

Decision aids and advance directives are prominent decision support tools

Both decision aids and advance directives are designed to facilitate medical decision-making and have been attracting increasing attention by researchers and policy makers worldwide [8]. They aim to guarantee the respect of patients' preferences, values and beliefs in decisions regarding their care, and to support doctor-patient-communication about difficult topics, such as potentially negative treatment outcomes or end-of-life decisions [9].

Decision aids provide specific, evidence-based information on the available healthcare options and aim to assist patients with clarifying and communicating the value they associate with each option [10, 11]. They are designed to engage patients in the decision-making process and to guide them towards (making) deliberated decisions that align with their preferences [12]. Decision aids explicitly state the decision to be made and explain in detail the risks and benefits

of the healthcare options available to patients. They help patients weigh-up the risks and benefits of their options and clarify their preferences [13]. Decision aids supplement the consultation, rather than replace it. They can be provided before, during or after the consultation [14], and have been delivered in various formats, including face-to-face information, written booklets or web-based tools [15].

Both decision aids and advance directives are based on the ideal of patient autonomy which embraces patient rights to refuse treatment [16]. Advance directives aim to extend patient autonomy by anticipating treatment withdrawal for situations where the patient has reached decisional incapacity [17-20]. Although most commonly used in end-of-life care, advance directives are used in other healthcare settings, such as mental health or dementia [21-24]. Also, both advance directives and decision aids are particularly prominent in cancer care. This might be due to the increasing incidence and prevalence of this disease type worldwide, the various cancer prevention, screening and treatment options available to many cancer patients and the slow progress of many cancers which, in theory, leads to an increased time patients spend with their doctors [25-27].

Decision support tools can improve patient outcomes

Decision support tools designed to guarantee respect for patients' preferences in medical decision-making have been shown to improve a number of patient outcomes, such as improved doctor-patient-communication, increases in patients' satisfaction with the consultation, their recall, their knowledge and understanding of the healthcare options available to them and reduced decisional conflict related to feeling uninformed and unclear about their personal values [6, 23, 28, 29]. It has also been suggested that decision support tools improve family relationships through the reduction of conflict around healthcare provision [30]. They might further reduce healthcare service use and costs associated to it [15, 31-33].

Decision aids and advance directives are not commonly used in clinical practice

Although decision support tools have been found to be effective in improving patient outcomes and some are legally binding in several Western European countries [34, 35], they are not commonly used in clinical practice [36-38]. When studying the implementation of decision support tools, they have mostly been considered separately. Given that both advance directives and decision aids aim to facilitate healthcare decision-making for patients and support doctor-patient-communication about difficult and complex topics, we reviewed the literature in both areas to find common barriers which might hinder the implementation of these tools. In this paper, we will make suggestions for how to overcome some of the main barriers we have found. We will discuss the following aspects: lack of specific communication trainings, lack of awareness, structural barriers and lack of applicability.

Discussion

Lack of specific communication training

Understanding the pros and cons of the treatment options available to patients and making an informed decision can be very challenging for patients. Many patients perceive a lack of medical understanding and do not feel capable of deciding on their care [39]. This is fuelled by the anxiety and distress many patients have to cope with when being confronted with their diagnosis and prognoses [40, 41]. Even if doctors explain the risks and benefits of patients' healthcare options and ask patients to make a decision, many patients feel overwhelmed by their emotions and the information provided to them. Thus, many do not want to make a decision regarding their care [42, 43].

Enabling patients to make decisions regarding their own care is a difficult task for doctors. Too often, patients receive too much, too little or not sufficiently tailored information which makes it hard for them to make decisions regarding their care [44, 45]. Simply providing decision support tools might not be enough to involve patients in medical decision-making. Doctors

need to be better trained on how to make decisions with their patients and how to discuss complex and often uncomfortable topics with their patients. Communication trainings have to go beyond teaching doctors how to break bad news [46, 47]. They should sensitize doctors regarding the mechanisms, challenges and benefits of patient-centred decision-making.

Rather than focusing on the employment of technical skills, communication training should include teaching doctors how to interact and engage with their patients in the decision-making process and how to show empathy and compassion with their patients [48, 49]. This might enable doctors to provide "true" support for patients to express and reflect on their preferences regarding their healthcare options. One step in this direction might be to ask patients "What matters to you?", rather than "What is the matter?". This could help elicit patients' preferences, goals and concerns [50, 51]. Doctors also need to ask patients about the amount and nature of information they would like to receive and how involved they would like to be in the decision-making process, in order to tailor care according to their needs and preferences [52, 53] Doctors would then try to ensure patients' understanding of the risks and benefits associated with their decisions, for example by using decision support tools, such as decision aids and advance directives. This would enable patients to actually become actively involved in the decision-making rather than just agree with the medical opinion. Yet, before effectively using decision support tools, awareness of their existence needs to be raised.

Lack of awareness

Many doctors have reported not be aware of the effectiveness and appropriate use of decision support tools, such as advance directives or decision aids [54-57]. The necessity and benefits of patient involvement in medical decision-making need to gain more public attention, for instance through media campaigns or further funding support for research in this area. The right of being involved in decisions regarding one's care has already been incorporated in policies and laws in a number of countries. For example, the German *Patientenrechtegesetz* of 2013

explicitly emphasises the right to be involved in decisions regarding one's own care [58]. In Australia, this right has been included in the Australian Charter of Healthcare rights which was endorsed by the Australian Health Ministers in 2008 [59]. More efforts are needed to raise awareness of patient rights to actively participate in medical decision-making, and the availability of validated tools designed to facilitate this process.

Information on such tools should be more explicitly integrated in clinical practice guidelines. For example, although the British General Medical Council Guidelines encourage healthcare providers to support the decision making process by "written material, or visual or other aids" [60], the advantages of formalised decision support tools should be highlighted, as well as the evidence of their effectiveness in improving patient outcomes. Many doctors use informal decision support, such as hand-drawn diagrams designed to explain healthcare options [61], or informal discussions about end-of-life decisions [38, 62]. Consequently, some doctors have argued that there is no need to conduct research to implement formalised decision support tools into routine care [61]. However, such tools help ensure that the best available evidence is delivered to patients and that quality criteria for information provision are adhered to [12, 63, 64]. A step-by-step plan providing doctors with guidance about how to discuss decisions with their patients could be helpful to facilitate medical decision-making. Initiatives, such as the Physicians Orders for Life Sustaining Treatment paradigm (POLST), are a step in this direction [65].

Efforts to raise awareness of patients' right to be involved in decisions regarding their care cannot only be directed to doctors. It seems surprising that many people put a lot of effort in various decisions that impact their lives, such as deciding on which house or car to buy or where to go for their next holiday, but they do not invest the same time and energy in decisions regarding their healthcare [66]. Campaigns are needed which educate patients on the preference-sensitive nature of many decisions in modern medicine and the fact that the "best"

choice cannot always be determined from a medical point of view. This goes beyond informing patients about the availability of decision support tools, such as decision aids or advance directives. It means educating patients regarding the fact that many decisions in modern medicine need to incorporate their preferences, values and concerns in order to identify and implement the "best choice" [3, 38]. As such, patients need to better understand that their involvement in medical decision-making is crucial to provide optimal healthcare [51, 35]. Yet, it is not only a bigger awareness that will improve the up-take of decision support tools but also practical issues such as time and resources.

Structural barriers

Both the literature on advance directives and decision aids have identified time constraints as one of the main barriers to implementing such tools in clinical practice [55, 67, 68]. One side of this problem is that some medical decisions need to be made quickly due to medical urgency. This, of course, limits the applicability of strategies to involve patients in decisions regarding their care [66]. The other side of the problem is doctors' perceived and actual workload. However, it is not clear yet whether formalised decision support tools actually do extend the consultation time [15]. Also, it might be an option to provide decision support tools in between two shorter consultations, rather than overwhelming patients with information and asking them to make a difficult healthcare decision within one longer consultation. To ensure patients' involvement in decisions regarding their care and to encourage the use of decisions support tools, continuity of care is needed. This means that patients can interact with the same healthcare providers over time [69]. Continuity of care may allow for a sustainable and continuous doctor-patient-relationship and further enhance a patient-centred approach towards medical decision-making [70].

Lack of applicability

Another barrier to the use of advance directives or decision aids is doctors' perception that these tools are not applicable to the circumstances and preferences of each individual patient [19, 33, 61, 71]. It has been shown patients' preferences for information provision and decision making vary [72-74]. They depend on various factors, such as patients' age, gender or health literacy levels [75, 76]. Patients' preferences for information provision and decision making can also change over time, for example depending on situational factors, such as changes in patients' disease status [77, 78]. Some patients do not wish to receive any information on the risks and benefits of their healthcare options and prefer their doctor to decide on their care [43]. For example, it has been argued that many older patients do not want to be involved in decision making regarding their treatment as they believe that "the doctor knows best" [79, 43]. However, even these patients have opinions and preferences regarding their care which should be taken into account [66]. Also, if patients wish not to make decisions regarding their care, they should at least be offered the choice of whether or not they want to be involved in decisions that will affect their health and wellbeing.

To ensure the applicability of decision support to the needs and preferences of different patient populations, tailored online tools could be provided to patients. This might mean that patients enter personal or disease-related characteristics into a secure online system and are then directed to information which is relevant to their individual circumstances and which supplements the consultation with their doctor. Such tools could help patients access tailored decision support and become more involved in decision making regarding their care. Also, flexible, interactive tools have been tested that can be used during the consultation to present evidence summaries at varying levels of detail to patients [80]. These interventions can be produced semi-automatically which facilitates updating the included evidence. It might be that face-to-face communication between doctor and patient is better suited to clarify patients'

values than exercises patients do alone at home. It enhances the promotion of dialogue and the increase of joint deliberation which is crucial to successfully implement both advance directives and decision aids into clinical practice [80]. Such an improved doctor-patient-communication would make decision support tools less vague and less difficult to apply [35, 81].

Conclusions

When trying to implement advance directives and/or decision aids into clinical practice, it might not be enough to ask doctors and patients about their perceived implementation barriers and to research ways of when and how to best deliver such tools to patients [36, 82, 83]. Future research should stop focusing on single decision support tools. For example, efforts have been made to incorporate the benefits of decisions aids into advance care planning and link them to advance directives [84, 85]. We need to go beyond looking at single tools and further investigate the complexity of such interventions as well as the underlying communication mechanisms which hinder their implementation.

We are convinced that both advance directives and decision aids can only be implemented if the communication between doctor and patient is balanced, frank, based on trust and empathy, and as such, truly patient-centred. This includes that patients are asked about their preferences for information provision and decision making, and that care is tailored accordingly in order to enable patients to participate in decisions regarding their care. More specific communication trainings and further public campaigns are needed which educate both doctors and patients about preference-sensitive decision-making and raise awareness of patients' rights to be involved in decisions regarding their care. Decision support should be tailored to patients' needs and preferences, for example by employing flexible, interactive tools. Such tools need to be embedded in comprehensive doctor-patient-communication which is the cornerstone of patient-centred decision-making. More time for decision-making should be scheduled to enable

patients to make rational, considerate rather than rushed, emotive decisions. This could also comfort patients and their loved ones that they made the right decision for a particular situation. Changing the way in which healthcare decisions are made will help ensure that each patient receives the care that mirrors their wishes.

Endnotes

[a] Hereafter referred to as decision aids.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and material

Not applicable.

List of Abbreviations

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding

Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship (UNIPRS), and a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship.

Ruth Horn's research is supported by a Society and Ethics Wellcome Trust Fellowship (100553/Z/12/Z).

Authors' contributions

AH and RH conceived of this paper together. AH drafted the paper independently under RH's supervision. Both authors reviewed and approved the final manuscript.

Acknowledgements

We would like to acknowledge funding support from a Strategic Research Partnership Grant (CSR 11-02) from Cancer Council New South Wales to the Newcastle Cancer Control Collaborative (New-3C), and infrastructure funding from the University of Newcastle and Hunter Medical Research Institute.

Authors' information (optional)

None

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- Watson R, Bryant J, Sanson-Fisher R, Turon H, Hyde L, **Herrmann A**: Do haematological cancer patients get the information they need about their cancer and its treatment? Results of a cross-sectional survey [submitted to *Patient Education and Counselling]*

Title: Do haematological cancer patients get the information they need about their cancer and its treatment? Results of a cross-sectional survey.

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Journal: Psycho-Oncology (IF = 3.3), Supportive Care in Cancer (IF = 2.4), Patient Education and Counseling (IF = 2.2)

Key words:

Word Limit: 4000 (40 references)

ABSTRACT

Background: The provision of appropriate information to cancer patients can influence their role and choices in decision-making regarding treatment, reduce psychological distress prior to treatment, and improve psychosocial outcomes including anxiety, depression and quality of life. However, patients' experiences of receiving information might not always be in line with guideline recommended care.

Aims: To explore the experiences of haematological cancer outpatients in obtaining information about their cancer and its treatment.

Methods: A cross-sectional survey of adult haematological cancer outpatients was conducted. Eligible patients were recruited in clinic waiting rooms and completed two pen-and-paper questionnaires: the first examined demographics and disease characteristics; the second was completed four weeks later, and asked patients about the cancer information they had received. Participants indicated whether they received the information they needed about medical procedures and self-management, experiences regarding doctor-patient communication, and self-efficacy in seeking information and support. Where possible, items were derived from Australian clinical practice guidelines for the psychosocial care of cancer patients.

Results: Two hundred and ninety three (84%) patients consented to participate, with 170 (58%) completing both questionnaires. The majority of participants reported receiving information in accordance with guidelines. Areas identified as requiring improvement included: difficulty recalling information (28%); information overload (26%); insufficient opportunity to ask questions (23%); and insufficient information about managing anxiety related to medical procedures (20%).

Conclusion: Findings highlight the need for effective strategies and support to ensure haematological cancer patients are provided with information tailored to their needs and preferences, and are enabled to make informed decisions about their care.

BACKGROUND

Impact of a diagnosis of haematological cancer

Haematological malignancies account for approximately eight percent of all annual cancer diagnoses globally[1]. In 2017, the estimated incidence of leukaemia and lymphoma in Australia is estimated to be 3,875 and 6,232 new cases respectively, ranking in the top 10 most commonly diagnosed cancers[2]. A diagnosis of haematological cancer is often associated with poor survival outcomes[3]. Common treatment options, such as bone marrow transplantation, peripheral blood cell transplantation and high dose chemotherapy, are lengthy, invasive, and often lead to debilitating side-effects, including fatigue, nausea, infection, and bleeding[3-5]. As a result, patients often have poor psychosocial outcomes. Approximately 20% of haematological cancer patients attending treatment centres experience clinically significant levels of anxiety and/or depression[6]. Prior to first treatment, the prevalence of anxiety increases to approximately 45% and to 25% for depression[7]. This leads to poorer quality of life, a higher number of unmet needs, and greater likelihood of adverse treatment outcomes[8-10].

Benefits of effective information provision

Patient-centred care, which is respectful of and responsive to patients' needs, values and preferences, is a central component of quality health care[11 12]. To enable patients to become active and engaged partners in their health care, it has been argued that patients must receive clear and explicit information regarding the options available to them[13 14]. Appropriate information may influence patients' treatment choice and facilitate collaborative decision-making based on the patient's informed preferences[15-17].

Enabling informed and active decision-making

Many haematological cancer patients have to make numerous decisions along the cancer trajectory, such as choosing between alternative treatments[18-20]. There is considerable evidence to suggest that patients who are involved in decision-making regarding their health care to the degree they want have better outcomes than those that do not, including reduced decisional conflict and increased satisfaction with care[21 22]. Patients who are actively involved in decision-making have also been shown to have higher physical and social functioning, significantly less fatigue and improved quality of life[23-25]. However, there are numerous barriers to patient involvement in decision-making that operate at the patient (e.g. poor

health, lower level of education), physician (e.g. interpersonal skills, presumptions about the patient), and system levels (e.g. lack of continuity of care, time restraints)[26].

Preparing patients for potentially threatening procedures

Poor preparation for medically threatening procedures can hinder treatment decision-making, and increase patients' levels of anxiety and concerns prior to treatment[27]. It is important that patients are adequately prepared and understand the implications of their treatment decisions. For optimal care it is recommended that a multidisciplinary network of health care professionals provide consistent and timely information about the sensory, procedural, psychosocial and behavioural aspects of treatment[27-30]. This includes what patients will see or feel, the sequence of events, the patient's role in facilitating the procedure, and how patients can best manage anxiety before, during and after treatment. The provision of such information has been found to reduce patients' levels of pain and psychological distress prior to cancer treatment[27 31], as well as improving patients' satisfaction with care[30].

Equipping patients with self-management strategies

The delivery of preparatory information is also integral in establishing patients' skills in the self-management of ongoing side-effects of treatment[30]. Self-management information, which describes what the patient can do to help themselves get well, is recognised as the fourth largest unmet need for all cancer patients[32] and one of the basic information needs of haematological cancer patients[33]. The provision of this information promotes a patient-centred approach to health care[34]. It allows patients to actively manage their own care and facilitates the acquisition of skills fundamental to the maintenance of health, including problem solving, resource utilisation, action planning and goal setting[35]. The provision of self-management information has been found to increase cancer patients' perceived level of control, and to improve fatigue, depression, anxiety and quality of life[34 35].

Various factors influence the effectiveness of information provision

Patients vary in their preferences for the type and amount of information they wish to receive, as well as the way information should be presented to them[24 36]. Patient age, the amount of information provided, high levels of anxiety, and a negative prognosis have also been shown to be associated with difficulties remembering information provided during medical consultations[37 38-40]. Strategies to improve recall and understanding include categorisation and prioritisation of information[41], using common and concrete terms, and presenting

information in multiple formats, such as written, face-to-face or video information[42]. Clinical practice guidelines recommend that patients be continually informed about their disease, symptom management and service availability, and that this information be adapted to the wishes of the individual[43]. Tailoring information to the unique circumstances and preferences of individual patients can improve anxiety levels, recall of information, self-perceived preparedness for treatment, and satisfaction with care[43 44]. This is likely to be particularly important for haematological cancer patients given the diversity of diagnoses within this group, which often require complex and rapidly changing treatment regimes[45].

Aims

To explore the views of haematological cancer outpatients regarding their experiences of receiving and obtaining information about their cancer and its treatment.

METHODS

Design and Setting

A cross-sectional questionnaire of haematological cancer outpatients was conducted in three metropolitan hospitals, each treating at least 300 patients for haematological cancer per year. Participating hospitals were located in three different Australian states.

Participants

Eligible patients were adults (aged 18 years or older) who had a diagnosis of any type of haematological cancer and were attending an outpatient clinic appointment at a participating hospital in relation to their cancer. Patients were excluded if they were unable to read or write English sufficiently to complete the questionnaire, were attending their first appointment at the clinic, or were unable to provide informed consent or meet the requirements of participation, as judged by clinic staff.

Recruitment

Appropriate ethics approval was obtained from the University of Newcastle Human Research Ethics Committee and the relevant governing bodies at the participating hospitals. Trained research assistants were responsible for participant recruitment and data collection at each hospital. A haematologist or nurse employed at the participating hospital assisted the research assistant to identify potentially eligible patients from the daily clinic appointment schedule. Patients identified as eligible were provided with a written information sheet and a verbal

explanation of the study by the research assistant. Patients who were willing to participate were asked to complete a consent form and return it to the research assistant. To enable the examination of consent bias, the research assistant recorded the gender and age of non-consenters on a study log sheet with their permission.

Data Collection

Consenting participants were asked to complete two pen-and-paper questionnaires; one at the time of recruitment and one approximately four weeks later. The initial questionnaire was provided to participants in the clinic waiting room and included questions about participants' demographics, their cancer diagnosis and treatments received. The second questionnaire was sent to participants via mail along with a pre-addressed reply paid envelope to return their completed questionnaire to the research team. This follow-up questionnaire contained items exploring chemotherapy side effects (reported elsewhere) and experiences of receiving and obtaining information about their cancer and its treatment. A reminder letter and another copy of the questionnaire was sent via mail to participants who did not return their completed questionnaire after two weeks, with a second reminder sent following a further two weeks of non-response.

Measures

Participants were asked to indicate whether they received the information they needed in relation to preparation for potentially threatening medical procedures or treatments and self-management when leaving hospital. Items were also included to explore participants' experiences regarding doctor-patient communication, and self-efficacy regarding information and support seeking. Participants provided responses to all questions on a five-point Likert scale (*1=strongly disagree* to *5=strongly agree*). A 'not applicable' response option was also available.

Interpersonal communication

Nine items were included to explore patients' experiences regarding the conversations they had with their doctor and family members about disease and treatment information. Items were derived from clinical practice guidelines for the psychosocial care of cancer patients[43] and experiences reported by haematological cancer patients in pilot work conducted by the authors.

Preparation for potentially threatening procedures

Eleven items were included to examine the type of information provided to patients prior to having medical procedures or treatments. These items were directly related to the clinical practice guidelines regarding preparation for potentially threatening procedures[43], and included questions addressing sensory and procedural aspects of treatment, anxiety management, and after-care.

Post-discharge self-management

Six items were included to explore information provided following discharge from hospital to support self-management of symptoms and side-effects of treatment. Items were derived from the clinical practice guidelines for the psychosocial care of cancer patients[43] and recommendations from a multi-disciplinary panel of experts in haematological cancer care regarding the information required by patients in the post-discharge phase.

Information-seeking self-efficacy

Four items were included to examine patients' confidence in their ability to seek support and information from family, friends, and their health care team.

Demographic, disease, and treatment characteristics

The following demographic, disease and treatment characteristics were reported by participants: date of birth, gender, marital status, highest level of education, employment status, country of birth, haematological cancer type, stage of disease at diagnosis, time since diagnosis, and treatments received.

Statistical analysis

Statistical analyses were conducted using SAS v9.4[46]. Age and gender of participants and non-consenters was compared to examine consent bias using F-adjusted Rao-Scott chi-square tests. Participant characteristics (age, gender, education, country of birth, cancer type) of those that completed both questionnaires were also compared with those who completed the first questionnaire only using F-adjusted Rao-Scott chi-square tests. Frequencies and percentages were calculated for each item with responses regrouped as Agree (*Strongly Agree* and *Agree*), Neutral, Disagree (*Strongly Disagree* and *Disagree*) and not applicable. Multivariate analysis to explore potential associations between patient characteristics and information experiences was not possible due to a high number of participants having 'not

applicable' responses (n=58). These participants could not be included in such analyses, therefore resulting in very limited power due to the small sample available.

RESULTS

Sample

Of the 349 patients identified as eligible to participate, 293 (84%) consented to take part in the study. Two hundred and thirty-six (81%) consenters completed and returned the first questionnaire. There was no indication of consent bias, with no significant differences in age ($p = 0.14$) or gender ($p = 0.31$) between completers and non-consenters. One hundred and seventy participants (72%) also completed the second questionnaire and are included in the following analyses. There were no significant differences in age ($p = 0.24$) or gender ($p = 0.56$) between those who completed the first questionnaire only and those who completed both questionnaires. Table 1 provides a summary of the socio-demographic, disease and treatment characteristics for the included sample.

Table 1. Participant socio-demographic and disease profile (n = 170)

Characteristic		**N (%)[a]**
Gender	*Male*	99 (58%)
	Female	71 (42%)
Age (years)	*18-34*	8 (5%)
	35-54	42 (25%)
	55-74	94 (57%)
	75+	22 (13%)
Marital status	*Married or partner*	112 (67%)
	Single, divorced, separated or widowed	55 (33%)
Education completed	*High school or below*	75 (45%)
	Vocational training or University	91 (55%)
Place of birth	*Australia*	113 (68%)
	Other	54 (32%)
Cancer type	*Non-Hodgkin Lymphoma*	51 (30%)
	Chronic Leukaemia	34 (20%)
	Myeloma	27 (16%)
	Acute Leukaemia	22 (13%)
	Hodgkin Lymphoma	12 (7%)
	Other	22 (13%)

Characteristic		N (%)[a]
Time since diagnosis (months)	*0-6*	14 (8%)
	7- 12	25 (15%)
	13-24	23 (14%)
	24+	107 (63%)
Stage of cancer	*Early*	54 (33%)
	Advanced	37 (22%)
	In remission	29 (18%)
	Don't know	45 (27%)
Treatment received[b]	*Chemotherapy*	141 (85%)
	Radiation therapy	36 (21%)
	Stem cell transplant	37 (22%)
	Surgery	31 (19%)
	Other	12 (7%)
	No treatment	66 (39%)

[a] not all columns sum to 170 due to missing data; [b] not mutually exclusive categories

Patient experiences of obtaining information related to their disease and treatment

Overall, self-reported information experiences were largely positive. Data from items assessing participant experiences regarding information about diagnosis and treatment are presented in Table 2. Areas where more than 15% of participants perceived care was not received in accordance with guidelines or indicated there was scope for improvement in information provision are presented in bold text.

Table 2. Patient experiences of obtaining information related to their disease and treatment

Item	Agree	Disagree	Neutral
		N (%)[a]	
When being told information about my disease and treatment:			
The way the doctor discussed the information was confusing	24 (14%)[b]	120 (71%)	23 (14%)
I felt my doctor told me everything s/he could	130 (77%)	18 (11%)	19 (11%)
I forgot important details of what the doctor told me	**47 (28%)[b]**	73 (44%)	44 (26%)
I felt too overwhelmed by the amount of information to make sense of it	**43 (26%)[b]**	84 (51%)	36 (22%)
There wasn't enough time to discuss all my questions with the doctor	**38 (23%)[b]**	106 (63%)	20 (12%)
There have been differing opinions among my family about:			
What the doctor has told us	**29 (18%)[b]**	94 (57%)	26 (16%)
The meaning of the information we have received	**28 (17%)[b]**	91 (55%)	31 (19%)
Decisions made regarding treatment	**24 (15%)[b]**	98 (59%)	29 (18%)
What is best for me	**29 (18%)[b]**	92 (56%)	31 (19%)
When having medical procedures or treatments, I got the information I needed about:			
Purpose of the procedure	148 (88%)	6 (4%)	8 (5%)
Benefits and risks of the procedure	142 (84%)	10 (6%)	10 (6%)
What the procedure involved	144 (85%)	6 (4%)	11 (7%)
Where the procedure would take place	150 (89%)	1 (1%)	9 (5%)
Who would perform the procedure	114 (69%)	10 (6%)	30 (18%)
How long it would take to recover from the procedure	106 (63%)	19 (11%)	29 (17%)
What care I would need after the procedure	116 (69%)	12 (7%)	23 (14%)
How to manage anxiety and stress before the procedure	59 (35%)	**37 (22%)**	56 (34%)
What I might feel during the procedure	124 (74%)	10 (6%)	20 (12%)
What I should do if I experienced pain or discomfort during the procedure	120 (71%)	6 (4%)	23 (14%)
How to manage anxiety or stress during the procedure	72 (43%)	**33 (20%)**	44 (26%)
When leaving hospital, I got the information I needed about:			

Who to call if I experienced worrying symptoms	135 (81%)	6 (4%)	14 (8%)
Which symptoms I should report to my health care team immediately	132 (79%)	7 (4%)	19 (11%)
How to manage symptoms and side effects	110 (65%)	11 (7%)	37 (22%)
Situations or activities I should avoid to reduce risk of infection or developing complications	125 (75%)	10 (6%)	18 (11%)
Foods I should avoid to reduce risk of infection or developing complications	98 (58%)	**26 (15%)**	24 (14%)
How to prepare food safely to reduce risk of infection or developing complications	90 (54%)	**28 (17%)**	29 (17%)
I feel confident in my ability to:			
Ask my family/friends for emotional support when I need it	113 (68%)	20 (12%)	27 (16%)
Ask my family/friends for practical support when I need it	128 (77%)	14 (8%)	20 (12%)
Ask my health care team questions about my disease and treatment options	143 (86%)	7 (4%)	12 (7%)
Be involved in making decisions about my care	137 (82%)	9 (5%)	17 (10%)

[a] not all rows sum to 170 due to missing data or 'not applicable' responses; [b] agreement indicates a negative patient experience as item was reverse-worded

Interpersonal communication

When asked about their discussions with their doctor and family regarding their cancer, a substantial minority of participants indicated problems recalling information provided by their doctor (28%), experiencing information overload (26%), and insufficient opportunity to seek further information and clarification regarding their diagnosis and treatment (23%). Further, 15%-18% of participants reported differing opinions among their family members regarding the information received and decisions about care.

Preparation for potentially threatening procedures

Most participants reported that guideline recommended information was provided regarding the procedural and most sensory aspects of medical procedures. However, provision of information about strategies for managing stress and anxiety associated with these procedures was identified as being suboptimal for 20-22% of patients.

Post-discharge self-management

While information provision regarding post-discharge self-management was perceived to be adequate, a small proportion of participants reported receiving insufficient information about foods to avoid (15%) and how to prepare food safely to reduce risk of infection or developing complications (17%).

Information-seeking self-efficacy

Most participants (68-86%) reported feeling confident in their ability to seek support and information from their family, friends, and health care team.

DISCUSSION

The results of this study indicate that haematological cancer outpatients have positive overall experiences in relation to obtaining required information about their cancer and its treatment. Despite 15-18% of participants reporting disagreement amongst family in terms of cancer information provision and decision-making, more than half of participants had a positive experience in terms of family involvement in these processes. This finding is consistent with the literature. A systematic review of patient-physician-companion communication found that cancer patients appreciated the emotional and information support roles fulfilled by their

companions during cancer consultations. This included taking notes, asking questions, recalling essential information post-consultation, and assistance with decision-making[47].

There is room for improvement in the provision of some aspects of guideline-recommended psychosocial care for haematological cancer patients. A substantial minority of participants forgot information they were given during the consultation with their doctor, didn't feel they had enough time to ask questions, and felt too overwhelmed by the amount of information presented to them to make sense of it. Previous research has reported that patients forgot or remembered incorrectly approximately 40-80% of medical information provided during a consultation[48]. In addition, higher levels of anxiety also has a negative impact on information recall[48 49], which is of particular importance for haematological cancer patients where the prevalence of anxiety may be as high as 45%[7]. Patient-centred information provision recommends that clinicians ask patients what information they would like to know and in how much detail[50]. This allows for information provision to be tailored according to patients' preferences and may minimise information overload[50]. Decision aids, question prompt lists, and patient coaching might also be useful strategies to improve recall and decision-making. Such interventions have been shown to decrease patient anxiety and help patients become engaged in decision-making regarding their care[51 52]. Additional strategies to aid recall of information post-consultation, minimise information overload, and provide additional opportunities to seek clarification regarding the information, might include having two consultations to discuss diagnosis and treatment information, or information to take home[42], such as audiotapes of the consultation[13].

Approximately one fifth of participants indicated that they did not receive the information they needed about managing stress and anxiety associated with a potentially threatening procedure or treatment. This finding may be due to a prioritisation of medical aspects of the procedure in preparatory information provision, highlighted by the comparatively better perception of information received in these areas. Alternatively, it may be that patients place a higher level of importance on procedural, behavioural and sensory aspects of care, leading to lower rates of patient recall of psychosocial information. A multi-disciplinary model of cancer care may be effective at addressing this issue, where various clinical staff are involved in the coordinated delivery of both medical and psychosocial preparatory information. This may result in greater opportunities for discussion, clarification and reinforcement of information[53]. Previous research has also found that providing information aids, such as

educational videos and audio-tapes, may assist in reducing anxiety and increasing satisfaction with preparatory information[27 53-55]. The internet provides one highly accessible and cost-effective modality in which to provide such multimedia information. However, further research is needed to explore the potential use of interactive technology in delivering preparatory information to cancer patients[55].

Several limitations should be considered when interpreting the study findings. Firstly, there was potential for recall bias in survey responses. Over 60% of participants were diagnosed more than 24 months ago and, therefore, may be in the follow-up phase of care rather than undergoing diagnosis and active treatment to which many of the survey items relate. Sensitivity of the items regarding preparation for potentially threatening procedures may be limited due to the framing of the item stem. Participants were asked to respond taking into account all of the procedures and tests they had received rather than referring to a specific or most recent procedure. There was also a substantial number of neutral responses which were difficult to interpret. Future research may employ an alternative response scale which elicits more discrete responses in terms of whether specific information was received and what patients' preferences for receiving information are.

CONCLUSIONS

While many haematological cancer patients report receiving adequate information, there is room for improvement in relation to some aspects of information provision. Findings highlight the need for implementation of effective strategies to minimise information overload, aid recall of information post-consultation, and manage anxiety and stress related to medical procedures.

ACKNOWLEDGEMENTS AND FUNDING

This research was funded by a Strategic Research Partnership grant provided by Cancer Council New South Wales to the Newcastle Cancer Control Collaborative, and infrastructure funding from the Hunter Medical Research Institute. The development of the survey instrument was also supported by the Cancer Institute New South Wales (10/THS/2-14). Dr. Jamie Bryant was supported by an Australian Research Council Post-Doctoral Industry Fellowship. Mrs Lisa Hyde is supported by an Australian Government Research Training Program Scholarship. Ms Anne Herrmann is supported by a University of Newcastle International Postgraduate Research Scholarship, a University of Newcastle/Hunter Cancer Research Alliance Research Scholarship and has received funding support from the Hunter Cancer Research Alliance Implementation Science Flagship Program as part of the 2017 Research Higher Degree Student Award initiative.

AUTHOR CONTRIBUTIONS

All authors contributed to preparation and review of the manuscript. In addition, HT was the project manager responsible for overseeing data collection. RW, JB, and RSF were responsible for development of the measure.

COMPETING INTERESTS

All authors declare that they have no competing interests.

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- Carey M, **Herrmann A**, Hall A, Mansfield E, Forshaw K: Exploring health literacy and preferences for risk communication among medical oncology patients [submitted to *Patient Education and Counselling*]

Title: Exploring health literacy and preferences for risk communication among medical oncology patients

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Conflict of Interest statement:

None to declare.

Abstract:

Objective: To explore medical oncology outpatients' understanding of and preferences for the format of health risk information.

Methods: Adult medical oncology outpatients were invited to complete two surveys: one which assessed sociodemographic characteristics and a second survey a month later which included questions about understanding of risk information and preferences for the format of such information.

Results: Three hundred and sixty-one (74%) patients consented. Of these, 210 completed at least one question on risk communication and were included in this analysis. The proportion of respondents who understood numeric risk information varied from 17% to 65% depending on the format of the information. More than 50% of people interpreted a "very good" chance of remission as greater than 80%, greater than 90% or 100% chance of remission. The most preferred format of information was to have it presented in both words and numbers (38% to 43%) followed by words alone (28% to 30%).

Conclusion Numeric risk information is misunderstood by 17% to 65% of respondents, depending on the format. Interpretation of verbal risk information is highly variable, posing a risk of misunderstanding.

Practice Implications. Provision of information in both words and numbers may assist in aiding comprehension.

1. Introduction

Communication of risk is essential to assisting informed decision making for people with cancer

Optimal cancer care is patient-centred, placing great emphasis on involving patients in their healthcare decisions [1]. To achieve this, healthcare providers need to communicate accurate and unbiased health information to patients. However, this can be challenging as many cancer patients have a number of treatment options available to them, and the outcomes associated with each of these are probabilistic, leading to ambiguity and uncertainty [2]. In order to decide upon a treatment, patients often have to weigh-up uncertain risks against uncertain benefits of the treatment options available to them [3].

The way in which risks are presented can influence patient decision making [4]. For example, it has been suggested that patients often overestimate risk if it is presented as relative (e.g. your risk is two times higher than rather than absolute risk (e.g. your risk is 5%) [5]. Therefore, risk and benefit information needs to be presented in a way that facilitates comparison across treatment options. This allows patients to integrate this information with their personal preferences and make informed decisions about their care [6].

What format should risk be communicated in to optimise comprehension?

Patients vary in how they understand risks. For example, there is evidence to suggest that women with low literacy skills are more likely to overestimate their risk of developing breast cancer, compared to women with high literacy skills [7]. Numerous studies have looked at how to best present risks to patients [8, 9]. For example, it has been suggested that risk can be presented in form of graphs, verbal or numerical formats. Understanding of graphical risk presentation, such as icons or curves, may be influenced by the amount of instruction given and patients' expertise [10]. There is considerable evidence to suggest that patients understand probabilistic information better if it is presented in numbers rather than words [11]. This may be because doctors and patients are likely to have different interpretations of what phrases like "low risk", "unlikely", or "high risk" mean [4]. Numbers are perceived to be precise, leading to more accurate perceptions of risk than the use of probability

phrases and graphical displays [5]. Studies suggest that numeric probabilities associated with descriptors of risk such as “low” or “high” risk might increase comprehension of risk [12-14]. There are several ways of presenting numerical risk information, including as percentages, odds, or natural frequencies. It has been suggested that risks should be presented as natural frequencies with a small denominator (e.g. 1 out of 10) [5, 15]. Also, presenting numerical risks based on individual estimates, i.e. based on each individual patient’s characteristics, seems to be more effective in changing patient knowledge, attitudes, and behaviours than presenting risks based on general estimates [8, 16].

What format do patients prefer risk to be communicated in?

Patients vary considerably in how they would like risk information to be presented to them [17]. While most patients prefer risks presented in numerical format rather than words [4, 5], this varies depending on sociodemographic characteristics, such as age, gender or educational level, as well as health status [17-19]. Findings from previous cross-sectional studies indicate that a range of complementary formats, including verbal and numerical description of risk, might be more appreciated by patients than the use of one format only [20-22].

Despite the increasing research effort in the area of risk communication, previous studies have to be considered in the light of several limitations. For example, many studies have been conducted with healthy people and findings might not be generalizable to people with serious medical conditions. There is little empirical data to guide our understanding of how adjectives should be used when communicating probabilities to people with cancer. Also, most studies in this area have involved recruitment of participants from just one clinic or hospital, and findings may not be applicable to all people with cancer. Further, most research has been conducted in the US [23, 24] and results may not be generalizable to other populations. Little is known about how Australian cancer patients understand different risk formats, and the way in which they want to be informed about the risks they face [19, 25].

Aims: To explore, among medical oncology outpatients, their: 1) understanding of numerical risk information and interpretation of adjectives used to describe risk; and 2) preferences for format of risk communication.

2. Methods

Setting: The study was conducted as part of a larger study exploring psychological outcomes among medical oncology outpatients. Questions about risk communication were administered to participants recruited from two of the medical oncology clinics participating in the larger study. Both clinics were located in metropolitan public hospitals in Queensland and South Australia. The study was approved by the University of Newcastle Human Research Ethics Committee (H-2010-1324) as well as ethics committees associated with each participating institution.

Participants: Medical oncology outpatients with a diagnosis of cancer, aged 18 or older and with sufficient English to complete the survey independently were eligible to participate.

Procedure: Patients attending medical oncology outpatient clinics were invited to participate in the study. Informed written consent was obtained from all participants. Participants were asked to complete two pen-and-paper surveys. The initial survey was either completed in the clinic at the time of recruitment or taken home and mailed back to the researchers within one week. The second survey was mailed to the person's home approximately one month later. For both surveys, reminder letters were sent to non-responders at two weeks. A second reminder letter was sent after four weeks of non-response.

Measures: The first survey contained questions on sociodemographic, disease and treatment characteristics; while the second survey contained questions on understanding of and preferences for risk information.

Sociodemographic characteristics: Participants were asked to report age, gender, highest level of education, postcode, marital status, and whether or not they had a health care card or veterans' affairs card and / or private health insurance. A concession card is a government issued card which enables access to health services and medicines at a lower cost.

Disease and treatment characteristics: Type of cancer, time since diagnosis, stage of cancer, treatments undertaken for cancer and reason for outpatient consultation were assessed.

Understanding of numerical risk information: Respondents were given three questions about their understanding of numerical risk information: 1) “If a certain cancer drug is said to have a 30% chance of long-term side-effects, which statement is true?“; 2) “If you are told that a cancer treatment has a 5% risk of serious complications, which of the following are true?”; and 3) “If you are told that 1 in 5 people will experience a short-term side-effect from a cancer treatment, which of the following is correct?” Multiple response options were provided for each question and respondents were asked to select all that applied.

Interpretation of adjectives to describe risk: Respondents were asked, “If you were told that your chances of remission (i.e. being cancer free) were ‘very good’, what would you guess your chances of remission were?” Response options included: “more than 20%”; “more than 30%”; “more than 40%”; “more than 50%”: “more than 60%”: “more than 70%”; “more than 80%”; “more than 90%” and “100%”. Respondents were asked to select one response only.

Preferences for risk communication: Respondents were asked three questions about their preferences for information on likelihood of side-effects, remission and survival. For example: “Your doctor is telling you about your chances of long-term side-effects. How would you like your doctor to describe your chances of having long-term side-effects?” Response options included “in words (e.g. “poor”, “good”, “very good”)”; “in numbers (e.g. “three out of every ten people”)”; “in both words

and numbers"; "I don't care how my doctor gives me this information"; "I don't want my doctor to give me this information".

Statistical analyses: All statistical analyses were conducted using SAS v9.4 (SAS Institute, Cary, North Carolina, USA). Descriptive statistics, including frequencies and percentages were calculated to answer each of the two aims.

3. Results

Six hundred and eight people were screened for eligibility. Of these 117 were ineligible, and of the remaining 491, 361 (74%) agreed to take part in the study. Of those who consented, 217 returned a copy of the second survey, of which 210 completed at least one question on risk communication and were thus included in this analysis. There were no significant differences between non-consenters and study participants in terms of sex. However, there was a significant difference between non-consenters and study participants with respects to age (p=0.02). Compared to non-consenters, there was a lower percentage of study participants aged less than 45 years (22% vs. 13%) and 65 years and over (36% vs. 30%); while there was a higher percentage of study participants aged between 45 and 64 years compared to non-consenters (57% vs. 42%).

Participant demographic and disease information are presented in Table 1. Almost half of participants were aged 60 years or over. Most were female, in a married or partnered relationship and were born in Australia. The most common cancer type was breast, with most cancers in the early stages. The main reason patients were visiting the treatment centre was to receive treatment.

Table 1. Sociodemographic characteristics of the sample (n=210).

Characteristics	%	n
Age		
Missing	3.3	7
<45 years	12.9	27
>=45 and <60 years	38.6	81
>=60 years	45.2	95
Sex		
Missing	2.9	6
Male	20.5	43
Female	76.7	161
Marital status		
Missing	3.8	8
Married/partner	63.8	134
Single, divorced, separated or widowed	32.4	68
Education level		
Missing	3.3	7
High school or below	52.9	111
Trade, vocational training or University	39.5	83
Other	4.3	9
Country of birth		
Missing	3.3	7
Australia	67.6	142
Other	29.0	61
Health insurance		
Missing	3.3	7
Yes	19.5	41
No	77.1	162
Concession card		
Missing	3.8	8
Yes	54.3	114
No	41.9	88
Cancer type		
Missing	4.3	9
Breast	47.1	99
Colorectal	7.6	16

Characteristics	%	n
Lung	4.8	10
Other	36.2	76
Time since diagnosis		
Missing	3.3	7
0-6 months	25.7	54
7-12 months	17.6	37
13-24 months	15.7	33
24+ months	37.6	79
Cancer stage		
Missing	6.2	13
Early	56.2	118
Progressed/advanced	30.0	63
NA or don't know	7.6	16
Reason for visit		
Missing	5.2	11
To discuss treatment options	6.7	14
To receive treatment	43.8	92
To have a check-up during treatment	15.7	33
To have a check-up after treatment	24.3	51
Other	4.3	9

Understanding of risk information

Two hundred and four participants provided a response to the question: “If a certain cancer drug is said to have a 30% chance of long term side-effects, which statement is true?” Of these, most participants (n=125; 61%) endorsed only the correct response: “3 out of every 10 people who take this drug will have long term side-effects.” A smaller number of people endorsed the correct response and one or more incorrect responses (n=18; 8.8%), with the remaining respondents endorsing incorrect responses only (n=61; 30%).

Two hundred and three participants answered the question: “If you are told that a cancer treatment has a 5% risk of serious complications, which of the following are true?” For this question, two responses

were considered correct: “The risk of complications is low but I am still at risk” was the most frequently endorsed correct response (endorsed by n=154; 76%) and “50 out of 1000 people will experience this complication” (endorsed by n=74; 36%). Thirty-five (17%) endorsed both correct answers, and 137 (67%) endorsed one of these correct responses: “The risk of the complications is low but I am still at risk” and “50 out of 1000 people will experience this complication”. While 67% (n=137) endorsed one of these responses only. A further 15 (7.4%) respondents selected at least one of the correct responses together with an incorrect option. Sixteen participants (7.9%) selected only incorrect responses.

A total of 199 participants answered the question: “If you are told that 1 in 5 people will experience a short-term side-effect from a cancer treatment, which of the following is correct?” Of these respondents, 130 (65%) endorsed only the correct response, which was “The risk of experiencing short-term side-effects from this treatment is 20%”. A small number endorsed both the correct response and at least one incorrect response (n=6; 3.0%), while almost a third selected only incorrect responses (n=63; 32%). Of the incorrect responses the most frequently endorsed by participants was “The risk of experiencing short-term side-effects from this treatment is 5%” (n=43; 22%).

Interpretation of adjectives to describe risk

Two hundred and one participants provided an answer to the question: “If you were told that your chances of remission (i.e. being cancer free) were ‘very good’, what would you guess your chances of remission were?” The results of participant responses are presented in Figure 1. The most common estimate was “more than 80%” with 54 (27%) of respondents selecting this option. This was closely followed by “more than 90%”, which was endorsed by 48 (24%) of respondents. The least frequent response option selected by respondents was “more than 30%” (n=3; 1.5%).

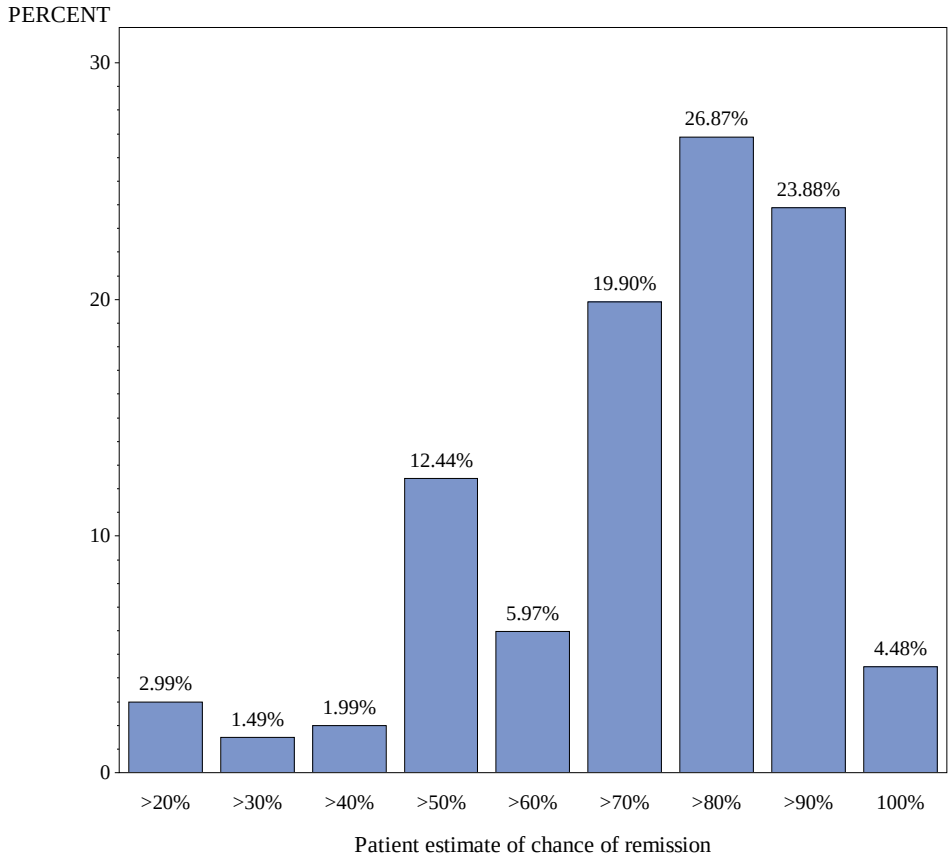

Figure 1. Participants' interpretation of a "very good" chance of remission as a percentage

Preferences for format of health risk communication

When participants were asked how they would like to have their chances for long-term side-effects, remission and five-year survival communicated to them, the most frequently reported preference for all three topics was for both words and numbers to be used (Table 2). Words alone was the second most frequently endorsed option across all three topics, while only a small minority of patients indicated a preference for not being told about their chances at all.

Table 2. Preferences for health risk communication

Preferred format of communication	Chances of long-term side-effects	Chances of remission	Chances of five year survival
Missing	5 (2.4%)	5 (2.4%)	8 (3.8%)
Words	59 (28%)	62 (30%)	58 (28%)

Preferred format of communication	Chances of long-term side-effects	Chances of remission	Chances of five year survival
Numbers	33 (16%)	21 (10%)	17 (8.1%)
Both words or numbers	79 (38%)	88 (42%)	90 (43%)
Don't care	33 (16%)	33 (16%)	31 (15%)
Prefer not to be told	1 (0.5%)	1 (0.5%)	6 (2.9%)

4. Discussion and conclusion

Discussion

This study is one of few to examine the understanding and interpretation of health risk information and format preferences in Australian medical oncology outpatients. Overall, our findings revealed that in relation to numerical risk information, natural frequencies with a small denominator were the most understood format. However, in relation to risk wording, a wide variation in patient interpretations was found. The use of both words and numbers was the most frequently patient-preferred format for risk communication.

When numerical risk information was presented simply using natural frequencies and a small denominator (e.g. “3 out of every 10 people”), approximately 61% of people understood the information. Of the 32% who selected an incorrect response regarding their understanding of the term “1 in 5 people…”, almost a quarter of respondents (22%) perceived that the risk meant a 5% rather than 20% risk, indicating that misunderstandings may be significant in some cases. When presented with a larger denominator (e.g. “50 out of 1000 people”), the number of people who understood the information reduced to about one third (36%). This supports previous findings that information presented with a small denominator are more likely to be understood and should be used to present risk information to patients [9].

Our findings revealed a wide variation in the way that patients interpreted risk adjectives. Participant interpretations of what a "very good" chance of remission equated to ranged from "more than 20%" to "100%". It is notable that 28% of participants perceived that "very good" meant a 90% or greater chance; while over half the sample (55%) perceived that this meant 80% or greater. This suggests that there is great potential for misunderstanding where only verbal risk descriptors are used. The wide variation in responses is consistent with previous research which has found that patients more accurately understand risk information if it is presented in numbers rather than words [9].

The most frequently reported preference for the format of information regarding long-term side-effects, remission, and five-year survival was for both words and numbers to be used, at 38%, 42% and 43%, for each of the three risk topics, respectively. The second most frequently endorsed option was for words alone to be used, which was endorsed by approximately 30% of respondents across all three risk topics. While patients vary in how they would like risks to be presented to them [17], our results differ from other research which has suggested that most patients prefer risks to be presented in a numerical format [4, 5, 17-19]. However, most prior research has not been conducted in an oncology setting, and patients' preferences may be affected by illness severity, health status and other sociodemographic factors [4].

Our findings must be considered in view of several limitations. Firstly, participants were recruited from three medical oncology clinics, and so are unlikely to be representative of Australian medical oncology patients. While a consent rate of 74% was achieved, there were a number of participants who did not return the second survey which contained the health literacy questions. This may have further impacted on generalisability of results. When asking participants about their understanding of a 5% risk of serious complications, we counted the following response as one of two possible correct answers: "The risk of complications is low, but I am still at risk". We acknowledge that interpretation of 5% risk as "low" is subjective and could be debated.

Conclusion

Our results suggest that risk information presented in natural frequencies with small denominators (e.g. 1/5) is understood by 61%-65%, depending on the scenario presented. When risk information is presented with large denominators, a lower proportion indicate that they understand (36%). We found substantial variation in patients' interpretation of risk descriptors (e.g. "good", "very good"), highlighting the dangers of providing patients with risk descriptors without accompanying numeric information. Patients were most likely to have a preference for receiving risk information as both words and numbers.

Practice Implications

The findings provide guidance as to how physicians should communicate risk information about outcomes of treatment such as possible side-effects, and likelihood of remission and survival. The variation in patents' interpretation of risk information when this is presented in words only may result in unrealistic expectations regarding outcomes. To overcome this variation, risk information in words should be combined with risk information in numbers. Together with other studies [9, 26], our findings suggest that numeric information should be presented as natural frequencies with small rather than large denominators to aid patient understanding.

However, it is important to note that a large proportion of patients (just under one third) did not understand the risk information when it was presented in this 'optimal' format. This suggests that physicians should probe patient understanding of risk, and utilise other formats to supplement this information if necessary. This could include, for example, diagrams showing the number of people out of 10 who are likely to experience a certain outcome, or bar charts showing the proportion of patients likely to experience each outcome. Graphical formats have been shown to improve patients' understanding of risk information [9], and may also reduce participants' reliance on anecdotal evidence when making decisions [27].

Acknowledgements

This research was supported by a National Health & Medical Research Council Project Grant (ID 1010536), a Strategic Research Partnership Grant (CSR 11-02) from Cancer Council NSW to the Newcastle Cancer Control Collaborative (New-3C), and infrastructure funding from the Hunter Medical Research Institute (HMRI). A/Prof Mariko Carey was supported by a NHMRC TRIP Fellowship with co-funding from the Cancer Institute of New South Wales (APP 1073031). Our thanks to the participating cancer treatment centres; Rochelle Smits, Alison Zucca, Heidi Turon and Hannah Small for research support; Sandra Dowley for data management; and Tiffany Evans for statistical assistance.

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Appendix 8: HUNTER NEW ENGLAND LOCAL HEALTH DISTRICT CERTIFICATES OF HUMAN RESEARCH ETHICS APPROVAL

Appendix 8.1: Research ethics approval related to Paper One

12 May 2015

Laureate Professor Rob Sanson-Fisher
Health Behaviour Research Group
Hunter Medical Research Institute

Dear L/Professor Sanson-Fisher,

Re: Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients (15/04/15/4.04)

HNEHREC Reference No: 15/04/15/4.04
NSW HREC Reference No: HREC/15/HNE/128

Thank you for submitting the above application for single ethical review for a multi-centre study. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **15 April 2015.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise that following acceptance under delegated authority of the requested clarifications and revised Participant Information Statement and the Surveys by Dr Nicole Gerrand Manager, Research Ethics & Governance, the Hunter New England Human Research Ethics Committee has granted ethical approval of the above project.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

- For the Participant Information Statement (Version 2 dated 8 May 2015);
- For the Consent Form (Version 1 dated 26 March 2015);
- For the In-Clinic Patient Survey (Version 2 dated 8 May 2015);
- For the Follow Up Patient Survey (Version 2 dated 8 May 2015);
- For the Cover Letter for Follow Up Patient Survey (Version 1 dated 26 March 2015); and
- For the Patient Reminder Letter (Version 1 dated 26 March 2015)

For the study: **Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients**

Hunter New England Research Ethics & Governance Unit
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Approval has been granted for this study to take place at the following sites:

- **Calvary Mater Newcastle, Waratah NSW**
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- **Tamworth Rural Referral Hospital, Tamworth NSW**
- **Moree Hospital, Moree NSW**
- **Gosford Hospital, Gosford NSW**
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- **Campbelltown Hospital, Campbelltown NSW**
- **Bankstown-Lidcombe Hospital, Bankstown NSW**
- **Parkes District Hospital, Parkes NSW**
- **Bathurst Base Hospital, Bathurst NSW**
- **Dubbo Base Hospital, Dubbo NSW**
- **Orange Health Service, Orange NSW**

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of 3 years from the date of this letter, after which a renewal application will be required if the protocol has not been completed.

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- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
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- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, as soon as possible.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **15/04/15/4.04** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Acting Chair
Hunter New England Human Research Ethics Committee

Hunter New England Research Ethics & Governance Unit
Locked Bag 1
New Lambton NSW 2305
Telephone. (02) 49214850 Facsimile. (02) 49214818
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NSW GOVERNMENT Health
Hunter New England Local Health District

18 June 2015

Laureate Professor Rob Sanson-Fisher
Health Behaviour Research Group
Hunter Medical Research Institute

Dear L/Professor Sanson-Fisher

Re: Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients (15/04/15/4.04)

HNEHREC Reference No: 15/04/15/4.04
NSW HREC Reference No: HREC/15/HNE/128

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Hunter New England Human Research Ethics Committee. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has granted ethical approval for the following amendment requests:

- For the addition of Dr Heidi Turon as project manager;
- For the addition of Dr Timothy Regan as project manager;
- To change In-Clinic Survey administration from iPad to pen and paper format;
- For the addition of a reminder letter, for participants who have not returned the In-Clinic Survey, to be sent within 2 weeks of the date of consent, and a second reminder letter sent after a further 2 weeks of non-response;
- For the Information for Participants (Master Version 3 dated 28 May 2015);
- For the In-Clinic Patient Survey (Version #3 dated 28 May 2015);
- For the Patient Reminder Letter_In-Clinic Survey (Version 1 dated 28 May 2015);
- For the Follow Up Patient Survey – Module 1 (Version #3 dated 28 May 2015);
- For the Follow Up Patient Survey – Module 2 (Version #3 dated 28 May 2015)

For the study: Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients

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Approval from the Hunter New England Human Research Ethics Committee for the above study is given for a maximum of 3 years from the date of the approval letter of your initial application, after which a renewal application will be required if the study has not been completed. The above study is approved until **May 2018.**

Approval has been granted for this study to take place at the following sites

- **Armidale Rural Referral Hospital, Armidale NSW**
- **Bankstown-Lidcombe Hospital, Bankstown NSW**
- **Bathurst Base Hospital, Bathurst NSW**
- **Calvary Mater Newcastle, Waratah NSW**
- **Campbelltown Hospital, Campbelltown NSW**
- **Dubbo Base Hospital, Dubbo NSW**
- **Gosford Hospital, Gosford NSW**
- **Liverpool Hospital, Liverpool NSW**
- **Moree Hospital, Moree NSW**
- **Orange Health Service, Orange NSW**
- **Parkes District Hospital, Parkes NSW**
- **Tamworth Rural Referral Hospital, Tamworth NSW**
- **Wyong Hospital, Hamlyn Terrace NSW**

The *National Statement on Ethical Conduct in Human Research (2007)* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above study be submitted at 12 monthly intervals. Your review date is **May 2016.** A proforma for the annual report will be sent two weeks prior to the due date.
- A final report must be submitted at the completion of the above study, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.
- All variations or amendments to this study, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
    - any serious or unexpected adverse events
        - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure.
        - Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Ethics Officer of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.
        - Copies of serious adverse event reports from other sites should be sent to the Hunter New England Human Research Ethics Committee for review as soon as possible after being received.

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- Serious adverse events are defined as:
  - Causing death, life threatening or serious disability.
  - Cause or prolong hospitalisation.
  - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.
- Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above study does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, the Manager, Research Ethics and Governance Unit as soon as possible.

The Hunter New England Human Research Ethics Committee also has delegated authority to approve the commencement of this research on behalf of the Hunter New England Local Health District. This research may therefore commence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per the contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Hunter New England Local Health District website.

Please quote **14/04/15/4.04** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Acting Chair
Hunter New England Human Research Ethics Committee

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NSW GOVERNMENT Health
Hunter New England
Local Health District

9 July 2015

Laureate Professor Rob Sanson-Fisher
Health Behaviour Research Group
Hunter Medical Research Institute

Dear L/Professor Sanson-Fisher,

Re: Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients (15/04/15/4.04)

HNEHREC Reference No: 15/04/15/4.04
NSW HREC Reference No: HREC/15/HNE/128

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Hunter New England Human Research Ethics Committee. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has granted ethical approval for the following amendment requests:

- For the addition of Dr Dion Forstner as Principal Investigator at Liverpool Hospital;
- For the addition of Dr Craig Kukard as Principal Investigator at Gosford Hospital;
- For the Protocol (Version 1 dated 6 July 2015); and
- For the Participant Consent Form (Master Version 2 dated 6 July 2015)

For the study: **Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients**

Approval from the Hunter New England Human Research Ethics Committee for the above study is given for a maximum of 3 years from the date of the approval letter of your initial application, after which a renewal application will be required if the study has not been completed. The above study is approved until **May 2018.**

Approval has been granted for this study to take place at the following sites

- **Armidale Rural Referral Hospital, Armidale NSW**

- **Bankstown-Lidcombe Hospital, Bankstown NSW**
- **Bathurst Base Hospital, Bathurst NSW**
- **Calvary Mater Newcastle, Waratah NSW**
- **Campbelltown Hospital, Campbelltown NSW**

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- **Dubbo Base Hospital, Dubbo NSW**
- **Gosford Hospital, Gosford NSW**
- **Liverpool Hospital, Liverpool NSW**
- **Moree Hospital, Moree NSW**
- **Orange Health Service, Orange NSW**
- **Parkes District Hospital, Parkes NSW**
- **Tamworth Rural Referral Hospital, Tamworth NSW**
- **Wyong Hospital, Hamlyn Terrace NSW**

The *National Statement on Ethical Conduct in Human Research (2007)* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above study be submitted at 12 monthly intervals. Your review date is **May 2016.** A proforma for the annual report will be sent two weeks prior to the due date.

- A final report must be submitted at the completion of the above study, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.

- All variations or amendments to this study, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.

- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

    - any serious or unexpected adverse events

        - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure.

        - Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Ethics Officer of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.

        - Copies of serious adverse event reports from other sites should be sent to the Hunter New England Human Research Ethics Committee for review as soon as possible after being received.

        - Serious adverse events are defined as:

            - Causing death, life threatening or serious disability.
            - Cause or prolong hospitalisation.
            - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.

    - Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above study does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, the Manager, Research Ethics and Governance Unit as soon as possible.

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The Hunter New England Human Research Ethics Committee also has delegated authority to approve the commencement of this research on behalf of the Hunter New England Local Health District. This research may therefore commence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per the contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Hunter New England Local Health District website.

Please quote **15/04/15/4.04** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Acting Chair
Hunter New England Human Research Ethics Committee

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Appendix 8.2: Research ethics approval related to Papers Two and Three

30 January 2015

Dr Nicholas Zdenkowski
Australia and New Zealand Breast Cancer Trials Group
Trials Coordination Department
PO Box
Hunter Region Mail Centre NSW 2310

Dear Dr Zdenkowski,

Re: ANZ 1301: DOMINO: A phase II study evaluating a decision aid for women considering neoadjuvant systemic therapy for operable invasive breast cancer (14/12/10/4.05)

HNEHREC Reference No: 14/12/10/4.05
NSW HREC Reference No: HREC/14/HNE/502

Thank you for submitting the above application for single ethical review for a multi-centre study. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **10 December 2014.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise that following acceptance under delegated authority of the requested clarifications and revised Participant Information Statements by Dr Nicole Gerrand Manager, Research Ethics & Governance, the Hunter New England Human Research Ethics Committee has granted ethical approval of the above project.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

- For the NEAF [Submission Code: AU/1/200C110];
- For the Victorian Specific Module – Sections 1-5, signed 24 November 2014;
- For the DOMINO Protocol Administrative Change 1 dated 19 January 2015;
- For the DOMINO Protocol Administrative Change 1, Summary of Changes dated 19 January 2015;
- For the Screening Participant Information Statement (Version 2 dated 19 January 2015);
- For the Participant Information Statement (Version 2 dated 19 January 2015);
- For the DOMINO Decision Aid dated 13 January 2015;
- For the DOMINO Screening Form dated 19 January 2015;

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- For the DOMINO Screening Form Summary of Changes dated 19 January 2015;
- For the Withdrawal of Consent Form (Version 1 dated 19 January 2015;
- For the Participant Questionnaires – Appendix C-P DOMINO Protocol;
- For the Participant Telephone Interview – Appendix Q DOMINO Protocol; and
- For the NSW Privacy Form dated 20 November 2014

For the study: **ANZ 1301: DOMINO: A phase II study evaluating a decision aid for women considering neoadjuvant systemic therapy for operable invasive breast cancer (14/12/10/4.05)**

Approval has been granted for this study to take place at the following sites:

- **Calvary Mater Newcastle, Waratah NSW**
- **Mater Adult Hospital, North Sydney NSW**
- **The Royal Melbourne Hospital, Parkville VIC**

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of 3 years from the date of this letter, after which a renewal application will be required if the protocol has not been completed.

The *National Statement on Ethical Conduct in Human Research (2007),* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above protocol be submitted at 12 monthly intervals. Your review date is **January 2016.** A proforma for the annual report will be sent two weeks prior to the due date.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.
- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - any serious or unexpected adverse events
    - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure. These do not need to be reported to the Hunter New England Human Research Ethics Committee
    - Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Manager, Research Ethics & Governance, of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.

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- All other safety reporting should be in accordance with the NHMRC's Safety Monitoring Position Statement – May 2009 available at http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf

- Serious adverse events are defined as:

  - Causing death, life threatening or serious disability.
  - Cause or prolong hospitalisation.
  - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.

- Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, as soon as possible.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **14/12/10/4.05** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Professor M Parsons
Chair
Hunter New England Human Research Ethics Committee

Hunter New England Research Ethics & Governance Unit
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Appendix 8.3: Research ethics approval related to Papers Four and Five

11 December 2014

L/Professor Rob Sanson-Fisher
School of Medicine and Public Health
University of Newcastle
W4, HMRI Building

Dear Professor Sanson-Fisher,

Re: Who decides and at what cost? Comparing patient, surrogate decision makers and provider perceptions about end of life decision making (14/11/19/4.04)

HNEHREC Reference No: 14/11/19/4.04
NSW HREC Reference No: HREC/14/HNE/458

Thank you for submitting the above application for single ethical review. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **19 November 2014.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise that following acceptance under delegated authority of the requested clarifications and revised Information Statements by Dr Nicole Gerrand Manager, Research Ethics & Governance, the Hunter New England Human Research Ethics Committee has granted ethical approval of the above project.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

- For the Invitation to Participants (Version 2 dated 26 November 2014);
- For the Participant Information Statement (Version 2 dated 26 November 2014);
- For the Participant Consent Form (Version 2 dated 26 November 2014);
- For the Participant Baseline Survey (Version 2 dated 26 November 2014);
- For the Participant 3 month Survey (Version 2 dated 26 November 2014);
- For the Surrogate Information Statement (Version 2 dated 26 November 2014);
- For the Surrogate Consent Form (Version 2 dated 26 November 2014);
- For the Support Person Baseline Survey (Version 2 dated 26 November 2014);
- For the Support Person 3 month Survey (Version 2 dated26 November 2014);
- For the Provider Information Statement (Version 2 dated 26 November 2014);
- For the Provider Consent Form (Version 2 dated 26 November 2014); and
- Provider Survey Draft version 2 26 November 2014

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For the study: **Who decides and at what cost? Comparing patient, surrogate decision makers and provider perceptions about end of life decision making**

Approval has been granted for this study to take place at the following site:

- **Calvary Mater Newcastle**

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of 3 years from the date of this letter, after which a renewal application will be required if the protocol has not been completed.

The *National Statement on Ethical Conduct in Human Research (2007),* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above protocol be submitted at 12 monthly intervals. Your review date is **December 2015.** A proforma for the annual report will be sent two weeks prior to the due date.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.
- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - any serious or unexpected adverse events
    - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure. These do not need to be reported to the Hunter New England Human Research Ethics Committee
    - Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Manager, Research Ethics & Governance, of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.
    - All other safety reporting should be in accordance with the NHMRC's Safety Monitoring Position Statement – May 2009 available at http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf
    - Serious adverse events are defined as:
      - Causing death, life threatening or serious disability.
      - Cause or prolong hospitalisation.

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- Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.

- Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, as soon as possible.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **14/11/19/4.04** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Professor M Parsons
Chair
Hunter New England Human Research Ethics Committee

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12 October 2015

L/Professor Rob Sanson-Fisher
School of Medicine and Public Health
University of Newcastle
W4, HMRI Building

Dear Professor Sanson-Fisher

Re: Who decides and at what cost? Comparing patient, surrogate decision makers and provider perceptions about end of life decision making (14/11/19/4.04)

HNEHREC Reference No: 14/11/19/4.04
NSW HREC Reference No: HREC/14/HNE/458
SSA reference number: SSA/15/HNE/3

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Hunter New England Human Research Ethics Committee. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has granted ethical approval for the following amendment requests:

- For the addition of Ms Anne Herrmann as student researcher;
- For the Patient Baseline Survey (Version 4 dated 9 September 2015);
- For the Support Person Survey (Version 4 dated 9 September 2015);
- For the Patient 3 Month Survey (Version 4 dated 9 October 2015);
- For the Surrogate 3 Month Survey (Version 4 dated 9 October 2015);
- For the Discrete Choice Experiment Attributes (version undated); and
- For the Provider Survey (Version 5 dated 9 October 2015)

For the study: **Who decides and at what cost? Comparing patient, surrogate decision makers and provider perceptions about end of life decision making**

Approval has been granted for this study to take place at the following site:

Hunter New England Research Support & Development Office
Locked Bag No 1
New Lambton NSW 2305
Telephone: (02) 49214950 Facsimile: (02) 49214818
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

- **Calvary Mater Newcastle**

Approval from the Hunter New England Human Research Ethics Committee for the above study is given for a maximum of 3 years from the date of the approval letter of your initial application after which a renewal application will be required if the study has not been completed. The above study is approved until **December 2017.**

The *National Statement on Ethical Conduct in Human Research (2007)* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above study to be submitted at 12 monthly intervals. Your review date is **December 2015.** A proforma for the annual report will be sent two weeks prior to the due date.
- A final report must be submitted at the completion of the above study, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.
- All variations or amendments to this study, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
    - any serious or unexpected adverse events
        - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this study. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure.
        - Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Ethics Officer of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.
        - Copies of serious adverse event reports from other sites should be sent to the Hunter New England Human Research Ethics Committee for review as soon as possible after being received.
        - Serious adverse events are defined as:
            - Causing death, life threatening or serious disability.
            - Cause or prolong hospitalisation.
            - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.
    - Unforeseen events that might affect continued ethical acceptability of the project.
- If for some reason the above study does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, the Manager, Research Support & Development Office as soon as possible.

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New Lambton NSW 2305
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Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

The Hunter New England Human Research Ethics Committee also has delegated authority to approve the commencement of this research on behalf of the Hunter New England Local Health District. This research may therefore commence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per the contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Hunter New England Local Health District website.

Please quote **14/11/19/4.04** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Acting Chair
Hunter New England Human Research Ethics Committee

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Appendix 9: SURVEYS AND QUESTION GUIDELINE

Appendix 9.1: Survey related to Paper One

Version #3, dated 28/05/2015
In-Clinic Patient Survey

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

In-ClinicPatientSurvey

The survey has 8 sections. It will only take about 15–20 minutes to complete.

The information you give us in this survey will help us to identify how cancer care might be improved in the future. If you are called in for your appointment before you have finished the survey, please inform the research person or clinic staff member. You will be given a postage paid envelope so you can take the survey with you and mail it back to the research team.

Please remember that any information you give us will remain confidential.

If you would like more information about this survey please call our research team on **1800 084 755**.

If completing this survey reminds you of any questions or concerns you have about cancer, we recommend that you discuss these with your doctor. You can also contact the Cancer Council on 13 11 20 to speak with a specialist cancer nurse who can provide you and your family with further information and support.

INSTRUCTIONS

Use a blue or black ballpoint pen or 2B pencil. Do not use a red or felt-tip pen.

PLEASE MARK BY FILLING IN THE BUBBLE OF YOUR CHOICE, AS SHOWN:

Option 1
Option 2
Option 3

IF YOU MAKE A MISTAKE, EITHER ERASE OR PLACE AN 'X' THROUGH THE INCORRECT BUBBLE AND FILL IN THE CORRECT BUBBLE, AS SHOWN:

Option 1
Option 2
Option 3

Thank you for taking the time to complete this survey.

SECTION A: ABOUT YOU

This section asks questions about you and your background. Please fill in the bubble next to the option that best describes your answer or write your answer in the space provided.

A1. What is your date of birth?

☐☐ / ☐☐ / ☐☐☐☐
Day Month Year

A2. How many times have you visited this centre to receive cancer care in the last 6 months?
Please shade one bubble only

- ○ None, this is my first visit
- ○ 1–2 times
- ○ 3–5 times
- ○ 6–10 times
- ○ More than 10 times

A3. Are you male or female?
Please shade one bubble only

- ○ Male
- ○ Female

A4. What is your home postcode?

☐☐☐☐

A5. Are you of Aboriginal or Torres Strait Islander origin?
Please shade one bubble only

- ○ No
- ○ Yes, Aboriginal
- ○ Yes, Torres Strait Islander
- ○ Yes, both Aboriginal and Torres Strait Islander

A6. What is the highest level of education that you have completed?
Please shade one bubble only

- ○ Primary school (Year 6)
- ○ High school (Year 9, 10 or 12)
- ○ Trade or vocational training (e.g. TAFE or college)
- ○ University degree
- ○ Other *(please specify)*

A7. What country were you born in?
Please shade one bubble only

- ○ Australia
- ○ United Kingdom
- ○ New Zealand
- ○ Italy
- ○ China
- ○ India
- ○ Other *(please specify)*

A8. What best describes your employment at this time?
Please shade one bubble only

- ○ Full-time work
- ○ Part-time or casual work
- ○ Home duties
- ○ Unemployed
- ○ Retired or mature age pension
- ○ Disability pension
- ○ Other (please specify)

A9. Do you have an active home internet connection?
Please shade one bubble only

- Yes
- No
- Don't know

A10. On average, how long does it take to get to this centre from where you are currently living?

minutes

A11. Do you have private health insurance?
Please shade one bubble only

- Yes
- No

A12. Do you hold a concession card?
e.g. Health Care Card, Pensioner Concession Card, Department of Veterans' Affairs Card.
Please shade one bubble only

- Yes
- No

A13. What is the date today?

Day / Month / Year

SECTION B: YOUR CANCER JOURNEY

This section asks questions about your cancer and treatment you have received. **If you have been diagnosed with cancer more than once, please answer these questions in relation to your most recent cancer diagnosis.** Please fill in the bubble next to the option that best describes your answer or write your answer in the space provided.

B1. What type of cancer do you have?
Please shade one bubble only

- Haematological or blood (e.g. leukaemia, myeloma)
- Breast
- Colorectal
- Prostate
- Lung
- Melanoma
- Other *(please specify)*

B2. What stage was your cancer when it was first diagnosed?
Please shade one bubble only

- Early
- Advanced and/or incurable
- Don't know

B3. How long ago were you diagnosed with cancer?
Please shade one bubble only

- 0–3 months
- 4–6 months
- 7–12 months
- 1–2 years
- More than 2 years

B4. Have you received any of the following treatments for your cancer?
Please shade all that apply

- ○ Surgery
- ○ Chemotherapy
- ○ Radiation therapy (radiotherapy)
- ○ Hormone therapy (e.g. Tamoxifen, Zoladex, Anodron)
- ○ Biological therapy (e.g. Herceptin, Mabthera)
- ○ Bone marrow transplant
- ○ Stem cell transplant
- ○ I haven't had any treatment
- ○ Other *(please specify)*

B5. Where are you in your cancer journey?
Please shade one bubble only

- ○ I haven't had any treatment, 'watch and wait' only
- ○ I am receiving treatment to try and cure my cancer
- ○ I have completed treatment to cure my cancer and am now in follow-up
- ○ I have been told my cancer cannot be cured and am receiving anticancer treatment
- ○ I have been told my cancer cannot be cured and am not currently receiving anticancer treatment

SECTION C: YOUR QUALITY OF LIFE

We are interested in some things about you and your health. Please answer all of the questions yourself by filling in the bubble that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

	NOT AT ALL	A LITTLE	QUITE A BIT	VERY MUCH
C1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or suitcase?	○	○	○	○
C2. Do you have any trouble taking a long walk?	○	○	○	○
C3. Do you have any trouble taking a short walk outside of the house?	○	○	○	○
C4. Do you need to stay in bed or a chair during the day?	○	○	○	○
C5. Do you need help with eating, dressing, washing yourself or using the toilet?	○	○	○	○
During the past week:				
C6. Were you limited in doing either your work or other daily activities?	○	○	○	○
C7. Were you limited in pursuing your hobbies or other leisure time activities?	○	○	○	○
C8. Were you short of breath?	○	○	○	○
C9. Have you had pain?	○	○	○	○
C10. Did you need to rest?	○	○	○	○
C11. Have you had trouble sleeping?	○	○	○	○

During the past week:	NOT AT ALL	A LITTLE	QUITE A BIT	VERY MUCH
C12. Have you felt weak?	○	○	○	○
C13. Have you lacked appetite?	○	○	○	○
C14. Have you felt nauseated?	○	○	○	○
C15. Have you vomited?	○	○	○	○
C16. Have you been constipated?	○	○	○	○
C17. Have you had diarrhoea?	○	○	○	○
C18. Were you tired?	○	○	○	○
C19. Did pain interfere with your daily activities?	○	○	○	○
C20. Have you had difficulty in concentrating on things, like reading the newspaper or watching television?	○	○	○	○
C21. Did you feel tense?	○	○	○	○
C22. Did you worry?	○	○	○	○
C23. Did you feel irritable?	○	○	○	○
C24. Did you feel depressed?	○	○	○	○
C25. Have you had difficulty remembering things?	○	○	○	○
C26. Has your physical condition or medical treatment interfered with your family life?	○	○	○	○
C27. Has your physical condition or medical treatment interfered with your social activities?	○	○	○	○
C28. Has your physical condition or medical treatment caused you financial difficulties?	○	○	○	○

For the following questions please select the number between 1 and 7 that best applies to you:

C29. How would you rate your overall health during the past week?

(1) (2) (3) (4) (5) (6) (7)

Very poor ——— Excellent

C30. How would you rate your overall quality of life during the past week?

(1) (2) (3) (4) (5) (6) (7)

Very poor ——— Excellent

SECTION D: YOUR FINANCIAL SITUATION

We are interested in the financial needs of people with cancer and whether cancer and its treatment causes financial strain on patients and their households. Please answer the following questions as honestly and as accurately as you can. Please fill in the bubble next to the option that best describes your answer.

D1. Overall, how would you describe the current financial circumstances of your household?
Please shade one bubble only

- (1) Spend more money than we get
- (2) Just break even most weeks
- (3) Able to save money most weeks

D2. How would you rate the financial burden you (and your household) have experienced as a result of your cancer?
Please shade one bubble only

- (1) I/We are better off financially than before being diagnosed
- (2) I/We are doing about the same financially as before being diagnosed
- (3) I/We are a little worse off financially than before being diagnosed
- (4) I/We are much worse off financially than before being diagnosed
- (5) I/We are extremely worse off financially than before being diagnosed

D3. Since your cancer diagnosis, has a doctor, nurse or other health care provider provided you with information about where to get support for dealing with financial issues?
Please shade one bubble only

- (1) Yes, and I got the information I wanted
- (2) Yes, but I did not get the information I wanted
- (3) Yes, but I did not want this information
- (4) No, but I wanted this information
- (5) No, but I did not want this information
- (6) Not applicable

D4. Since your cancer diagnosis, have any of the following scenarios happened because of a shortage of money?
Please shade all that apply

- Could not pay rent/or missed a mortgage repayment
- Could not pay electricity, gas or phone bills on time
- Could not pay for car registration or insurance on time
- Pawned or sold something
- Went without some meals
- Unable to heat or cool my home
- Sought assistance from welfare/community organisations
- Sought financial help from friends or family
- None of the above

D5. Since your cancer diagnosis, have you delayed or gone without any of the following medical treatments or other health care because of a shortage of money?
Please shade all that apply

- Medication
- Medical procedure
- Doctor / specialist visit or appointment
- Home modification (e.g. ramp, rails)
- Complementary or alternative therapy
- In home care (e.g. nurse visits)
- Out of home care (e.g. respite)
- None of the above

SECTION E: YOUR DECISIONS ABOUT TREATMENT

This section asks questions about decisions you have faced regarding your cancer treatment. **When answering these questions, please think back to your last important decision about your cancer treatment.** Please fill in the bubble next to the option that best describes your answer.

E1. How involved were you in making that decision?
Please shade one bubble only

- I made the decision about which treatment I would receive
- I made the final decision about my treatment after seriously considering my doctor's opinion
- Both my doctor and I shared responsibility for deciding which treatment was best for me
- My doctor made the final decision about which treatment would be used, but seriously considered my opinions
- I left all decisions regarding my treatment to my doctor

E2. How involved would you like to be in making the decision?
Please shade one bubble only

- I prefer to make the decision about which treatment I will receive
- I prefer to make the final decision about my treatment after seriously considering my doctor's opinion
- I prefer that my doctor and I share responsibility for deciding which treatment is best for me
- I prefer that my doctor makes the final decision about which treatment will be used, but seriously considers my opinions
- I prefer to leave all decisions regarding my treatment to my doctor

E3. Did a doctor, nurse or other health care provider:	YES, AND I WANTED THIS	YES, BUT I DID NOT WANT THIS	NO, BUT I WANTED THIS	NO, BUT I DID NOT WANT THIS	NOT APPLICABLE
a. Ask you how involved you would like to be in making decisions about your cancer care?	1	2	3	4	5
b. Inform you about the possible benefits of your decision?	1	2	3	4	5
c. Inform you about the possible risks of your decision?	1	2	3	4	5
d. Provide you with enough time to think about the options?	1	2	3	4	5

E4. Would you feel comfortable declining a treatment that was recommended by your doctor?
Please shade one bubble only

1. Yes, if I thought it was not in my best interests
2. No, I trust the doctor to know what is best for me

SECTION F: YOUR MEDICATIONS

This sections asks questions about medications you have taken **to treat your cancer**. Please fill in the bubble next to the option that best describes your answer.

F1. In the last week, have you:
Please shade all that apply

1. Missed one or more doses of your medication
2. Taken one or more of your medications at the wrong time
3. Taken the wrong dose of one or more of your medications (This can include taking more medication or less medication than you were prescribed.)
4. Taken your medication exactly as instructed for the entire week
5. I have not been prescribed medication to treat my cancer

F2. In the last 6 months, have you stopped taking any prescribed cancer-related medications without first discussing this with your doctor?
Please shade one bubble only

1. Yes
2. No
3. Don't know
4. Not applicable

SECTION G: YOUR DISCUSSIONS ABOUT LIFE EXPECTANCY

The following section asks questions about your discussions with your cancer doctor about how cancer will affect the length of your life (i.e. your life expectancy). These questions have nothing to do with your current state of health. We are asking everyone that attends this clinic to answer these questions. Your answers will help us to identify how care might be improved in the future. Life expectancy may be a sensitive topic for some people. **If you would prefer not to answer these questions, please fill in the bubble below and skip to Section H; otherwise please continue to G1.**

○ I do not wish to answer these questions

Please fill in the bubble next to the option that best describes your answer.

G1. What information would you like your doctor to tell you about your life expectancy?
Please shade all that apply

- ○ Only the news my doctor thinks I can handle
- ○ Only the good news
- ○ Everything my doctor can tell me
- ○ I would prefer my family to decide what I should be told
- ○ Don't know
- ○ I don't want any information about life expectancy

G2. Since being diagnosed with cancer, have you and your doctor talked about your life expectancy?
Please shade one bubble only

- ○ Yes, and I wanted to talk about it
- ○ Yes, but I did not want to talk about it
- ○ No, but I wanted to talk about it → **Go to Section H**
- ○ No, but I did not want to talk about it → **Go to Section H**

G3. Did your doctor ask you what information you wanted to know about life expectancy?
Please shade one bubble only

- ○ Yes, and I got the information I wanted
- ○ Yes, but I did not get the information I wanted
- ○ No, but I got the information I wanted
- ○ No, and I did not get the information I wanted

G4. Did your doctor discuss the information in a sensitive and respectful manner?
Please shade one bubble only

- ○ Yes
- ○ No

SECTION H: YOUR DISCUSSIONS ABOUT END OF LIFE CARE

The following section asks questions about your discussions with your cancer doctor about the end of life care you would want to receive. These questions have nothing to do with your current state of health. We are asking everyone that attends this clinic to answer these questions. Your answers will help us to identify how care might be improved in the future. End of life care may be a sensitive topic for some people. **If you would prefer not to answer these questions, you can fill in the bubble below and stop the survey here; otherwise please continue to H1.**

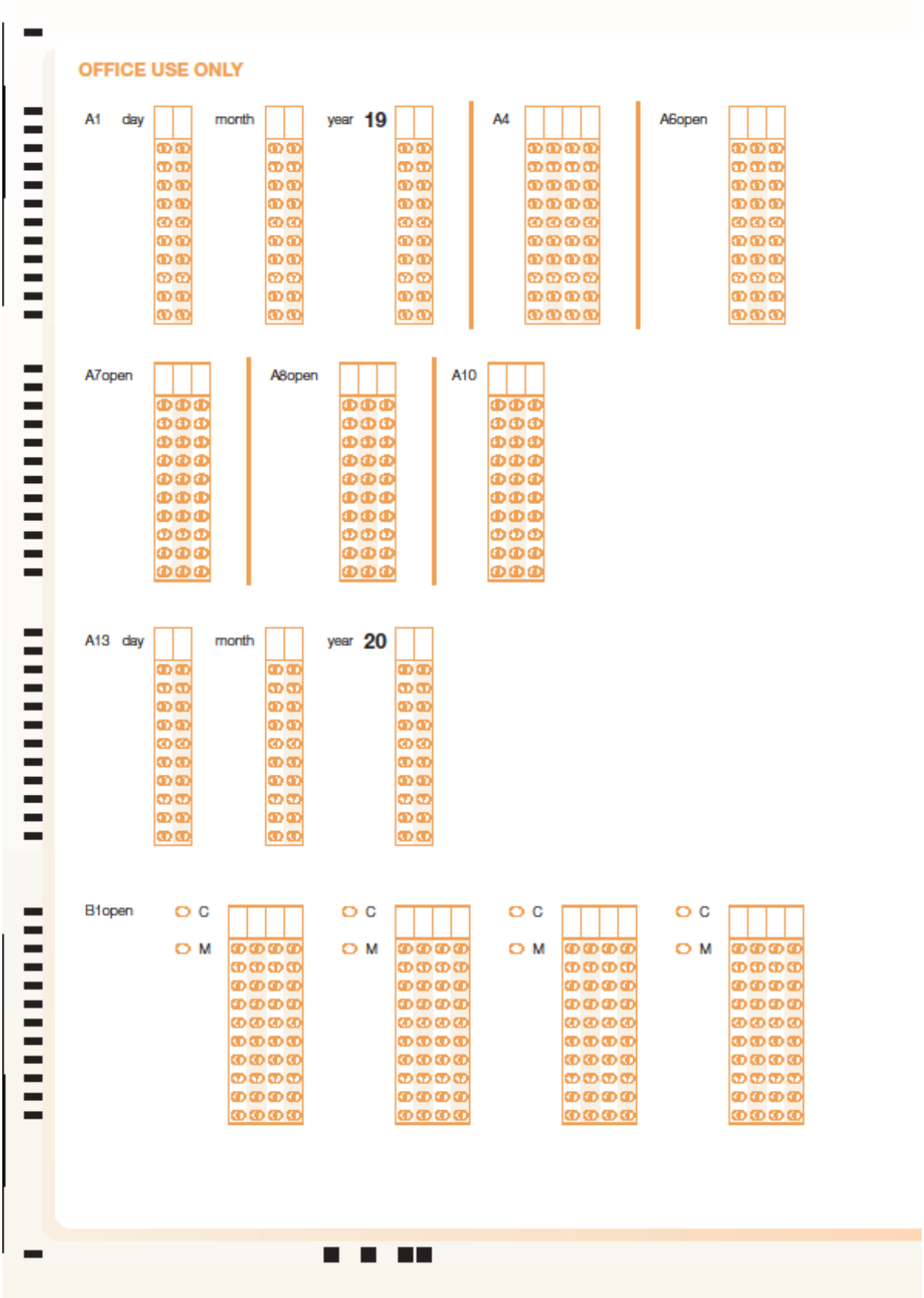
○ I do not wish to answer these questions

Please fill in the bubble next to the option that best describes your answer.

H1. My preferences for the type of care I would want to receive at the end of life:	YES, AND I WANTED THIS	YES, BUT I DID NOT WANT THIS	NO, BUT I WANTED THIS	NO, BUT I DID NOT WANT THIS	NOT APPLICABLE
a. Have been discussed between myself and a member of my health care team (doctor, nurse or other health worker)	○ 1	○ 2	○ 3	○ 4	○ 5
b. Have been discussed between myself and my support person (family member or friend)	○ 1	○ 2	○ 3	○ 4	○ 5
c. Have been recorded in a written document (e.g. an advance directive or advance care plan)	○ 1	○ 2	○ 3	○ 4	○ 5

END OF SURVEY
THANK YOU!

Appendix 9.1: Survey related to Paper One



Appendix 9.2: Question guideline related to Papers Two and Three

Evaluation of a decision aid for women considering neoadjuvant systemic therapy for operable breast cancer (ANZ 1301 DOMINO)

Opening Script Detail

- *Hello, my name is ……;*
- *I'm a cancer researcher working with the Australia and New Zealand Breast Cancer Trials Group.*
- *I am contacting you to ask you about your recent experience participating in the breast cancer decision aid research project.*
- *I would like to talk to you about this and ask you a few questions, which will take up to 30 minutes of your time.*
- *Are you still happy to participate? If so, is now appropriate time to talk to you (If not, can I make a time with you to call back)?*
- *Before we begin I would like to let you know that these interviews will be recorded and typed, and will remain confidential.*

Telephone Interview Question Guide
Preamble - Experience with the decision aid

- *I would like to talk to you about your decision for or against chemotherapy before surgery.*
- *I'm interested in how you made that decision and if you used the decision aid, I will also ask some questions regarding that.*
- *But first, it would be great if you could tell me everything that comes into your mind when you think of this decision.*
- *I will listen carefully, take notes and ask further questions later on.*
- *Now, could you tell me: How did you make the decision for or against chemotherapy before surgery?*

Appendix 9.2: Question guideline related to Papers Two and Three

Information needs

1. Where did you get information to help make a decision about whether to have chemotherapy before surgery?
    a. Surgeon
    b. Medical Oncologist
    c. Other health professional, specify:
    d. Family/friends
    e. Written information, source:
    f. Internet information, source:
    g. Other, specify:
2. Which of these did you find most useful?
3. What exactly was the information that helped you make the decision? In other words, what facts were you given that helped you make the decision?
4. Were you given enough information to allow you to make a decision?
5. What other information would you like to have received?
6. How would you like it presented to you?
    a. Verbally
    b. Written
    c. Interactive process - computer or paper
    d. Other, specify:

Decision-making

7. Who made the decision in the end?
8. What was difficult about making the decision?
9. How certain were you about the decision at the time?
    a. Very
    b. Quite
    c. Somewhat
    d. Uncertain
10. How certain are you now, that you made the right decision?
    a. Very
    b. Quite
    c. Somewhat
    d. Uncertain
11. If your certainty changed, can you say why?

Psychological concerns

12. Do you/did you worry that your cancer will get worse whilst having chemotherapy?
13. What aspects of the period of chemotherapy and surgery did you find most difficult? (mentally and physically)
14. Do you worry that your cancer will come back?

Experiences with the DA

I would like to ask you some more question about the decision aid.

15. How much time did you spend using the decision aid?
16. Did it provide additional information to that provided by the doctors, nurses and other health professionals?
17. Was the information relevant to your decision?
    a. In what way was it relevant/not relevant?
    b. How did it factor into your decision?
18. Was the information trustworthy?
19. Was it presented in a way that was easy to understand?
20. Was it too long, about right or too short?
21. Was the amount of information too much, about right, or too little?
22. Did the DA favour NAST, was it balanced or did it favour surgery?
23. Do you have any other comments on the DA?

Factors relevant to the decision about neoadjuvant chemotherapy

Finally, a few more questions about factors that might have influenced your decision.

24. How important were each of these factors to you?
    a. Having breast conserving surgery (lumpectomy)
    b. Being able to know whether the cancer responded to chemotherapy
    c. Having treatment sooner for the whole body, not just the breast
    d. Being involved in a clinical trial
25. Did your doctor talk to you about participating in a clinical trial?
    a. How did that affect your decision?
26. Did your ability to have children in the future affect your decision? e.g. IVF cycles and egg collections.
    a. How did it affect the decision?
27. Are you aware of breast cancer being inherited in your family, e.g. BRCA1/BRCA2?
    a. Was that relevant to your decision?
28. What other issues did you consider when making a decision?
    a. Financial
    b. Logistic: availability of surgery or chemotherapy
    c. Other:
29. Did you consider having a breast reconstruction?
    a. How did that affect the decision?

Thank you.

Other comments

30. Do you have any other comments that you would like to make?

Closing remarks

- *Those are all of the questions that I wanted to ask you.*
- *Just a reminder, our conversation today is confidential and the results will only be used and presented anonymously without any reference to your identity.*
- *Thank you for your time, your information has been very helpful.*
- *Your comments will be used to improve the content of the decision aid, and the way that it is used.*
- *If you have any questions or concerns later on, please feel free to contact the study coordinator at the site where you were recruited to this trial.*

Appendix 9.3: Surveys related to Papers Four and Five

Version # 3, dated 6/05/2015
Who decides and at what cost

School of Medicine and Public Health

PATIENT BASELINE SURVEY

The survey will take about 15-20 minutes to complete.

The information you give us by completing this survey will help us to identify how cancer care might be improved in the future. **These questions have nothing to do with your current state of health.**

Any information you give us will remain confidential.

If you would like more information about the purpose of this survey please call the research team on 1800 084 755.

If this survey has raised questions or concerns about your cancer, we suggest that you discuss these with your doctor. You can also contact the 13 11 20 Information and Support which is staffed by health professionals.

Thank you for taking the time to complete this survey

The following questions ask for some background information about you. *Please **circle the number** that corresponds to your answer.*

1	Are you **male** or **female**?	**1** Male **2** Female
2	What is your **date of birth**?	___ ___ / ___ ___ / ___ ___ ___ ___ Day Month Year
3	What **type of cancer** do you have?	**1** Breast **2** Prostate **3** Lung **4** Colorectal **5** Other (please specify) _____
4	**Where are you** in your cancer journey?	**1** I am receiving treatment to try and cure my cancer **2** I have completed treatment to cure my cancer and am now in follow-up **3** I have been told my cancer cannot be cured and I am receiving anticancer treatment (e.g. chemotherapy, radiotherapy) **4** I have been told my cancer cannot be cured, and am not currently receiving anticancer treatment
5	What is your **postcode**?	___ ___ ___ ___
6	What country were you born in?	**1** Australia **2** Other (please specify) _____
7	Are you of **Aboriginal or Torres Strait Islander** origin?	**1** No **2** Yes, Aboriginal **3** Yes, Torres Strait Islander **3** Yes, both Aboriginal and Torres Strait Islander
8	How would you rate your current **quality of life**? *Please circle one number*	1 2 3 4 5 6 7 8 9 10 Poor Exceller

PLEASE continue to NEXT PAGE

Advance care planning (ACP) provides an opportunity for people to think, discuss and plan for the medical treatment they would prefer if they became too ill in the future to express their wishes. Everyone should consider advance care planning, regardless of their age or health. But, it is particularly important for people who have ongoing health problems.

These questions ask for your views and experiences in talking and making decisions about your future medical care, including end of life care. End of life care refers to care that helps people with advanced, incurable illness to live as well as possible until they die.

These questions have nothing to do with your current state of health. We are asking everyone that attends this clinic to answer these questions.

Have you ever discussed the type of end of life care you would like to receive with your:	**Yes**	**No**
9 Doctor	1	2
10 Support person *(e.g. spouse/partner, family member or friend).*	1	2
Have you ever discussed where you would like to be cared for at the end of your life with your:	**Yes**	**No**
11 Doctor	1	2
12 Support person *(e.g. spouse/partner, family member or friend).*	1	2
Have you:	**Yes**	**No**
13 Written down your wishes for end of life care *(e.g. in an advance directive or advance care plan)?*	1	2
14 Appointed an enduring guardian? *(i.e. someone legally appointed to make medical decisions on your behalf if you are unable to make decisions yourself)*	1	2

15 If you became physically or mentally unable to make decisions on your own, would you prefer your end of life care to be decided by:	**1**	A **plan you had made** before you got too sick to make decisions.
	2	**Your doctor with your family/friends,** based on their views of what was best
	3	Only **your doctor**, based on their view of what was best for you

Appendix 9.3: Surveys related to Papers Four and Five (patient baseline survey, Calvary Mater Newcastle)

These questions ask **what you would want if you were facing the end of your life**. These questions have nothing to do with your current state of health. We are asking everyone that attends the clinic to answer these questions.

I If I needed end of life care, I would be worried about:	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
16 Being in pain	1	2	3	4	5
17 Loss of dignity	1	2	3	4	5
18 Being alone when I die	1	2	3	4	5
19 Not being at peace	1	2	3	4	5
20 Not being able to recognise family/friends	1	2	3	4	5
21 Family / friends seeing me in pain	1	2	3	4	5
22 Family / friends having to become full-time carers	1	2	3	4	5
23 Doctors not providing information about all of the treatments available to me	1	2	3	4	5
24 Receiving a treatment I do not want	1	2	3	4	5
I would want my health care team to ask me:	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
25 How involved I want to be in decisions about my end of life care	1	2	3	4	5
26 Where I would prefer to die (e.g. at home, in hospital, hospice, other care facility)	1	2	3	4	5
27 How important it is that my pain is managed well at the end of life	1	2	3	4	5
28 How important it is I remain conscious and able to talk with my loved ones.	1	2	3	4	5
29 How important it is that my care extends my life for as long as possible	1	2	3	4	5

I would <u>want to be able to:</u>	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
30 Access palliative care (*i.e. care that aims to manage symptoms and improve quality of life*)	1	2	3	4	5
31 Have my family / friends present when discussing my end of life care options	1	2	3	4	5
32 Write down my wishes for end of life care *(e.g. in an advance directive or care plan)*	1	2	3	4	5
33 Appoint someone to make decisions on my behalf if I was unable to make decisions myself	1	2	3	4	5
34 Access medications that allow me to end my own life if I wish	1	2	3	4	5
35 Die in the location of my choice (e.g. at home, hospital, hospice, other facility)	1	2	3	4	5

36 When would it be best to have **the first conversation** with your doctor about end of life care? *Please circle one number*	**1** When you are first diagnosed **2** When your cancer becomes incurable **3** When you decide to raise the matter **4** When your doctor decides to raise it **5** Would not want to discuss at all
37 If you could choose, would you **prefer end of life care** that focuses on:	**1** **Extending life as much as possible**, even if it meant more pain and discomfort **2** **Relieving pain and discomfort** as much as possible, even if it meant not living as long **3** **Unsure**
38 What is **your estimation** of your life expectancy?	**1** Less than 6 months **2** 6 months – 1 year **3** 1-2 years **4** More than 2 years **5** Don't know, but I would like this information **6** Don't know and I do not want this information

PLEASE continue to NEXT PAGE

A recent study compared patients who had palliative chemotherapy with those who did not have such care. All patients had a life expectancy of up to six months. Patients who had palliative chemotherapy lived no longer than those who did *not* have this treatment. There were other differences between the two groups of patients in the last week of life. These differences are shown below.

Type of care received in the last week of life	% of patients who received this type of care	
	Patients who did not have chemotherapy	Patients who had chemotherapy
Put on a breathing machine and/or had cardiopulmonary resuscitation (CPR)	2%	14%
Died in an intensive care unit	2%	11%
Fed through a tube	5%	11%
Died at home	66%	47%
Died in their preferred location	80%	65%
Referred late to specialist palliative care	37%	54%

39 If you were in this situation would you choose to have palliative chemotherapy?

Please circle one number	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
I would choose to have palliative chemotherapy	1	2	3	4	5

PLEASE continue to NEXT PAGE

PLEASE NOTE: YOU WILL ONLY NEED TO ANSWER QUESTIONS ON ONE OF THE COLOURED PAGES AS INDICATED IN THE RESPONSE OPTIONS IN Q40 BELOW

40	If you had a choice, **where would you prefer** to be cared for at the end of life?	**1** In your own home (go to **blue page** 8) **2** In a relative's home (go to **blue page** 8) **3** In a hospital (go to **yellow page** 9) **4** In a hospice / palliative care unit (go to **green page** 10)

BLUE PAGE – PREFERRED CARE AT HOME

41 Which of the following might be benefits to receiving end of life care AT HOME? Please select your TOP 3 benefits in order of importance by placing a '1', '2' or '3' in the corresponding box (1=most important to you). Please select THREE boxes only.

	Receiving care from family and/or friends
	Familiar environment
	Not being alone
	Having the food I like
	Religious/spiritual beliefs and needs (or lack thereof) will be respected
	Using own bathroom
	Feeling like dying is a natural process
	Family might be able to have a more "normal life"
	Physical closeness to loved ones and/or sharing a bed

42 Which of the following might you be most worried about if you received end of life care AT HOME? Please select the TOP 3 things that might worry you by placing a '1', '2' or '3' in the corresponding box (1='most worrying'). Please select THREE boxes only.

	Not having expert medical care
	Not knowing who to call if I need help
	Emotional "scarring" of family/friends
	Not having people who can or will care for me at home.
	Family/friends not knowing what to do during and after death
	Not having access to special equipment (e.g. hospital bed, commode)
	Dying alone
	Dying and not being found for several hours
	Being isolated
	Not having my pain managed well

PLEASE SKIP TO PAGE 11

YELLOW PAGE – PREFERRED CARE AT HOSPITAL

43 Which of the following might be benefits to receiving end of life care IN A HOSPITAL? Please select your TOP 3 benefits in order of importance by placing a '1', '2' or '3' in the corresponding box (1=most important to you). Please select THREE boxes only.

	Lots of medical care
	Pain being managed well
	Not being alone
	Don't have to "burden" family/friends
	Medical staff on call
	Family might be able to have more of a "normal life"
	Not having to cook and clean
	Access to special equipment (e.g. hospital bed, commode)

44 Which of the following might you be most worried about if receiving end of life care IN HOSPITAL? Please select the TOP 3 things that might worry you by placing a '1', '2' or '3' in the corresponding box (1='most worrying'). Please select THREE boxes only.

	Not having my wishes respected.
	Not being treated respectfully
	The environment may be clinical and unfriendly
	Being isolated
	Lack of privacy
	Other people being unwell
	Noisy surroundings
	Family/friends last memory being of me in a hospital environment
	Getting an infection or getting sicker from being at hospital
	Visitor's hours may be limited
	Being woken up for tests
	Hospital may be a distance for visitors to travel
	Difficulty being physically close to loved ones or sharing a bed
	Religious/spiritual beliefs and needs (or lack thereof) not being respected

PLEASE SKIP TO PAGE 11

GREEN PAGE – PREFERRED CARE AT HOSPICE

45 Which of the following might be benefits to receiving end of life care IN A HOSPICE (palliative care)? Please select your TOP 3 benefits by placing a '1', '2' or '3' in the corresponding box (1=most important to you). Please select THREE boxes only.

	Specialised medical care
	Pain being managed well
	Medical staff on call
	Not being alone
	Religious/spiritual beliefs and needs (or lack thereof) will be respected
	Feeling like dying is a natural process
	Family might be able to have more of a "normal life"
	Staff are used to people dying
	Don't have to cook or clean
	Don't have to "burden" family/friends

46 Which of the following might you be most worried about if you received end of life care IN A HOSPICE? Please select the TOP 3 things that might worry you by placing a '1', '2' or '3' in the corresponding box (1='most worrying'). Please select THREE boxes only.

	Not being resuscitated
	The environment may be clinical and unfriendly
	Religious/spiritual beliefs (or lack thereof) not being respected
	Being isolated
	Lack of privacy
	Getting used to the environment
	Other people dying
	Not being able to smoke or drink
	Being woken up for tests
	Hospice may be a distance for visitors to travel
	Might not be "ready" to die

	Difficulty being physically close to loved ones or sharing a bed
	Family/friends last memory of me being of me in a hospice
	Potential for getting infections

PLEASE continue to next page

47 Has this survey caused you any stress?	**1** Yes, and I would prefer not to answer these questions **2** Yes, but I think these questions are important **3** No
48 Did you need help completing this survey?	**1** I completed on my own **2** My support person helped **3** My doctor/nurse helped

Are you willing to be complete a second survey about your experiences in 3 months' time? The information you give will allow us to improve the quality of cancer care.

Please tick (✓) one box to indicate your answer.

□ **Yes**

Title (Please circle one) Dr / Mr / Mrs / Ms / Miss	
First Name:	**Last name:**
Postal address:	
State:	**Postcode:**
Phone number:	**Email:**
Signature:	
Preferred method of contact (*circle all that apply):* **Mail Email Telephone**	

□ **No**

Thank you for completing the survey. Your time is greatly appreciated. If you have any additional comments please write them below or on the back of the page.

_____
_____
_____
_____
_____
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_____
_____
_____
_____

Version # 4, dated 09/10/2015

Who decides and at what cost

PATIENT 3 month SURVEY

The survey will take about 15-20 minutes to complete.

The information you give us by completing this survey will help us to identify how cancer care might be improved in the future. **These questions have nothing to do with your current state of health.**

Any information you give us will remain confidential.

If you would like more information about the purpose of this survey or the questions we are asking, please call the research team on 1800 084 755.

If this survey has raised questions or concerns about your cancer, we suggest that you discuss these with your doctor. You can also contact the 13 11 20 Information and Support which is staffed by health professionals.

Thank you for taking the time to complete this survey

Appendix 9.3: Surveys related to Papers Four and Five (patient follow-up survey, Calvary Mater Newcastle)

The following questions ask for your views about your involvement in making decisions about your medical care. Please answer every question, unless the instructions ask you to skip ahead to another question. **Please circle the number next to the answer that best describes your answer to each question, unless otherwise stated.** If you are unsure about an answer, please give the best answer you can.

1	**When making important treatment decisions, how involved would you like to be in making the decision?** **I would prefer:** *(Please circle one number only)*	1. To make the final decision 2. To make the final decision after seriously considering my doctors opinion 3. My doctor and I share responsibility for deciding 4. My doctor makes the final, after listening to my opinion 5. To leave all decisions to my doctor
2	**Thinking back to when you last made a decision about your cancer treatment, how involved were you in making that decision?** *(Please circle one number only)*	1. I made the final decision 2. I made the final decision after seriously considering my doctors opinion 3. My doctor and I shared responsibility for deciding 4. My doctor made the final decision, after listening to my opinion 5. I let my doctor make the final decision
3	**What was the treatment decision that you last made?**	1. Chemotherapy 2. Radiation therapy (or radiotherapy) 3. Surgery 4. Other (please specify)
4	**Looking back at your treatment decision, would you make the same decision again?**	1. Yes 2. No 3. Unsure
5	**What treatment are you currently receiving?** ***(please circle all that apply)***	1. Chemotherapy 2. Radiation therapy (or radiotherapy) 3. Surgery 4. Palliative care 5. None 6. Other (please specify)

Appendix 9.3: Surveys related to Papers Four and Five (patient follow-up survey, Calvary Mater Newcastle)

The goal of my current treatment is to:	Yes	No
6 Help me live longer	1	2
7 Try to make me feel better	1	2
8 Get rid of all my cancer	1	2

Imagine the following: Your doctor has told you about different treatment options for your cancer. He has asked you to decide which treatment you would like to have.

Importantly:

- **There is no difference between the treatment options in terms of how they will affect your length of life.**
- **However, the treatment options have different pros and cons. Your doctor believes that it is important that the decision is yours. He is happy for you to have either type of treatment. The decision depends on how you feel about the pros and cons of the options.**
- **Whichever treatment you choose it will start in two weeks from your first appointment.**

We are interested in finding out what you think would help you most in making this decision.
If you were in that situation, which of the scenarios below would you like most? Also, which of the scenarios would you like least?
For each question please choose one option only by ticking one of the relevant boxes.[1]

[1] **Please note:** For each questionnaire, the order of the scenarios was randomly allocated. As such, the surveys included in the appendices of this thesis show examples of sets of scenarios presented to participants.

	Scenario 1	**Scenario 2**	**Scenario 3**	**Scenario 4**
Time to make a decision	Your doctor explains your treatment options in **one 40 minute visit**. You discuss your options with your doctor. You choose a treatment together by the end of your visit.	Your doctor explains your treatment options in **one 20 minute visit**. You have **another 20 minute visit** one week later. You discuss your options with your doctor. You choose a treatment together by the end of the second visit.	Your doctor explains your treatment options in **one 40 minute visit**. You discuss your options with your doctor. You choose a treatment together by the end of the visit.	Your doctor explains your treatment options in **one 20 minute visit**. You have **another 20 minute visit** one week later. You discuss your options with your doctor. You choose a treatment together by the end of the second visit.
Additional information	Your doctor gives you **a booklet** with extra written information about your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options. Your doctor also provides you with access to **a website** with further written and video information on your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options. Your doctor also provides you with access to **a website** with further written and video information on your treatment options.
I would like MOST Please tick <u>one</u> box in this row:	☐	☐	☐	☐
I would like LEAST Please tick <u>one</u> box in this row:	☐	☐	☐	☐

Advance care planning (ACP) provides an opportunity for people to think, discuss and plan for the medical treatment they would prefer if they became too ill in the future to express their wishes. These questions ask for your views and experiences in talking and making decisions about your future medical care, including end of life care.

These questions have nothing to do with your current state of health.

Have you discussed the type of end of life care you would like to receive with your:	**Yes**	**No**
9 Doctor	1	2
10 Support person *(e.g. spouse/partner, family member or friend).*	1	2
Have you discussed where you would like to be cared for at the end of your life with your:	**Yes**	**No**
11 Doctor	1	2
12 Support person *(e.g. spouse/partner, family member or friend).*	1	2
Have you:	**Yes**	**No**
13 Written down your wishes for end of life care *(e.g. in an advance directive or advance care plan)?*	1	2
14 Appointed an enduring guardian? *(i.e. someone legally appointed to make medical decisions on your behalf if you are unable to make decisions yourself)*	1	2

The next set of questions present an imaginary scenario where a person is asked to choose between three different types of care. We are interested in finding out what type of care you think you would choose if you were in that situation.

EXAMPLE: This is an example only. Your questions begin on the next page (Page 8).

SCENARIO

- A patient has been told that they have incurable cancer and they only have about a month to live.
- The doctor tells the patient there are three types of care they can have.
- Each type of care will be different in terms of how it affects their length of life, how much pain they will feel and how much of the time they will be conscious (i.e. mentally alert).
- The person must choose one of the three care types (Care A, B or C).

If you were the one being asked to choose between Care A, B or C below which type of care would you:

- **Most prefer** for yourself.
- **Least prefer** for yourself.

	Care A	Care B	Care C
Patient will feel	Mild pain (3 out of 10)	Moderate pain (5 out of 10)	Severe pain (8 out of 10)
Patient will be conscious *(i.e mentally aware of people and surroundings and able to communicate)*	Some of the time	Half of the time	Most of the time
Patient's length of life will be extended by:	Two weeks	One week	Three weeks
I would MOST PREFER *(PLEASE TICK ONE BOX):*	√	☐	☐
I would LEAST PREFER *(PLEASE TICK ONE BOX):*	☐	√	☐

Please answer Q10 and 11 below

SCENARIO

- A patient has been told that they have incurable cancer and they only have about a month to live.
- The doctor tells the patient there are three types of care they can have.
- Each type of care will be different in terms of how it affects their length of life, how much pain they will feel and how much of the time they will be conscious (i.e. mentally alert).
- The person must choose one of the three care types (Care A, B or C).

If you were the one being asked to choose between Care A, B or C below which type of care would you:

- **Most prefer** for yourself.
- **Least prefer** for yourself.

	Care A	Care B	Care C
Patient will feel	Moderate pain (5 out of 10) (10 = worst pain)	Mild pain (3 out of 10) (10 = worst pain)	Severe pain (8 out of 10) (10 = worst pain)
Patient will be conscious *(i.e mentally aware of people and surroundings and able to communicate)*	Some of the time	Half of the time	Most of the time
Patient's length of life will be extended by:	Two weeks	One week	Three weeks
10 If I was being asked to choose, I would MOST PREFER *(PLEASE TICK ONE BOX):*	☐	☐	☐
11 If I was being asked to choose, I would LEAST PREFER *(PLEASE TICK ONE BOX):*	☐	☐	☐

Please answer Q12 and 13 below

SCENARIO

- A patient has been told that they have incurable cancer and they only have about a month to live.
- The doctor tells the patient there are three types of care they can have.
- Each type of care will be different in terms of how it affects their length of life, how much pain they will feel and how much of the time they will be conscious (i.e. mentally alert).
- The person must choose one of the three care types (Care A, B or C).

If you were the one being asked to choose between Care A, B or C which type of care would you:

- **Most prefer** for yourself.
- **Least prefer** for yourself.

	Care A	Care B	Care C
Patient will feel	Mild pain (3 out of 10) (10 = worst pain)	Severe pain (8 out of 10) (10 = worst pain)	Moderate pain (5 out of 10) (10 = worst pain)
Patient will be conscious *(i.e mentally aware of people and surroundings and able to communicate)*	Most of the time	Half of the time	Some of the time
Patient's length of life will be extended by:	One week	Three weeks	Two weeks
12 If I was being asked to choose, I would MOST PREFER *(PLEASE TICK ONE BOX):*	☐	☐	☐
13 If I was being asked to choose, I would LEAST PREFER *(PLEASE TICK ONE BOX):)*	☐	☐	☐

Please answer Q14 and 15 below

SCENARIO

- A patient has been told that they have incurable cancer and they only have about a month to live.
- The doctor tells the patient there are three types of care they can have.
- Each type of care will be different in terms of how it affects their length of life, how much pain they will feel and how much of the time they will be conscious (i.e. mentally alert).
- The person must choose one of the three care types (Care A, B or C).

If you were the one being asked to choose between Care A, B or C which type of care would you:

- **Most prefer** for yourself.
- **Least prefer** for yourself.

	Care A	Care B	Care C
Patient will feel	Mild pain (3 out of 10) (10 = worst pain)	Moderate pain (5 out of 10) (10 = worst pain)	Severe pain (8 out of 10) (10 = worst pain)
Patient will be conscious *(i.e mentally aware of people and surroundings and able to communicate)*	Some of the time	Most of the time	Half of the time
Patient's length of life will be extended by:	Three weeks	One week	Two weeks
14 If I was being asked to choose, I would MOST PREFER *(PLEASE TICK ONE BOX):*	☐	☐	☐
15 If I was being asked to choose, I would LEAST PREFER *(PLEASE TICK ONE BOX):*	☐	☐	☐

The following questions ask for some background information about you. *Please **circle the number** that corresponds to your answer.*

16 Where are you in your cancer journey?	**1** I am receiving treatment to try and cure my cancer **2** I have completed treatment to cure my cancer and am now in follow-up **3** I have been told my cancer cannot be cured and I am receiving anticancer treatment (e.g. chemotherapy, radiotherapy) **4** I have been told my cancer cannot be cured, and am not currently receiving anticancer treatment
17 How would you rate your current **quality of life**? *Please circle one number*	1 2 3 4 5 6 7 8 9 10 Poor Excellent
18 How would you rate your current **overall health**? *Please circle one number*	1 2 3 4 5 6 7 8 9 10 Poor Excellent
19 If you could choose, would you **prefer end of life care** that focuses on:	**1** **Extending life as much as possible**, even if it meant more pain and discomfort **2** **Relieving pain and discomfort** as much as possible, even if it meant not living as long **3** **Unsure**
20 What is **your estimation** of your life expectancy?	**1** Less than 6 months **2** 6 months – 1 year **3** 1-2 years **4** More than 2 years **5** Don't know, but I would like this information **6** Don't know and I do not want this information

21 **If you could choose, where would you prefer** to be cared for at the end of life?	**1** In my own home **2** In a relative's home **3** In a hospital **4** In a hospice / palliative care unit

Thank you for completing the survey. Your time is greatly appreciated. If you have any additional comments please write them below or on the back of page.

PATIENT SURVEY

The survey will take about 5 minutes to complete.

The information you give us by completing this survey will help us to identify how cancer care might be improved in the future. **These questions have nothing to do with your current state of health.**

Any information you give us will remain confidential.

If you would like more information about the purpose of this survey please call the research team on 1800 084 755.

If this survey has raised questions or concerns about your cancer, we suggest that you discuss these with your doctor. You can also contact the 13 11 20 Information and Support which is staffed by health professionals.

Thank you for taking the time to complete this survey

Imagine the following: Your doctor has told you about different treatment options for your cancer. He has asked you to decide which treatment you would like to have.

Importantly:

- **There is no difference between the treatment options in terms of how they will affect your length of life.**
- **However, the treatment options have different pros and cons. Your doctor believes that it is important that the decision is yours. He is happy for you to have either type of treatment. The decision depends on how you feel about the pros and cons of the options.**
- **Whichever treatment you choose it will start in two weeks from your first appointment.**

We are interested in finding out what you think would help you most in making this decision.

If you were in that situation, which of the scenarios below would you like most? Also, which of the scenarios would you like least?

For each question please choose one option only by ticking one of the relevant boxes.[2]

[2] **Please note:** For each questionnaire, the order of the scenarios was randomly allocated. As such, the surveys included in the appendices of this thesis show examples of sets of scenarios presented to participants.

	Scenario 1	**Scenario 2**	**Scenario 3**	**Scenario 4**
Time to make a decision	Your doctor explains your treatment options in **one 40 minute visit**. You discuss your options with your doctor. You choose a treatment together by the end of your visit.	Your doctor explains your treatment options in **one 20 minute visit**. You have **another 20 minute visit** one week later. You discuss your options with your doctor. You choose a treatment together by the end of the second visit.	Your doctor explains your treatment options in **one 40 minute visit**. You discuss your options with your doctor. You choose a treatment together by the end of the visit.	Your doctor explains your treatment options in **one 20 minute visit**. You have **another 20 minute visit** one week later. You discuss your options with your doctor. You choose a treatment together by the end of the second visit.
Additional information	Your doctor gives you **a booklet** with extra written information about your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options. Your doctor also provides you with access to **a website** with further written and video information on your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options. Your doctor also provides you with access to **a website** with further written and video information on your treatment options.
I would like MOST Please tick <u>one box in this row</u>:	☐	☐	☐	☐
I would like LEAST Please tick <u>one box in this row</u>:	☐	☐	☐	☐

The following questions ask for some background information about you. *Please **circle the number** that corresponds to your answer.*	
1 Are you **male** or **female**?	**1** Male **2** Female
2 What is your **date of birth**?	___ ___ / ___ ___ / ___ ___ ___ ___ Day Month Year
3 Do you have **private health insurance**?	**1** Yes **2** No
4 Do you have a **health care card**?	**1** Yes **2** No
5 What **type of cancer** do you have?	**1** Breast **2** Prostate **3** Lung **4** Colorectal **5** Other (please specify) _____
6 **What stage** was your breast cancer **when it was first diagnosed**? Please circle one number that best applies to you	**1** Early (the cancer was contained in the region where it first began. It has not spread to other parts of your body) **2** Progressed or advanced (the cancer had spread to other parts of body) **3** Don't know
7 How **long ago** were you diagnosed with breast cancer? *If you have had more than one diagnosis, please think about your **most recent cancer***	_____ months
8 Do you have a **support person**? *A support person is someone who is a primary source of practical and emotional support.*	**1** No **2** Yes, my Spouse/ partner **3** Yes, my parent **4** Yes, my child **5** Yes, other (please specify) _____

9 **Where are you** in your cancer journey?	**1** I am receiving treatment to try and cure my cancer **2** I have completed treatment to cure my cancer and am now in follow-up **3** I have been told my cancer cannot be cured and I am receiving anticancer treatment (e.g. chemotherapy, radiotherapy) **4** I have been told my cancer cannot be cured, and am not currently receiving anticancer treatment
10 Have you been diagnosed with a **type of cancer** other than breast cancer?	**1** Yes **2** No If yes, please specify: **1** Breast **2** Prostate **3** Lung **4** Colorectal **5** Other (please specify) _____
11 What is your **postcode**?	___ ___ ___ ___
12 What country were you born in?	**1** Australia **2** Other (please specify) _____
13 Are you of **Aboriginal or Torres Strait Islander** origin?	**4** No **5** Yes, Aboriginal **6** Yes, Torres Strait Islander **3** Yes, both Aboriginal and Torres Strait Islander
14 What is your **marital status**?	**1** Married **2** Living with a partner **3** Divorced or widowed **4** Single or never married

15 What is the **highest level of education** you have completed?	**1** Year 10/School Certificate or lower **2** Higher School Certificate **3** Trade or vocational training (e.g. TAFE or college) **4** Bachelor degree **5** Postgraduate degree **6** Other
16 How would you rate your current **quality of life**? *Please circle one number*	1 2 3 4 5 6 7 8 9 10 Poor Excellent

Thank you for completing the survey. Your time is greatly appreciated. If you have any additional comments please write them below or on the back of page.

Version # 3, dated 9/09/2015
Who decides and at what cost

THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

School of Medicine and Public Health

SUPPORT PERSON SURVEY

The survey will take about 15-20 minutes to complete.

As a support person of someone diagnosed with cancer, your answers will help us to identify how cancer care might be improved in the future. **These questions have nothing to do with the current state of health of the person diagnosed with cancer.**

Please remember that any information you give us will remain confidential.

If you would like more information about this survey please call the research team on 1800 084 755.

If this survey reminds you of any questions or concerns you have, we suggest that you discuss these with your GP. You can also contact the 13 11 20 Information and Support which is staffed by health professionals.

Thank you for taking the time to complete this survey

Appendix 9.3: Surveys related to Papers Four and Five (support person baseline survey, Calvary Mater Newcastle)

	SECTION A: ABOUT YOU	
1	Are you male or female?	**1** Male **2** Female
2	What is your **date of birth**?	___ ___ / ___ ___ / ___ ___ ___ ___ Day Month Year
3	What is your **postcode**?	___ ___ ___ ___
4	What **country** were you **born in**?	**1** Australia **2** Other (please specify) _____
5	Are you of **Aboriginal or Torres Strait Islander** origin?	**1** No **2** Yes, Aboriginal **3** Yes, Torres Strait Islander **4** Yes, both Aboriginal and Torres Strait Islander
6	What is **your relationship** to the person with cancer?	**1** Spouse/partner **2** Parent **3** Brother/sister **4** Daughter/son **5** Other relative **6** Paid live in carer **7** Other _____
7	Do you **live with the person** with cancer?	**1** Yes **2** No
8	On average, **how much time** do you spend caring for the person diagnosed with cancer per week? (*Please circle one number*)	**1** Less than 20 hours **2** 20-40 hours **3** More than 40 hours **4** Unsure **5** Do not provide any care
9	How would you rate **your own** overall quality of life? **(Circle one number)**	1 2 3 4 5 6 7 8 9 10 Poor Excellent
10	How would you rate the overall quality of life **of the person you support**? **(Circle one number)**	1 2 3 4 5 6 7 8 9 10 Poor Excellent

Advance care planning (ACP) provides an opportunity for people to think, discuss and plan for the medical treatment they would prefer if they became too ill in the future to express their wishes. Everyone should consider advance care planning, regardless of their age or health. But, it is particularly important for people who have ongoing health problems.

These questions ask for your views and experiences in talking and making decisions about future medical care of the person you support, including end of life care. End of life care refers to care that helps people with advanced, incurable illness to live as well as possible until they die.

These questions have nothing to do with the current state of health of the person you support. We are asking everyone that attends this clinic to answer these questions.

Would you want to be involved in discussions with the person you support about:	**Yes**	**No**
11 Writing down his/her wishes for end of life care *(e.g. in an advance directive or advance care plan)*	1	2
12 Appointing an enduring guardian *(i.e. someone appointed to make medical decisions on a person's behalf in case they are unable to make decisions later)*	1	2
13 The type of end of life care they want to receive	1	2
14 Where they want to receive care at the end of life	1	2
Has the person you support already:	**Yes**	**No**
15 Written down his/her wishes for end of life care *(e.g. in an advance directive or advance care plan)*	1	2
16 Appointed an enduring guardian *(i.e. someone legally appointed to make medical decisions on their behalf if they are unable to make decisions themselves)*	1	2
17 Discussed the type of end of life care he/she would like to receive with you	1	2
18 Discussed where they want to receive care at the end of life	1	2

19 If the person you support became physically or mentally unable to make decisions on their own, would they prefer their end of life care to be decided by:	**1** A **plan they had made** before they got too sick to make decisions. **2** **Their doctor with their family/friends,** based on their views of what was best **3** Only **their doctor**, based on their view of what was best
20 What is the estimated life expectancy of the person you support?	**1** Less than 6 months **2** 6 months – 1 year **3** 1-2 years **4** More than 2 years **5** Don't know, but I would like this information **6** Don't know and I do not want this information
21 If they had a choice, do you think the person you care for would prefer end of life care that focuses on:	**1** **Extending life as much as possible**, even if it meant more pain and discomfort **2** **Relieving pain and discomfort** as much as possible, even if it meant not living as long **3** **Unsure**
22 If the person I support lost capacity to make decisions on his/her own, **I would want to make decisions** on his/her behalf	**1** Strongly agree **2** Agree **3** Neutral **4** Disagree **5** Strongly disagree
23 I feel confident that I **know what treatment the person I support would want** at the end of life	**1** Strongly agree **2** Agree **3** Neutral **4** Disagree **5** Strongly disagree
24 If they had a choice, **where do you think** the **person you support would prefer** to be cared for at the end of life?	**1** In their own home **2** In a relative's home **3** In a hospital **4** In a hospice / palliative care unit

PLEASE NOTE: YOU WILL ONLY NEED TO ANSWER QUESTIONS ON **ONE OF THE COLOURED PAGES AS INDICATED** IN THE RESPONSE OPTIONS **IN Q25 BELOW**

25 If you had a choice, **where would you prefer the person you support to be cared for** at the end of life?	**1** In their own home (go to **blue page 5**) **2** In a relative's home (go to **blue page 5**) **3** In a hospital (go to **yellow page 6**) **4** In a hospice / palliative care unit (go to **green page 7**)

BLUE PAGE – PREFERRED CARE AT HOME

26 Which of the following might be benefits of the person you support receiving end of life care AT HOME? Please select the TOP 3 benefits in order of importance by placing a '1', '2' or '3' in the corresponding box (1=most important to you). Please select THREE boxes only.

	Receiving care from family and/or friends
	Familiar environment
	Not being alone
	Having the food they like
	Religious/spiritual beliefs and needs (or lack thereof) will be respected
	Using own bathroom
	Feeling like dying is a natural process
	Family might be able to have a more "normal life"
	Physical closeness to loved ones and/or sharing a bed

27 Which of the following might you be most worried about if the person you support received end of life care AT HOME? Please select the TOP 3 things that might worry you by placing a '1', '2' or '3' in the corresponding box (1='most worrying'). Please select THREE boxes only.

	Not having expert medical care
	Not knowing who to call if I need help
	Emotional "scarring" of family/friends
	Not having people who can or will care for them at home
	Family/friends not knowing what to do during and after death
	Not having access to special equipment (e.g. hospital bed, commode)
	Dying alone
	Dying and not being found for several hours
	Being isolated
	Not being able to manage their pain

Please SKIP to page 8

YELLOW PAGE – PREFERRED CARE AT HOSPITAL

28 Which of the following might be benefits of the person you support receiving end of life care IN A HOSPITAL? Please select the TOP 3 benefits in order of importance by placing a '1', '2' or '3' in the corresponding box (1=most important to you). Please select THREE boxes only.

	Lots of medical care
	Pain being managed well
	Not being alone
	Don't have to "burden" family/friends
	Medical staff on call
	Family might be able to have more of a "normal life"
	Not having to cook and clean
	Access to special equipment (e.g. hospital bed, commode)

29 Which of the following might you be most worried about if the person you support received end of life care IN A HOSPITAL? Please select the TOP 3 worrying things by placing a '1', '2' or '3' in the corresponding box (1='most worrying'). Please select THREE boxes only.

	Not having my wishes respected.
	Not being treated respectfully
	The environment may be clinical and unfriendly
	Being isolated
	Lack of privacy
	Other people being unwell
	Noisy surroundings
	Family/friends last memory being of me in a hospital environment
	Getting an infection or getting sicker from being at hospital
	Visitor's hours may be limited
	Being woken up for tests
	Hospital may be a distance for visitors to travel
	Difficulty being physically close to loved ones or sharing a bed
	Religious/spiritual beliefs and needs (or lack thereof) not being respected

Please SKIP to page 8

GREEN PAGE – PREFERRED CARE AT HOSPICE

30 Which of the following might be benefits of the person you support receiving end of life care IN A HOSPICE (palliative care)? Please select the TOP 3 benefits by placing a '1', '2' or '3' in the corresponding box (1=most important to you). Please select THREE only.

	Specialised medical care
	Pain being managed well
	Medical staff on call
	Not being alone
	Religious/spiritual beliefs and needs (or lack thereof) will be respected
	Feeling like dying is a natural process
	Family might be able to have more of a "normal life"
	Staff are used to people dying
	Don't have to cook or clean
	Don't have to "burden" family/friends

31 Which of the following might you be most worried about if the person you support received end of life care IN A HOSPICE? Please select the TOP 3 worrying things by placing a '1', '2' or '3' in the corresponding box (1='most worrying'). Please select THREE boxes only.

	Not being resuscitated
	The environment may be clinical and unfriendly
	Religious/spiritual beliefs (or lack thereof) not being respected
	Being isolated
	Lack of privacy
	Getting used to the environment
	Other people dying
	Not being able to smoke or drink
	Being woken up for tests
	Hospice may be a distance for visitors to travel
	Might not be "ready" to die
	Difficulty being physically close to loved ones or sharing a bed
	Family/friends last memory of me being of me in a hospice
	Potential for getting infections

Please CONTINUE to next page

32 Has this survey caused you any stress?	**1** Yes, and I would prefer not to answer these questions **2** Yes, but I think these questions are important **3** No

Are you willing to be complete a second survey about your experiences in 3 months' time? The information you give will allow us to improve the quality of cancer care.

Please tick (✓) one box to indicate your answer.

□ Yes

Title (Please circle one) Dr / Mr / Mrs / Ms / Miss	
First Name:	Last name:
Postal address:	
State:	Postcode:
Phone number:	Email:
Signature:	
Preferred method of contact (*circle all that apply):* Mail Email Telephone	

□ No

Thank you for completing the survey. Your time is greatly appreciated. If you have any additional comments please write them below or on the back of the page.

Version # 4, dated 09/10/2015

Who decides and at what cost

SUPPORT PERSON 3 month SURVEY

The survey will take about 15-20 minutes to complete.

As a support person of someone diagnosed with cancer, your answers will help us to identify how cancer care might be improved in the future. **These questions have nothing to do with the current state of health of the person diagnosed with cancer.**

Please remember that any information you give us will remain confidential.

If you would like more information about the purpose of this survey or the questions being asked, please call the research team on 1800 084 755.

If this survey reminds you of any questions or concerns you have, we suggest that you discuss these with your GP. You can also contact the 13 11 20 Information and Support which is staffed by health professionals.

Thank you for taking the time to complete this survey

Appendix 9.3: Surveys for Papers Four and Five (support person follow-up survey, Calvary Mater Newcastle)

The following questions ask for your views about your involvement in making decisions about the patient's medical care. Please answer every question, unless the instructions ask you to skip ahead to another question. **Please circle the number next to the answer that best describes your answer to each question, unless otherwise stated.** If you are unsure about an answer, please give the best answer you can.

1	**When making important decisions about medical care, how involved would you like to be in making the decision?** **I would prefer :**	1 The patient makes the decision without involving me 2 The patient makes the final decision after seriously considering my opinion 3 The patient and I share the responsibility for deciding 4 I make the final decision, but seriously consider the patient's opinion 5 The patient leaves all decisions regarding treatment to me
2	**Thinking back to making decisions about cancer treatment, how involved were you in making those decisions?** *(Please circle one number only)*	1 The patient made the decision without involving me 2 The patient made the final decision after seriously considering my opinion 3 The patient and I shared the responsibility for deciding 4 I made the final decision, but seriously considered the patient's opinion 5 The patient left all decisions regarding treatment to me
3	**I have been involved as much as I wanted to be in helping to make decisions**	1 Strongly agree 2 Agree 3 Disagree 4 Strongly disagree
4	**I have been involved as much as the patient wanted me to be in helping to make decisions**	1 Strongly agree 2 Agree 3 Disagree 4 Strongly disagree

Imagine the following: You have been diagnosed with cancer. Your doctor has told you about different treatment options for your cancer. He has asked you to decide which treatment you would like to have.

Importantly:

- **There is no difference between the treatment options in terms of how they will affect your length of life.**
- **However, the treatment options have different pros and cons. The doctor believes that it is important that the decision is yours. He is happy for you to have either type of treatment. The decision depends on how you feel about the pros and cons of the options.**
- **Whichever treatment you choose it will start in two weeks from your first appointment.**

We are interested in finding out what you think would help you most in making this decision.
If you were in that situation, which of the scenarios below would you like most? Also, which of the scenarios would you like least?
For each question please choose one option only by ticking one of the relevant boxes.[3]

[3] **Please note:** For each questionnaire, the order of the scenarios was randomly allocated. As such, the surveys included in the appendices of this thesis show examples of sets of scenarios presented to participants.

	Scenario 1	**Scenario 2**	**Scenario 3**	**Scenario 4**
Time to make a decision	Your doctor explains your treatment options in **one 40 minute visit**. You discuss your options with your doctor. You choose a treatment together by the end of the visit.	Your doctor explains your treatment options in **one 20 minute visit**. You have **another 20 minute visit** one week later. You discuss your options with your doctor. You choose a treatment together by the end of the second visit.	Your doctor explains your treatment options in **one 40 minute visit**. You discuss your options with your doctor. You choose a treatment together by the end of the visit.	Your doctor explains your treatment options in **one 20 minute visit**. You have **another 20 minute visit** one week later. You discuss your options with your doctor. You choose a treatment together by the end of the second visit.
Additional information	Your doctor gives you **a booklet** with extra written information about your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options. Your doctor also provides you with access to **a website** with further written and video information on your treatment options.	Your doctor gives you **a booklet** with extra written information about your treatment options. Your doctor also provides you with access to **a website** with further written and video information on your treatment options.
I would like most **Please tick one box in this row:**	☐	☐	☐	☐
I would like least **Please tick one box in this row:**	☐	☐	☐	☐

Advance care planning (ACP) provides an opportunity for people to think, discuss and plan for the medical treatment they would prefer if they became too ill in the future to express their wishes. Everyone should consider advance care planning, regardless of their age or health. But, it is particularly important for people who have ongoing health problems.

These questions ask for your views and experiences in talking and making decisions about future medical care of the person you support. **They have nothing to do with the current state of health of the person you support. We are asking everyone that attends this clinic to answer these questions.**

Would you want to be involved in discussions with the person you support about:	**Yes**	**No**	**Unsure**
5 Writing down his/her wishes for end of life care *(e.g. in an advance directive or advance care plan)*	1	2	3
6 Appointing an enduring guardian *(i.e. someone appointed to make medical decisions on a person's behalf in case they are unable to make decisions later)*	1	2	3
7 The type of end of life care they want to receive	1	2	3
8 Where they want to receive care at the end of life	1	2	3
Has the person you support already:	**Yes**	**No**	**Unsure**
9 Written down his/her wishes for end of life care (e.g. in an advance directive or advance care plan)	1	2	3
10 Appointed an enduring guardian (i.e. someone legally appointed to make medical decisions on their behalf if they are unable to make decisions themselves)	1	2	3
11 Discussed the type of end of life care he/she would like to receive with you	1	2	3
12 Discussed where they want to receive care at the end of life	1	2	3

Appendix 9.3: Surveys for Papers Four and Five (support person follow-up survey, Calvary Mater Newcastle)

The next set of questions present an imaginary scenario where a person is asked to choose between three different types of care. We are interested in finding out what type of care you think you would choose for the person you support if you were in that situation.

EXAMPLE: This is an example only. Questions begin on the next page (Page 7).

SCENARIO

- A patient has been told that they have incurable cancer and they only have about a month to live.
- The doctor tells the patient there are three types of care they can have.
- Each type of care will be different in terms of how it affects their length of life, how much pain they will feel and how much of the time they will be conscious (i.e. mentally alert).
- The person must choose one of the three care types (Care A, B or C).

If you were the one being asked to choose between Care A, B, C for the person you support, which type of care would you:

- **Most prefer** for the person you support.
- **Least prefer** for the person you support.

	Care A	Care B	Care C
Patient will feel	Mild pain (3 out of 10)	Moderate pain (5 out of 10)	Severe pain (8 out of 10)
Patient will be conscious *(i.e mentally aware of people and surroundings)*	Some of the time	Half of the time	Most of the time
Patient's length of life will be extended by:	Two weeks	One week	Three weeks
I would MOST PREFER *(PLEASE TICK ONE BOX):*	√	☐	☐
I would LEAST PREFER *(PLEASE TICK ONE BOX)*	☐	√	☐

Please answer Q13 and Q14 below

SCENARIO

- A patient has been told that they have incurable cancer and they only have about a month to live.
- The doctor tells the patient there are three types of care they can have.
- Each type of care will be different in terms of how it affects their length of life, how much pain they will feel and how much of the time they will be conscious (i.e. mentally alert).
- The person must choose one of the three care types (Care A, B or C).

If you were the one being asked to choose between Care A, B, C for the person you support, which type of care would you:

- **Most prefer** for the person you support.
- **Least prefer** for the person you support.

	Care A	Care B	Care C
Patient will feel	Moderate pain (5 out of 10) (10 = worst pain)	Mild pain (3 out of 10) (10 = worst pain)	Severe pain (8 out of 10) (10 = worst pain)
Patient will be conscious *(i.e mentally aware of people and surroundings and able to communicate)*	Some of the time	Half of the time	Most of the time
Patient's length of life will be extended by:	Two weeks	One week	Three weeks
13 If I was being asked to choose, I would MOST PREFER *(PLEASE TICK ONE BOX):*	☐	☐	☐
14 If I was being asked to choose, I would LEAST PREFER *(PLEASE TICK ONE BOX)*	☐	☐	☐

Please answer Q15 and Q16 below

SCENARIO

- A patient has been told that they have incurable cancer and they only have about a month to live.
- The doctor tells the patient there are three types of care they can have.
- Each type of care will be different in terms of how it affects their length of life, how much pain they will feel and how much of the time they will be conscious (i.e. mentally alert).
- The person must choose one of the three care types (Care A, B or C).

If you were the one being asked to choose between Care A, B, C for the person you support, which type of care would you:

- **Most prefer** for the person you support.
- **Least prefer** for the person you support.

	Care A	Care B	Care C
Patient will feel	Mild pain (3 out of 10) (10 = worst pain)	Severe pain (8 out of 10) (10 = worst pain)	Moderate pain (5 out of 10) (10 = worst pain)
Patient will be conscious *(i.e mentally aware of people and surroundings and able to communicate)*	Most of the time	Half of the time	Some of the time
Patient's length of life will be extended by:	One week	Three weeks	Two weeks
15 If I was being asked to choose, I would MOST PREFER *(PLEASE TICK ONE BOX):*	☐	☐	☐
16 If I was being asked to choose, I would LEAST PREFER *(PLEASE TICK ONE BOX)*	☐	☐	☐

Please answer Q17 and Q18 below

SCENARIO

- A patient has been told that they have incurable cancer and they only have about a month to live.
- The doctor tells the patient there are three types of care they can have.
- Each type of care will be different in terms of how it affects their length of life, how much pain they will feel and how much of the time they will be conscious (i.e. mentally alert).
- The person must choose one of the three care types (Care A, B or C).

If you were the one being asked to choose between Care A, B, C for the person you support, which type of care would you:

- **Most prefer** for the person you support.
- **Least prefer** for the person you support.

	Care A	Care B	Care C
Patient will feel	Mild pain (3 out of 10) (10 = worst pain)	Moderate pain (5 out of 10) (10 = worst pain)	Severe pain (8 out of 10) (10 = worst pain)
Patient will be conscious *(i.e mentally aware of people and surroundings and able to communicate)*	Some of the time	Most of the time	Half of the time
Patient's length of life will be extended by:	Three weeks	One week	Two weeks
17 If I was being asked to choose, I would MOST PREFER *(PLEASE TICK ONE BOX):*	☐	☐	☐
18 If I was being asked to choose, I would LEAST PREFER *(PLEASE TICK ONE BOX)*	☐	☐	☐

19 How would you rate your own overall quality of life? **(Circle one number)**	1 2 3 4 5 6 7 8 9 10 Poor ——— Excellent
20 How would you rate the overall quality of life **of the person you support**? **(Circle one number)**	1 2 3 4 5 6 7 8 9 10 Poor ——— Excellent
21 What is the **estimated life expectancy** of the person you support?	**1** Less than 6 months **2** 6 months – 1 year **3** 1-2 years **4** More than 2 years **5** Don't know, but I would like this information **6** Don't know and I do not want this information
22 If a decision about treatment needed to be made and the person you support **could not speak for him/herself,** would you prefer:	**1** The doctor makes the decision without involving you **2** The doctor makes the final decision after seriously considering your opinion **3** You share the responsibility for deciding with the doctor **4** You make the final decision, but seriously consider the doctor's opinion **5** The doctor leaves all decisions regarding treatment to you
23 If the **person you support could choose,** do you think they would prefer end of life care that focuses on:	**1** **Extending life as much as possible**, even if it meant more pain and discomfort **2** **Relieving pain and discomfort** as much as possible, even if it meant not living as long **3** **Unsure**
24 **Where do you think the person you support would prefer** to be cared for at the end of life?	**1** In their own home **2** In a relative's home **3** In a hospital **4** In a hospice / palliative care unit
25 **Where would you prefer the person you support** to be cared for at the end of life?	**1** In their own home **2** In a relative's home **3** In a hospital **4** In a hospice / palliative care unit

Thank you for completing the survey. Your time is greatly appreciated.
If you have any additional comments please write them below or on the back of page.

Appendix 10: STANDARDISED STUDY PROCEDURES AND MATERIALS

Appendix 10.1: Participant information statement, consent form and reminder related to Paper One

Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients

INFORMATION FOR PARTICIPANTS

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Project Number: [INSERT SSA APPROVAL NUMBER]

Principal Site Investigator: [INSERT PRINCIPAL SITE INVESTIGATOR NAME]

Location: [INSERT SITE NAME]

Research Team: L/Prof Rob Sanson-Fisher, University of Newcastle (UoN), Dr Mariko Carey, UoN, A/Prof Anthony Proietto, Hunter New England Local Health District (HNELHD), Dr James Lynam (HNELHD), Dr Lisa Mackenzie (UoN), Dr Alix Hall (UoN), Ms Rochelle Smits (UoN), Ms Breanne Hobden (UoN)

Introduction

You are invited to take part in the research project named above which is being conducted by the Research Team from the University of Newcastle and Hunter New England Local Health District. This research is being funded by the Cancer Institute NSW.

This information sheet tells you about the research project. Knowing what is involved will help you decide if you want to take part. Please read the information carefully and ask questions about anything you don't understand or want to know more about.

Before deciding whether or not to take part, you might want to talk about it with a relative, friend, your doctor or an Aboriginal liaison officer. If you would like to wait until someone can come with you before filling out any forms for this research, please tell the person who gave this information sheet to you.

What is the research about?

We are trying to see if cancer patients that are less well off in terms of money, education, or employment have different needs and experiences of care than cancer patients who are more well off. This research may help to change cancer care to support people experiencing hardship.

Who can take part in the research?

We are looking for English-speaking patients over the age of 18 years who have been diagnosed with cancer to take part. If you have not been to this treatment centre/hospital for your cancer care at least once in the last 6 months, then unfortunately you cannot take part.

What choice do you have?

Participation in this research is entirely your choice. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you can stop taking part at any stage without giving a reason. You can also withdraw any information you have already provided to researchers.

If you do decide to take part, you will be asked to sign a Consent Form. Only those people who give their informed consent will be included in the project. Your decision about whether to take part will not affect your treatment or your relationship with the people treating you. You will receive the best possible care whether or not you take part.

What would you be asked to do if you agree to take part?
If you agree to take part, you will be asked to complete two surveys. You will be asked to complete the first survey as soon as you have signed the consent form. The first survey will be a pen and paper survey. You will be asked to fill it in and hand it back to the person who gave it to you when you are done. If you are called in for your appointment before you are able to finish the survey, you will be given a postage paid envelope so you can take the survey with you and mail it back to the researchers once you have finished it. The second survey will also be a pen and paper survey. This survey will be sent to you in the mail in about 4 weeks' time. You will also be sent a postage paid envelope to mail the second survey back to the research team once you have filled it in. You may also be sent reminder letters in the mail if the research team does not hear from you.

The first survey contains questions about you (such as your gender), your cancer and treatment, your quality of life, your financial circumstances, and medicines you are taking. It also asks about conversations you have had with your doctor about how long you will live and care you would want to receive if you cancer became more advanced. The second survey may include questions about your health care team, your coping skills, respect shown to you by clinic staff, recent procedures you have had, support that is available to you, and how the clinic staff have communicated with you. You will have the option to skip any questions you do not wish to answer. It is expected that each survey will take about 15-20 minutes to fill in. All information provided in surveys will be kept confidential.

If you are willing, a member of the research team may also call you in 8 weeks' time to get a better understanding about your needs and the care you have received. This telephone interview is expected to take about 15-20 minutes. You are able to choose whether you just want to complete the surveys or if you would also like to take part in the telephone interview.

What are the risks and benefits of taking part?
Risks
We do not expect there will be any risks to you by taking part. It is possible that taking part may cause you to think about your cancer care and may raise questions about cancer. If you do have questions about cancer, we recommend you talk to your doctor. You can also call the Cancer Council on 13 11 20 to speak with a cancer nurse who can provide information and support to people with cancer and their families.

Benefits
We cannot promise you any benefit from taking part in this research. The results of this research will help to show how care can be improved for future cancer patients.

Will the study cost you anything?
Participation in this study will not cost you anything, and you will not be paid.

How will your privacy be protected?
An ID number will be used instead of your name to store your survey answers. Your name and contact details will be stored separately from your survey answers, and will only be linked by the ID number. Surveys and consent forms that you fill out today will be stored separately in paper copy in a locked filing cabinet for a brief period at the hospital/treatment centre. Completed materials will then be mailed via registered post to researchers at the University of Newcastle, where they will also be stored in a locked filing cabinet. All other paper files will be stored in a locked filing cabinet at the University of Newcastle. Computer files will be password protected and stored on the University of Newcastle server. This information will only be accessed by the researchers. No-one else will have access to your information unless you give permission, except as required by law. Data will be kept for at least 7 years.

Your anonymous survey data may be made available for additional analysis at a later date. Separate ethics approval will be sought beforehand. Where data is used for further analysis, it will not contain any of your personal information (e.g. name, phone number). Only summarised results from everyone who took part in the study will be presented in any reports of publications arising from this research. No individual will be able to be identified and your privacy will be protected.

How will the information collected be used?
The information collected will be presented in a report to the Cancer Institute NSW. The results may also be presented at conferences in Australia and overseas, and published in scientific journals. If requested by the treatment centre/hospital, we will also provide them with summarised information about the survey results of patients attending their clinic. Your individual results will not be provided to the hospital. At the end of the study we can send you a summary of the key findings of the project. If you would like this information sent to you, please check the appropriate box on the consent form.

What do you need to do to take part?
Please read this Information Statement and be sure you understand it before you agree to take part. Please ask questions if there is anything you do not understand, or if you would like more information. If you would like to take part, please complete the consent form attached and return it to the person who provided it to you. You will then be provided with a pen and paper survey to fill out.

Further Information
If you have any questions of want more information about this project you can contact the research team on **1800 084 755** or you can contact the Principal Site Investigator on [insert phone number].

Complaints about this research
This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference [15/04/15/4.04].

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email Hnehrec@hnehealth.nsw.gov.au

The conduct of this study at the [name of site] has been authorised by the [name of organisation]. Any person with concerns or complaints about the conduct of this study may also contact the [Research Governance Officer or other officer] on [telephone number] and quote reference number [15/04/15/4.04].

You are also free to discuss any concerns about this trial, not only with you medical team, but also your family, friends, other health care professionals or legal advisors.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Consent Form

Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients

Project Number: [INSERT SSA APPROVAL NUMBER]

Principal Site Investigator: [INSERT PRINCIPAL SITE INVESTIGATOR NAME]

Location: [INSERT SITE NAME]

Research Team: L/Prof Rob Sanson-Fisher, University of Newcastle (UoN), Dr Mariko Carey, UoN, A/Prof Anthony Proietto, Hunter New England Local Health District (HNELHD), Dr James Lynam (HNELHD), Dr Lisa Mackenzie (UoN), Dr Alix Hall (UoN), Ms Rochelle Smits (UoN), Ms Breanne Hobden (UoN)

Declaration by Participant

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to completing (please tick box):

☐ One pen and paper survey now and 1 survey in 4 weeks' time

☐ One telephone interview in 8 weeks' time

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

Title: Mr / Mrs / Miss / Ms / Dr (please circle one) Other _____		
Name:		
Postal Address:		
Suburb:	**State:**	**Postcode:**
Home phone:	**Mobile:**	
E-mail address:		

Name of Participant (please print)_____

Signature _____ Date _____

If you would like to receive a summary of the results of the overall project via email or post, please tick the appropriate box below.

☐ YES, via email (please tick) ☐ YES, via post (please tick)

Declaration by Staff Member

I believe that the participant has understood what participation involves.
I have confirmed that the participant meets all of the eligibility requirements.

Name of Staff Member (please print) _____

Signature _____ Date _____

«AddressBlock»

«Date»

«GreetingLine»

RE: Understanding the role of socioeconomic disadvantage on the needs and experiences of care of cancer patients

We would like to thank you for agreeing to take part in the above-mentioned study. You may recall receiving a study survey at [insert hospital name] about 2 weeks ago. Your answers to the survey are very important to us. As I have not yet received your completed survey, I am writing to you again to ask you to consider contributing to our research. I have enclosed another copy of the survey in case you need it.

If you have returned your survey in the last few days, please disregard this letter.

Completion of the survey is of course voluntary, and your answers will be kept confidential. If you decide to complete the survey, please return it to us in the reply-paid envelope provided in the next week. If you have any questions about the survey or the study, please call our research team on **1800 084 755**.

We appreciate your contribution to this study. However, if at any time you decide that you no longer want to take part, please telephone us. If we do not hear otherwise, we will continue to include you in the study.

Thank you again for your help.

Yours sincerely,

Rob Sanson-Fisher
Laureate Professor of Health Behaviour
University of Newcastle

Research Team: L/Prof Rob Sanson-Fisher, University of Newcastle (UoN), Dr Mariko Carey, UoN, A/Prof Anthony Proietto, Hunter New England Local Health District (HNELHD), A/Prof Jarad Martin (HNELHD), Dr James Lynam (HNELHD), Dr Lisa Mackenzie (UoN), Dr Alix Hall (UoN), Ms Rochelle Smits (UoN), Ms Breanne Hobden (UoN)

Complaints about this research
This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 15/04/15/4.04.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email Hnehrec@hnehealth.nsw.gov.au

Appendix 10.1: Participant reminder related to Paper One

The conduct of this study at the [name of site] has been authorised by the [name of organisation]. Any person with concerns or complaints about the conduct of this study may also contact the [Research Governance Officer or other officer] on [telephone number] and quote reference number [insert SSA reference number].

You are also free to discuss any concerns about this trial, not only with you medical team, but also your family, friends, other health care professionals or legal advisors.

Appendix 10.2: STROBE checklist related to Paper One

STROBE (Strengthening The Reporting of OBservational Studies in Epidemiology) Checklist

A checklist of items that should be included in reports of observational studies. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Section and Item	Item No.	Recommendation	Reported on Page No.
Title and Abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/Rationale	2	Explain the scientific background and rationale for the investigation being reported	2-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study Design	4	Present key elements of study design early in the paper	4-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	N/A
		Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	N/A
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	4-5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	N/A
		Case-control study—For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-7

Appendix 10.2: STROBE checklist related to Paper One

Section and Item	Item No.	Recommendation	Reported on Page No.
Data Sources/ Measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-8
Bias	9	Describe any efforts to address potential sources of bias	7-8; 12-13
Study Size	10	Explain how the study size was arrived at	4-8
Quantitative Variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-8
Statistical Methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	5-8
		(c) Explain how missing data were addressed	8-9
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed	N/A
		Case-control study—If applicable, explain how matching of cases and controls was addressed	N/A
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8-9
		(b) Give reasons for non-participation at each stage	8-9
		(c) Consider use of a flow diagram	N/A
Descriptive Data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	8-9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome Data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	N/A
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	N/A
		Cross-sectional study—Report numbers of outcome events or summary measures	8-9

Appendix 10.2: STROBE checklist related to Paper One

Section and Item	Item No.	Recommendation	Reported on Page No.
Main Results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-9
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other Analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-9
Discussion			
Key Results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	10-14
Other Information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Title page

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Appendix 10.3: Data coding manual related to Paper One

Coding and analysis rules
In Clinic Patient Survey – SES study Version 1, 3/11/15
Scanned data file

Section A: About You

Item # in survey	Question	Scan variable	Scan code	Option	Coding rules
A1	What is your date of birth?	A1	 99	dd/mm/yyyy Missing	If incomplete code the year (if year is provided). If year is not provided code as 'missing' *complete grid on page 12 of scannable survey. Colour ALL ovals eg if 1st January 1979, 01/01/79
A2	How many times have you visited this centre to receive cancer care in the last 6 months?	A2	1 2 3 4 5	None, this is my first visit 1-2 times 3-5 times 6-10 times More than 10 times	If 2 or more are selected code as code higher number
A3	Are you male or female?	A3	1 2 99	Male Female Missing	If 'missing' or 'nonsense' then get from the participant database (re, title and name)
A4	What is your home postcode?	A4	 99	Four digit postcode Missing/ incomplete	If incomplete/missing then get from the participant database. *complete grid on page 12 of scannable survey. Colour ALL ovals.

A5	Are you of Aboriginal or Torres Strait Islander origin?	A5	1 2 3 4 99	No Yes, Aboriginal Yes, Torres Strait Islander Yes, both Aboriginal and Torres Strait Islander Missing	- If 2 and 3 selected code as '4' - If 1 and either 2,3 or 4 selected code as 'missing'
A6	What is the highest level of education that you have completed? Please tick only ONE box.	A6	1 2 3 4 5 99	Primary school (year 6) High school (year 9, 10 or year 12) Trade or vocational training (e.g. TAFE or college) University degree Other Missing	If 2 or more are selected code the highest level of education "Year 9" coded as high school "leaving school certificate coded as high school" e.g. 3 and 4 selected code for '4' If patient writes "diploma" which could indicate a TAFE diploma or university diploma back code to trade or vocational training as you require a bachelor degree to get a diploma.
A6open	Other (please specify)	A6OTH	Please see 'Additional Coding Rules'		Back code where appropriate into A6 *Codes not pre-specified, but added to the list as we go. Please see 'Additional Coding Rules'. *complete grid on page 12 of scannable survey. Colour ALL ovals.
A7	What country were you born in?	A7	1 2 3 4 5 6 7 99	Australia United Kingdom New Zealand Italy China India Other (please specify) _____ Missing	If 2 or more are selected code as 'missing'
A7open	Other (please specify)	A7OTH	Please see 'Additional		Back code where appropriate into A7

			Coding Rules'		*Codes not pre-specified, but added to the list as we go. Please see 'Additional Coding Rules'. *complete grid on page 12 of scannable survey. Colour ALL ovals.
A8	What best describes your employment at this time?	A8	1 2 3 4 5 6 7 99	Full-time work Part-time or casual work Home duties Unemployed Retired or mature age pension Disability pension Other (please specify) _____ Missing	If 2 or more are selected code the employment status that entails the least amount of work e.g. If 2 and 5 are chosen code as '5'
A8open	Other (please specify)	A8OTH	Please see 'Additional Coding Rules'		Back code where appropriate into A8 *Codes not pre-specified, but added to the list as we go. Please see 'Additional Coding Rules'. *complete grid on page 12 of scannable survey. Colour ALL ovals.
A9	Do you have an active home internet connection?	A9	1 2 3 99	Yes No Don't know Missing	If two answers are selected code as 'missing'
A10	On average, how long does it take to get to this centre from where you are currently living?	A10	 99	3 digit code missing	*complete grid on page 12 of scannable survey. Colour ALL ovals. If patient writes 2 digit number, code first digit as "0" If a range given, code lower end of range

A11	Do you have private health insurance?	A11	1 2 99	Yes No Missing	If both answers are selected code as 'missing'
A12	Do you hold a concession card? (e.g. Health Care Card, Pensioner Concession Card, Department of Veterans' Affairs Card)	A12	1 2 99	Yes No Missing	If both answers are selected code as 'missing'
A13	What is the date today?	A13	 99	dd/mm/yyyy Missing	*complete grid on page 12 of scannable survey. Colour ALL ovals. When the item has been left blank then enter the date that the survey was received from the database.

Section B: Your cancer journey

Item # in survey	*CANCER HISTORY AND TREATMENT*				
	Question	Scan variable	Scan code	Option	Coding rules
B1	What type of cancer do you have? *Please tick only one box*	B1A B1B B1C B1D B1E B1F	 1= yes Not shaded=99	Haematological (Blood) Breast Colorectal Prostate Lung Melanoma Other	If a response written in 'other' back code where appropriate "use "Additional Coding Rules" to help classify cancer types If multiple are coded, attempt to code primary cancer *don't code sites where primary has metastasised.

B1 open	Other, please specify_____	B1OTH1 B1OTH2 B1OTH3 B1OTH4	Missing *.**** *.**** *.**** *.****	C= 1 M = 2 Return as decimal eg 1.1315, 2.1111	"use "Additional Coding Rules" to help classify cancer types (up to four additional cancer types can be coded) *complete grid on page 12 of scannable survey. Only colour the grid you need starting with the first, and colour ALL ovals.
B2	What stage was you cancer when it was first diagnosed? *Please tick only one box.*	B2	1 2 3 99	Early Advanced and/or incurable Don't know Missing	If 2 or more answers are selected code as 'missing'
B3	How long ago were you diagnosed with cancer?	B3	1 2 3 4 5 99	0-3 months 4- 6 months 7-12 months 1-2 years More than 2 years Missing	If 2 or more answers are selected code as missing. (it is possible that most recent reflects recurrence or spread after diagnosis)
B4	Have you received any of the following treatments for your cancer?	B4A B4B B4C B4D B4E B4F B4G B4H B4I	1= yes Not shaded=99	Surgery Chemotherapy Radiation therapy Hormone therapy Biological therapy Bone marrow transplant Stem cell transplant I haven't had any treatment Other	Back code "other' into existing categories where appropriate. See "Additional Coding Rules" for a description of drugs and the category that they apply to" Do not code responses in relation to previous cancers, only current cancers. If 'other' cannot be back coded, enter into excel sheet saved in data folder

B5	Where are you in your cancer journey?	B5	1 2 3 4 5 99	I haven't had treatment, 'watch and wait' only I am receiving treatment to try and cure my cancer I have completed treatment to cure my cancer and am now in follow-up I have been told my cancer cannot be cured and am receiving anticancer treatment I have been told my cancer cannot be cured and am not currently receiving anticancer treatment missing	If 2 or more answers are selected code as 'missing'

[Sections C and D were not included as they were not relevant for the data analyses conducted as part of this thesis.]

Section E: Your decisions about treatment

This section asks questions about decisions you have faced regarding your cancer treatment. When answering these questions, please think back to your last important decision about your cancer treatment. Please fill in the bubble next to the option that best describes your answer.

	Question	Scan variable	Scan Code	Option	Coding rules -
E1	How involved were you in making that decision?	E1	1 2 3 4 5 99	I made the decision about which treatment I would receive I made the final decision about my treatment after seriously considering my doctor's opinion Both my doctor and I shared responsibility for deciding which treatment was best for me My doctor made the final decision about which treatment would be used, but seriously considered my opinions I left all decisions regarding my treatment to my doctor Missing	If two answers are selected code as missing

E2	How involved would you like to be in making the decision?	E2	1 2 3 4 5 99	I prefer to make the decision about which treatment I will receive I prefer to make the final decision about my treatment after seriously considering my doctor's opinion I prefer that my doctor and I share responsibility for deciding which treatment is best for me I prefer that my doctor makes the final decision about which treatment will be used, but seriously considers my opinions I prefer to leave all decisions regarding my treatment to my doctor Missing	If two answers are selected code as missing
E3	Did a doctor, nurse or other health care provider:				
	Ask you how involved you would like to be in making decisions	E3A	1 2 3	Yes and I wanted this Yes but I did not want this	If two answers are selected code as missing

	about your cancer care?		4 5 99	No but I wanted this No but I did not want this Not applicable Missing	
	Inform you about the possible benefits of your decision?	E3B	1 2 3 4 5 99	Yes and I wanted this Yes but I did not want this No but I wanted this No but I did not want this Not applicable Missing	If two answers are selected code as missing
	Inform you about the possible risks of your decision?	E3C	1 2 3 4 5 99	Yes and I wanted this Yes but I did not want this No but I wanted this No but I did not want this Not applicable Missing	If two answers are selected code as missing
	Provide you with enough time to think about the options?	E3D	1 2 3 4 5 99	Yes and I wanted this Yes but I did not want this No but I wanted this No but I did not want this Not applicable Missing	If two answers are selected code as missing
E4	Would you feel comfortable declining a treatment that was	E4	1 2	Yes if I thought it was not in my best interests	If both answers are selected, code as missing

	recommended by your doctor?		99	No I trust the doctor to know what is best for me Missing	

Additional Coding Rules

Section A, Q6, What is the highest level of education that you have completed "other"
Number used next: 14

Education	Allocated code (starting at 10)
Industry specific in house	10
Not applicable	11
Diploma (unclear if TAFE or industry)	12
Army Education Leaving	13

Section A, Q7, What country were you born 'other', Country name
Number used next: 81

Country	Allocated code (start at 9 and onwards)
Argentina	28
Austria	15
Austria (duplicate, merge 15 and 27)	27
Belarus (Republic of Belarus)	57
Borneo	68
Burma	58
Bangladesh	62
Canada	13
Chile	48

China (The People's Republic of China)	30
Colombia	72
Cook Islands	79
Croatia	26
Cyprus (Republic of Cyprus)	36
Czech Republic	46
Denmark	25
East Timor (Democratic Republic of Timor-Leste)	40
Egypt	31
Fiji	47
France	10
Germany	24
Greece	29
Hong Kong	35
Holland / Netherlands	12
Hungary	39
India	59
Indonesia	34
Iraq (Republic of Iraq)	49
Iran	55
Ireland	14
Israel	66
Japan	9
Jamaica	44
Jordan	69
Kenya	73
Korea	64
Lebanon (Lebanese Republic)	33
Macedonia	60
Malaysia	17
Malta	23
Netherlands/Holland	12

Niue	50
Norway	71
Pakistan	65
Papua New Guinea/ New Guinea/ Papua Island	16
Philippines	11
Poland	41
Romania	54
Russia	75
Samoa	42
Scotland	80
Serbia (Republic of Serbia)	45
Seychelles (Republic of Seychelles)	51
Singapore	53
Slovak Republic (Slovakia)	43
South Africa	19
Spain	61
Sri Lanka	37
Sudan	67
Switzerland	22
Taiwan	56
Tanzania	77
Thailand	52
Tonga	32
Tuvalu	70
Ukraine	38
United Arab Emirates	76
Uruguay	63
USA	21
Vietnam	78
Wales	20
Yugoslavia	18
Zimbabwe	74

Section A, Q8, What best describes your employment at this time "other"?

Next number = 17

Employment	Allocated code (starting at 10)
On leave (or some variant)	10
Carers pension	11
Carer for grandchildren	12
Self employed	13
Not working due to illness	14
Retrenched/laid off	15
Retired but farming	16

Section B. Q1 What type of cancer do you have?
Variable label: CA_TYPE

Code	Response Option	Please code all of these cancer types/names under the response option in the previous column	
C8195	Haematological (Blood) Cancer	Hodgkin's disease Non-Hodgkin's lymphoma (Waldenstrom Macroglobulinemia) Multiple myeloma Acute lymphoblastic leukaemia Other lymphoid leukaemias (Chronic lymphocyticLeukaemia Acute myeloid leukaemia Other myeloid leukaemia (Chronic myeloid leukaemia) Other specified leukaemias (Hairy cell leukaemia) Unspecified leukaemias	If they write in 'Other' category, back code into current response option categories
C50	Breast	Ducatal carcinoma in situ (DCIS) Invasive breast cancer HER2 positive breast cancer Rare type breast cancer Lobular carcinoma in situ Breast cancer of no special type Inflammatory breast cancer Paget's disease of the breast Lobular breast cancer	If they write in 'Other' category, back code into current response option categories
C1721	Colorectal	Colon and rectal cancer Bowel cancer Anal cancer Rectum, rectosigmoid	If they write in 'Other' category, back code into current response option categories
C61	Prostate	Early (localised) prostate cancer Locally advanced prostate cancer	If they write

		Advanced (Metastatic) prostate cancer	in 'Other' category, back code into current response option categories
C334	Lung	Small cell lung cancer Non-small cell lung cancer Varcinosarcoma Pulmonary blastoma Lung cancer, secondary bronchus	If they write in 'Other' category, back code into current response option categories
C43	Melanoma	Thin melanoma Superficial spreading melanoma Nodular melanoma Lentigo maligna melanoma Acral melanoma Advanced melanoma	If they write in 'Other' category, back code into current response option categories
Q13OTH	Other, please specify____	Variable output as= ICD code 1.0000=C00 Lip 1.0102=C0102 Tongue 1.0306=C0306 Mouth 1.0708=C0708 Salivary glands 1.0900=C0900 Tonsil (tonsillar SCC) 1.0910=C0910 Oropharynx 1.1100=C11 Nasopharynx 1.1213=C1213 Hypopharynx 1.1400=C14 Other and ill-defined sites in the lip, oral cavity and pharynx 1.1499=C1499 = Head and Neck unspecified 1.1500=C15 Oesophagus (gullet) 1.1600=C16 Stomach (gastric)	Code in A13OTH

		1.1721=C1721 Colorectal cancer: small intestine, colon, rectum, large bowel 1.2200=C22 Liver (hepatocellular carcinoma HCC, hepatoma, Angiosarcomas, haemangiosarcomas, Hepatoblastomas) 1.2210 = C22.1 Intrahepatic bile duct carcinoma (Cholangiocarcinoma: also known as colangial or cholangio cancer) 1.2324=C2324 Gallbladder (Bile duct cancer) 1.2500=C25 Pancreas (Pancreatic cancer, ductal adenocarcinoma, cystic tumours, acinar cell carcinomas, Gastroenteropancreatic tumours (GEPs) insulinomas, gastrinomas, glucagonomas, VIPomas, somatostatinomas) 1.3031=C3031 Nose, sinuses, etc 1.3200=C32 Larynx 1.3334=C3334 Bronchus, Lung 1.3738=C3738 Other thoracic organs 1.3800 =Malignant neoplasm of heart, mediastinum and pleura 1.4041=C4041 Bone (Ewing's sarcoma; Osteosarcoma; osteogenic sarcoma; Chondrosarcoma; Spindle cell sarcoma; Chordoma; Angiosarcoma). 1.4300=C43 Melanoma 1.4400=C44 Other skin (Basal cell carcinoma BCC (also called rodent ulcer); Squamous cell carcinoma SCC, Merkel cell carcinoma) [Only coded as this if specified as skin cancer. Otherwise coded as other (2.1111) since can occur elsewhere.] 1.3830=C38.3 Malignant neoplasm of the mediastinum 1.4500=C45 Mesothelioma 1.4600=C46 Kaposi's sarcoma 1.4749=C4749 Connective tissue, peripheral nerves (Fibrosarcomas, Myxofibrosarcomas, Desmoid tumours, Liposarcomas, Synovial sarcomas, Rhabdomyosarcomas, Leiomyosarcomas, Malignant peripheral nerve sheath tumours (MPNST), Angiosarcomas, Gastrointestinal stromal tumours (GIST), Ewing's tumours) 1.4800=C48 Retroperitoneum and peritoneum Mesentery, Mesocolon, Omentum, Peritoneum (parietal, pelvic) 1.4900=C49 Malignant neoplasm of other connective and soft tissue 1.5000=C50 Breast 1.5300=C53 Cervix (Cervical cancer) 1.5455=C5455 Uterus, Body & NOS (Womb, endometrial cancer)	

		1.5657=C5657 Ovary (Ovarian Cancer) 1.5800= Placenta 1.5900=C59 Other female genital organs (Fallopian tube cancer; Vagina cancer; Vulva cancer) 1.6100=C61 Prostate 1.6200=C62 Testis (Testicular cancer, seminomas, non-seminomatous germ cell tumours, teratomas) 1.6063=C6063 Other male genital organs (Penis cancer) 1.6468=C6468 Kidney, etc (renal cell cancers RCC, renal adenocarcinoma, transitional cell cancer TCC, Wilms' tumour) 1.6700=C67 Bladder 1.6900=C69 Eye (ocular melanoma, Uveal melanoma, conjunctival melanoma) 1.7100=C71 Brain (Gliomas, Astrocytic tumours, Oligodendroglioma, Ependymoma, Medulloblastoma, Pineal region tumours, Meningioma, Acoustic neuroma, vestibular schwannoma neurilemmoma, Haemangioblastoma, Spinal tumours, Glioblastoma) 1.7072=C7072 Central nervous system (Spinal cord tumours Intramedullary tumours, astrocytomas, ependymomas, Intradural extramedullary tumours, Extradural spinal tumours, chordomas, osteomasosteosarcomas, chondrosarcomas, fibrosarcomas). 1.7300=C73 Thyroid (Papillary, Follicular, Medullary, Anaplastic) 1.7475=C7475 Other endocrine glands (Adrenal gland tumours (phaeochromocytoma), Multiple endocrine neoplasia 1 (MEN1), Multiple endocrine neoplasia 2 (MEN2), Parathyroid gland tumours, Pituitary gland tumours (adenomas), Thymus cancer (thymoma and thymic carcinoma), Neuroendocrine tumours 1.7730=C77.3 Axillary and upper limb lymph nodes 1.8100=C81 Hodgkin's lymphoma 1.8285=C8285 Non-Hodgkin's lymphoma 1.8890=C8890 Multiple Myeloma 1.9140=C9140 Hairy-cell leukaemia 1.9195=C9195 All Leukaemias 1.9800=C98 Cancer of Unknown Primary 2.9500=M95 Other lymphatic haematopoietic, myelodysplasia 1.9640 = C9640 Follicular dendritic cell sarcoma	

		2.1111 = Other (carcinoid, pseudo myxoma, angiosarcoma (unspecified), adenocarcinoma (unspecified), “Right arm”, “pelvic”, “lymph node”, sarcoma, “tumor”) [Coded as M1111]	

Data obtained from: http://www.macmillan.org.uk/Cancerinformation/Cancertypes/AtoZ.aspx
Also good website: http://apps.who.int/classifications/icd10/browse/2010/en#/C

Please note: The terms, adenocarcinoma, squamous cell carcinoma, sarcoma, leiomyosarcomas, gastrointestinal stromal tumours (GISTs), carcinoid tumours are used interchangeably with different cancer types

Section B. Q4 Have you received any of the following treatments for your cancer? (*Please tick all that apply)*
Variable Label OTHER_TREAT

If any of the following are listed in ‘other’ please back code to the corresponding treatment

Hormone treatment		Antibody treatment, Biological therapy		Chemotherapy		Leave as ‘Other’ Or consider whether treatment is for side effects (not cancer)
Individual hormonal therapies by brand name	Individual hormonal therapies	By generic name	By brand name	Individual chemotherapy drugs by brand name	Individual chemotherapy drugs	
Arimidex® Aromasin® Casodex® Cyprostat® Decapeptyl® SR Depo-Provera® Drogenil®	Anastrozole Abiraterone acetate By brand name Bicalutamide Buserelin Cyproterone Degarelix Diethylstilbestrol Exemestane	90Y-Ibritumomab tiuxetan ADEPT Aldesleukin Alemtuzumab Bevacizumab Bortezomib Cetuximab Crizotinib	Avastin® BEXXAR® Erbitux® Glivec® Herceptin® IntronA® Iressa® MabCampath® Mabthera®	5FU Alimta® Alkeran® Amsidine® BiCNU® Busilvex® Caelyx® Campto®	Abraxane Amsacrine Azacitidine Bendamustine Bleomycin Busulfan Capecitabine Carboplatin Carmustine	

Fareston® Faslodex® Femara® Firmagon® Gonapeptyl Depot® Megace® Prostap® 3 Prostap® SR Provera® Sandostatin Stilboestrol® Suprefact® Xtandi Zoladex® (Breast) Zoladex®, Zoladex® LA (Prostate) Cabazitaxel Abiraterone Lucrin	Enzalutamide Flutamide Fulvestrant Goserelin (Breast) Goserelin (Prostate) Letrozole Leuprorelin acetate Medroxyprogesterone Megestrol acetate Octreotide Tamoxifen Toremifene Triptorelin Jevtana Zytiga	Dasatinib Denosumab Erlotinib Everolimus Gefitinib Gemtuzumab Imatinib Interferon alpha Interleukin-2 Iodine-131 tositumomab Ipilimumab Lapatinib Lenalidomide Panitumumab Pembrolizunab Rituximab Sorafenib Sunitinib Thalidomide Trastuzumab Verumafenib Trametinib Dabrafenib Lambrolizumab bacillus calmette-guerin (BCG) Pazopanib LUTATE	Mylotarg® Nexavar® Proleukin® Afinitor® Revlimid® Roferon-A® Sprycel® Sutent® Tarceva® Thalidomid® Tyverb® Vectibix® Velcade® Xgeva YERVOY™ MK3475 (Trial drug) Zevalin® Zelboraf Votrient Sandostatin TheraCys BCG, TICE BCG	Cosmegen Lyovac® DaunoXome® DTIC® Eldisine® Eloxatin® Etopophos® Erwinase® Evoltra® Fludara® Gemzar® Hycamtin® Hydrea® Lanvis® Leukeran® Leustat® Levact® Lysodren® Matrex® Mitoxana® Myleran® Myocet® Navelbine® Nipent® Oncovin® Pharmorubicin® Puri-Nethol® Taxol Taxotere® Temodal® Tomudex® Uftoral® Uromitexan®	Chlorambucil Cisplatin Cladribine Clofarabine Crisantaspase Cyclophosphamide Cytarabine Dacarbazine Dactinomycin Daunorubicin Docetaxel Doxorubicin Epirubicin Etoposide Fludarabine Fluorouracil Gemcitabine Gliadel implants Hydroxycarbamide Idarubicin Ifosfamide Irinotecan Leucovorin Liposomal daunorubicin Liposomal doxorubicin Lomustine Melphalan Mercaptopurine Mesna Methotrexate Mitomycin Mitotane	

				Velbe® Vepesid® Vidaza® Xeloda® Yondelis® Zanosar® Zavedos®	Mitoxantrone Oxaliplatin Paclitaxel Pemetrexed Pentostatin Procarbazine Raltitrexed Rasburicase Satraplatin StreptozocinM Tegafur-uracil Temozolomide Thiotepa Tioguanine Topotecan Trabectedin Treosulfan Vinblastine Vincristine Vindesine Vinorelbine	

Appendix 10.4: Participant information statements and reminders related to Papers Two and Three

Insert Header with institution's name or institution's letterhead

Screening Participant Information Statement

[Insert site name]

ANZ 1301: A phase II study evaluating a Decision Aid for women considering neoadjuvant chemotherapy for operable breast cancer

Short Title	DOMINO
Protocol Number	ANZ 1301
Project Sponsor	Australia and New Zealand Breast Cancer Trials Group
Principal Investigator	*[Principal Investigator]*

This Screening Participant Information Statement is <<XX>> pages long. Please make sure you have all the pages of this document. You will be given a copy of this information to keep.

1 Introduction

You are invited to consider taking part in a research study called DOMINO. This is because you have been diagnosed with breast cancer and you have been asked to think about having chemotherapy before surgery for your cancer (this is called neoadjuvant chemotherapy).

This document tells you about the information your doctor wants to collect to check if the DOMINO study is suitable for you – a process called screening. It asks for your consent (permission) for your doctor to send information about your breast cancer and your name, email address and phone number to the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG). The ANZBCTG will then send you a link to their website where you can read about taking part in the main DOMINO study.

To take part in the DOMINO study you need to have access to the internet, an active email account and a desktop or laptop computer.

2 Purpose and Background

The purpose of the DOMINO study is to find out if a Decision Aid is helpful to women who are deciding whether or not they will have chemotherapy treatment for breast cancer before surgery (neoadjuvant chemotherapy). A Decision Aid is a document that explains the pros and cons of the options that are available.

Agreeing to provide screening information does not automatically mean that you will participate in the main DOMINO study. You will receive an email from the ANZBCTG with a link to a separate online information form, which gives full details about the main DOMINO

study. It will take 1-2 business days for this access to be arranged by the ANZBCTG. After you read this information you can then decide whether you wish to take part.

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

3 Information about your breast cancer diagnosis

The following information about your breast cancer diagnosis may help you to decide about whether you wish to have surgery or chemotherapy first. It will help you get the most out of the decision aid, if you choose to take part in this study. Your surgeon or medical oncologist will record this information, if it is available.

Type of surgery possible NOW:	□ Mastectomy □ Breast Conserving Surgery
Type of surgery that may be possible AFTER chemotherapy or hormonal therapy:	□ Mastectomy □ Breast Conserving Surgery

Your doctor will be able to tell you about which type of breast cancer you have, if that information is available at the time you are given this document:

Type of breast cancer:

- □ Hormone receptor positive (oestrogen (ER+) and/or progesterone (PR+)), HER2 negative (HER2-)
- □ Hormone receptor positive (oestrogen (ER+) and/or progesterone (PR+)), HER2 positive (HER2+)
- □ Hormone receptor negative (oestrogen (ER-) and progesterone (PR-)), HER2 positive (HER2+)
- □ Hormone receptor negative (oestrogen (ER-) and progesterone (PR-)), HER2 negative (HER2-) (triple negative)
- □ Breast cancer type not yet known

Hormone receptors and HER2 are different types of proteins on the surface of cancer cells that make the cells act in a particular way. The type of treatment you have can depend on whether particular receptors are present (“positive”) or not present (“negative”).

You may wish to make a note of your preferred option for breast cancer surgery after talking to your surgeon or medical oncologist:	
I wish to have breast conserving surgery (lumpectomy) if possible:	☐ Yes ☐ No

4 What will happen to information about me?

By signing the Declaration by Participant section on the Screening Form, you consent to your doctor and the ANZBCTG collecting, using and storing personal information about you for the purpose of screening for the DOMINO study. All information collected will remain confidential. Once the study has been completed, records will be retained in a locked storage facility for a prolonged period (over 15 years).

You have the right to request access to the information collected and stored by the study team about you. Please contact the study team member named at the end of this document if you would like to access your information. Your personal details will not be included in any publication about this study.

5 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people, called a Human Research Ethics Committee (HREC). This study has been reviewed and given approval by Hunter New England Human Research Ethics Committee and HREC reference: 14/12/10/4.05.

This study will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This study and patient information material have been reviewed and endorsed by the ANZBCTG Consumer Advisory Panel.

6 Who to contact

If you would like any further information about this study you can contact your study doctor using the contact information below:

Name	*[Name]*
Position	*[Study doctor]*
Telephone	*[Phone number]*
Email	*[Email address]*

You can also contact the ANZBCTG staff listed below for further information about this study:

Name	Dr Nicholas Zdenkowski	Ms Elizabeth Hutchings
Position	Study Chair	Project Officer
Telephone	(02) 4985 0134	(02) 4985 0120
Email	nicholas.zdenkowski@anzbctg.org	elizabeth.hutchings@anzbctg.org

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

Reviewing HREC approving this research

Reviewing HREC	Hunter New England Local Health District HREC
HREC Executive Officer	Dr Nicole Gerrand
Telephone	(02) 4921 4950
Email	HNELHD-HREC@hnehealth.nsw.gov.au

Participant Information Statement

Australia and New Zealand Breast Cancer Trials Group

ANZ 1301: A phase II study evaluating a Decision Aid for women considering neoadjuvant chemotherapy for operable breast cancer

Short Title	DOMINO
Protocol Number	ANZ 1301
Project Sponsor	Australia and New Zealand Breast Cancer Trials Group
Principal Investigator	Dr Nicholas Zdenkowski

1 Introduction

You are invited to take part in this clinical research study because you have been diagnosed with breast cancer and your doctor has asked you to think about having chemotherapy treatment before surgery for your cancer (neoadjuvant chemotherapy).

This research study aims to work out if a Decision Aid helps women to make a decision about their treatment. Reading a Decision Aid, which explains the pros and cons of available treatment options may help women make the best possible decision.

Participation in this study is voluntary. If you don't wish to take part, you don't have to. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment.

If you decide you want to take part in this research study, please click on the "I Agree" button at the end of this information.

You can print or download a copy of this Participant Information Statement to keep.

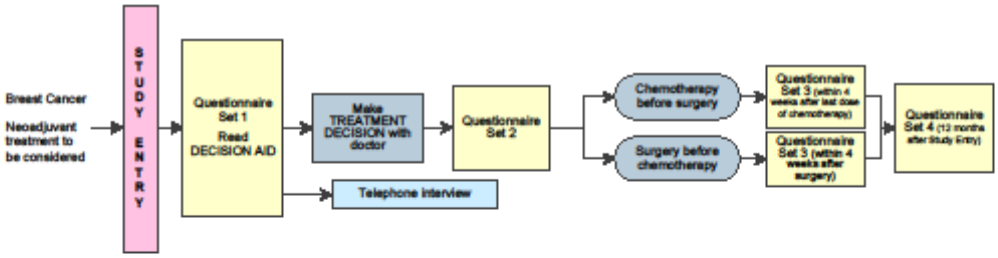
2 What does participation in this study involve?

If you decide to take part in the study, you will be asked to fill in questionnaires online at four different times. Your answers to the questions will help researchers work out whether the Decision Aid is useful. Each set will take from 10 to 20 minutes to complete. You will also have the opportunity to discuss the decision aid with your doctor.

You will also be asked to take part in a telephone interview during the study.

Another way to understand what is involved in the study is given below in a diagram.

Questionnaires



If you decide to take part in this study, there are 4 sets of questionnaires to complete at set times over a 12 month period. You will be reminded by email to access these questionnaires each time they are due to be filled in:

1. After you click "I Agree" at the end of this information, you will be asked to provide information about yourself, and to fill in **Questionnaire Set 1** online. These questions will ask you how you feel about the treatment options that have been explained to you at this stage. This set will take about 10 minutes to complete.

You will then be able to read the **Decision Aid** online. This can be downloaded and printed if you wish. The printed Decision Aid will be 23 pages long.

You will see a medical oncologist after this to discuss and make a decision about your treatment. He/she will also discuss any questions you have after reading the Decision Aid.

2. After you have made a decision about your treatment, an email will be sent to you with a link to **Questionnaire Set 2.** These questions should be filled in online as soon as possible after you have made your decision. This set of questionnaire will ask you how you feel about your treatment decision. It will take about 15-20 minutes to complete.
3. You will be asked to fill in **Questionnaire Set 3 either:**
   a. after your neoadjuvant chemotherapy is completed and before surgery, OR
   b. after surgery and before any chemotherapy treatment starts, if you decide to have surgery first.

   This questionnaire will take about 10-15 minutes to complete.
4. Twelve months after you entered the DOMINO study, you will be asked to fill in **Questionnaire Set 4**. This is the last set and will ask you how you feel about your decision 12 months after your breast cancer diagnosis. This set will take about 10-15 minutes to complete.

Please answer as many questions as you can. You do not have to answer all of the questions if you don't want to; even questions that are not answered can give information to the researchers about the usefulness of the Decision Aid.

Your doctor will also provide the researchers with information about your breast cancer.

Telephone Interview

The researchers will contact study participants by phone to understand individual women's experiences using the decision aid. The interview will take about 45 minutes.

The phone interview is optional; there is a box to check at the end of this information if you do not want to take part. If you agree to take part, then change your mind when the interviewer contacts you by phone, or you do not want to continue with the interview at any point, please let the interviewer know and the interview will be stopped straight away. You do not have to answer every question in the interview.

The interview will be recorded so that the information from all of the interviews can be assessed. All interview data will remain confidential.

3 What are the possible benefits of taking part?

This research may help women in the future who are diagnosed with breast cancer and who also need to make the same decision. It is an extra resource that may make it easier for women to decide which treatment option to choose; however, there may be no clear benefit to you from your participation in this study.

4 What are the possible disadvantages of taking part?

You might spend more time talking with your doctor as a result of reading the Decision Aid, so this visit might take longer. Completing the questionnaires will take up some of your time.

Some of the questions are personal and might lead to discomfort. If you become distressed as a result of filling in the questionnaires or during the telephone interview (if you participate), arrangements will be made for you to be followed up with your local health care provider and your doctor. You may also wish to call the Cancer Council Helpline on 13 11 20; this is a free and confidential support service.

5 What if I withdraw from this study?

If you wish to withdraw from this study please advise the study team. The study team will then give you a "Withdrawal of Consent" form to complete and sign.

If you do withdraw your consent during the study, the study doctor and relevant study staff will not collect additional personal information from you. The researchers would like to keep your personal information already collected and include this in the study analysis. However, if you wish, the information that has already been collected (personal information and questionnaire answers) will be removed. Please tell your study doctor or research nurse which option you prefer.

6 What happens when the study ends?

We plan to publish the results of this study in peer reviewed scientific/medical journals, in presentations at conferences and other professional forums. It is usual for a number of years to pass before the results of this type of study are available. Participants will not be named and no personal identifying information will be included in a publication or presentation.

7 What will happen to information about me?

By clicking the "I Agree" button at the end of this information, you consent to the study doctor and research staff collecting, using and storing personal information about you for the research study. All information collected for this study will remain confidential. Your information will be used for the purpose of this study and may be used for other purposes; it will only be used with your permission, except as required by law.

The ANZBCTG will store your contact details so that you can be phoned for reminders about the questionnaires and to take part in the telephone interview. Once the study has been completed, records will be retained in a locked storage facility for a prolonged period (over 15 years). Only staff involved with the study will have access to the information.

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

8 Who is organising and funding the study?

This study is being conducted by doctors who are members of the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) which conducts research throughout Australia and New Zealand to help develop better ways of preventing, diagnosing and treating breast cancer. No member of the research team will obtain any financial benefit from their involvement in this study.

The ANZBCTG and the HCF Health and Medical Research Foundation are providing financial support for the conduct of this study.

9 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people, called a Human Research Ethics Committee (HREC). This study has been reviewed and given approval by Hunter New England Human Research Ethics Committee and HREC reference: 14/12/10/4.05.

This study will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies. This study and patient information material have been reviewed and endorsed by the ANZBCTG Consumer Advisory Panel.

10 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you would like any further information about this study you can contact the following people using the contact information below:

Name	Dr Nicholas Zdenkowski	Ms Elizabeth Hutchings
Position	Study Chair	Project Officer
Telephone	(02) 4985 0134	(02) 4985 0120
Email	nicholas.zdenkowski@anzbctg.org	elizabeth.hutchings@anzbctg.org

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

Reviewing HREC approving this research

Reviewing HREC	Hunter New England Local Health District HREC
HREC Executive Officer	Dr Nicole Gerrand
Telephone	(02) 4921 4950
Email	HNELHD-HREC@hnehealth.nsw.gov.au

For matters relating to research at the site at which you are participating:

Local Research Governance Office contact

Name	Dr Nicole Gerrand
Position	Manager, Research Ethics and Governance
Telephone	(02) 4921 4950
Email	nicole.gerrand@hnehealth.nsw.gov.au

By clicking the 'I Agree' button, you indicate that you have read and accept the terms, and consent (agree) to participate in the ANZ 1301 DOMINO research study.

<<I AGREE>>

Only participants who agree to participate will see the following:

☐ Please check this box if you do not want to take part in a telephone interview for the DOMINO research study.

DOMINO Draft Auto Response Emails to Study Coordinators and to Study Participants

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
One		*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Study Information* *Dear potential DOMINO study participant,* *Thank you for your interest in the DOMINO Study.* *Please take a few minutes to read the information about DOMINO given to you by your doctor.* *You can access more information about DOMINO by clicking here. This will take you to the Participant Information Statement; please take as much time as you need to read this material. From there, you can start the study if you wish to take part. You will be asked to enter a password of your choice.* *Please note that this site is not optimised for use on a mobile phone.*	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Study Information - Reminder* *Dear potential DOMINO study participant,* *Thank you for your interest in the DOMINO Study.* *Please take a few minutes to read the information about DOMINO given to you by your doctor.* *You can access more information about DOMINO by clicking here.* *You will be asked to confirm your email address and enter a password of your choice.* *Please note that this site is not optimised for use on a mobile phone.* *It is important that you take as much time as you wish to read about DOMINO on our website; you can re-enter the website by*	DOMINO: Potential patient; Website not accessed *Patient Initials: XXXX* *Date of Birth: XXXX* *Contact patient to discuss*

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
		It is important that you take as much time as you wish to read about DOMINO on our website; you can re-enter the website by following the above steps as many times as you like. *DOMINO is conducted by the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG); your doctor is part of this research program. Please click here for further information about our research.* *DOMINO has been approved by the Hunter New England Local Health District Human Research Ethics Committee. (Reference Number: 14/12/10/4.05)* *Please do not reply to this email; if you require further information please click* domino@anzbctg.org *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	*following the above steps as many times as you like.* *DOMINO is conducted by the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG); your doctor is part of this research program. Please click here for further information about our research.* *DOMINO has been approved by the Hunter New England Local Health District Human Research Ethics Committee. (Reference Number: 14/12/10/4.05)* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
Two	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Patient Registered* *Dear DOMINO study coordinator,* *The following patient has consented and registered online to take part in the DOMINO Study.* *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Date registered: XXXX* *Referring Centre: XXXX* *Please print this email as a record of patient consent and study entry.* *Please login to the DOMINO website and enter the following data:* 1. *Appointment date*	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Study Confirmation* *Dear DOMINO study participant,* *Thank you for agreeing to take part in DOMINO, this email confirms your entry to the Study. You now have access to the DOMINO website.* *If you have not already done so, your next step is to read the DOMINO Decision Aid and to answer the first set of questionnaires. Once you have completed this stage you will receive a confirmation email.* *You can access the first set of DOMINO questionnaires by clicking here; you will be asked to enter the below information:* • *User Name – your email address*	NIL	DOMINO: New patient registration *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Registration Date: XXXX* *Site: XXXXX* *Medical Oncologist: XXXXX* *No action required*

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	2. *Medical oncologist name and email address. This email address will be used for the Decision Aid Investigator-Reported Accessibility & Feasibility Survey – see DOMINO Protocol Section 6.10 for further information)* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Kind regards,* *The ANZBCTG DOMINO Study Team*	• *Password* *If at any time during the study you forget your password, please click here.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Thank you again for supporting the DOMINO Study. By volunteering for this research you will help the ANZBCTG advance our understanding of breast cancer and improve treatment and prevention strategies available to women.* *The ANZBCTG DOMINO Study Team*		
Three	*ONLY GENERATED WHEN A PARTICIPANT HAS SUBMITTED QUESTIONNAIRE SET ONE* *Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set One Received*	*ONLY GENERATED WHEN A PARTICIPANT HAS SUBMITTED QUESTIONNAIRE SET ONE* *Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set One Received*	*ONLY GENERATED IF PARTICIPANT EXITS THE SITE AFTER REGISTRATION WITHOUT SUBMITTING SET ONE QUESTIONNAIRES*	*ONLY GENERATED IF PARTICPANT EXITS THE SITE AFTER REGISTRATION WITHOUT SUBMITTING SET ONE QUESTIONNAIRES AND AFTER EMAIL REMINDER*

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	Dear DOMINO study coordinator, *For information. The following patient has completed DOMINO Questionnaire Set One.* *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Kind regards,* *The ANZBCTG DOMINO Study Team*	*Dear DOMINO study participant,* *Thank you for completing Questionnaire Set One. This email confirms that we received your answers.* *We will contact you after your appointment with your medical oncologist, at which time we will ask you to complete the second set of DOMINO questionnaires.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set One Reminder* *Dear DOMINO study participant,* *We noticed that you did not complete Questionnaire Set One. Please try to login by <<date>> to answer the questionnaires.* *To complete the questionnaires click here (to take you to the DOMINO website) and enter your DOMINO user name and password.* • *User Name – your email address* • *Password* *If at any time during the study you forget your password, please click here.* *Please do not reply to this email; if you require further*	DOMINO: Questionnaire Set One: Incomplete *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Site: XXXXX* *Contact patient to discuss*

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
			information please click domino@anzbctg.org *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	
Four	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Request for Data - Treatment Decision Visit* *Dear DOMINO study coordinator,* *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Please login to the DOMINO website and enter the following data:* 1. *Treatment decision*	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Two Available* *Dear DOMINO study participant,* *Thank you for your ongoing support of DOMINO. Please follow the below a link to access Set Two of the DOMINO Study Questionnaires. To complete the questionnaires click here (to take you to the DOMINO website) and enter your DOMINO user name and password.*	*ONLY GENERATED IF PARTICIPANT EXITS THE SITE WITHOUT SUBMITTING SET TWO OR DOES NOT ACCESS THE LINK* *Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Two Reminder* *Dear DOMINO study participant,* *We noticed that you did not complete Questionnaire Set Two. Please try to login by <<date>> to answer the questionnaire.*	*ONLY GENERATED IF PARTICIPANT EXITS THE SITE WITHOUT SUBMITTING SET TWO OR DOES NOT ACCESS THE LINK AFTER EMAIL REMINDER* DOMINO: Questionnaire Set Two: Incomplete TO: DOMINO TEAM *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Site: XXXXX*

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	2. *Expected date of last dose of chemo- or endocrine therapy (NAST) or planned date of surgery(adjuvant therapy)* 3. *Diagnostic and Pathology Data* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Kind regards,* *The ANZBCTG DOMINO Study Team*	• *User Name – your email address* • *Password* *If at any time during the study you forget your password, please click here.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	*To complete the questionnaires click here (to take you to the DOMINO website) and enter your DOMINO user name and password.* • *User Name – your email address* • *Password* *If at any time during the study you forget your password, please click here.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	*Contact patient to discuss.* *ONLY GENERATE IF SITE HAS NOT COMPLETED EXPECTED DATE OF LAST DOSE OF CHEMO- OR ENDOCRINE THERAPY (NAST) OR PLANNED DATE OF SURGERY (ADJUVANT THERAPY) DATA FIELD* DOMINO: Project date of NAST/ Surgery: Field Incomplete TO: DOMINO TEAM *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Site: XXXXX* *Contact site to discuss.*
Five	*ONLY GENERATED WHEN A PARTICIPANT HAS SUBMITTED QUESTIONNAIRE SET*	*ONLY GENERATED WHEN A PARTICIPANT HAS SUBMITTED QUESTIONNAIRE SET*	NIL	*SEE ADDITIONAL EMAILS REQUIRED AT BOTTOM OF TABLE – POINT 1*

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Two Received *Dear DOMINO study coordinator,* *For information. The following patient has completed DOMINO Questionnaire Set Two.* *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *If your patient's <<projected end date of NAST>> OR << date of surgery>> has changed from <<date>> please respond to this email with new details.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Kind regards,*	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Two Received* *Dear DOMINO study participant,* *Thank you for completing Questionnaire Set Two. This email confirms that we received your answers.* *We will contact you either:* • *<<after your last dose of chemo- or endocrine therapy (if you are having neoadjuvant treatment)>>* *OR* • *<<after your surgery (if you are having adjuvant treatment)>>,* *at which time we will ask you to complete the third set of DOMINO questionnaires.*		

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	The ANZBCTG DOMINO Study Team	*Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Thank you again for your ongoing support of the DOMINO Study.* *The ANZBCTG DOMINO Study Team*		
Six	*ONLY GENERATE IF SITE HAS NOT ENTERED PROJECTED NAST END DATE OR DATE OF SURGERY* *Subject Line: ANBCTG: ANZ 1301 (DOMINO): Request for Data - Treatment Dates* *Dear DOMINO study coordinator,* *Patient Initials: XXXX* *Date of Birth: XXXX*	NIL	NIL	NIL

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	Registration ID Number: XXXX *Please login to the DOMINO website to confirm the expected date* *<<of last dose of chemo- or endocrine therapy (NAST)>>* *OR* *<<planned date of surgery (if patient will not receive NAST and will proceed to surgery)>>* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Kind regards,* *The ANZBCTG DOMINO Study Team*			
Seven	NIL	*EMAIL TRIGGERED AFTER DATE OF SURGERY/ END NEOADJUVANT CHEMOTHERAPY OCCURS*	*ONLY GENERATED IF PARTICIPANT EXITS THE SITE WITHOUT SUBMITTING SET THREE OR DOES NOT ACCESS THE LINK*	*ONLY GENERATED IF PARTICIPANT EXITS THE SITE WITHOUT SUBMITTING SET THREE OR DOES NOT*

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
		Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Three Available *Dear DOMINO study participant,* *Thank you for your ongoing support of DOMINO. Please follow the below steps to access Set Three of the DOMINO Study Questionnaires.* *Click here (to take you to the DOMINO website) and enter your DOMINO user name and password:* • *LOGIN – your email address* • *Password* *If at any time during the study you forget your password, please click here.* *Please do not reply to this email; if you require further*	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Three Reminder* *Dear DOMINO study participant,* *We noticed that you did not complete Questionnaire Set Three. Please try to login by <<date>> to answer the questionnaires.* *To complete the questionnaires click here (to take you to the DOMINO website) and enter your DOMINO user name and password.* • *User Name – your email address* • *Password* *If at any time during the study you forget your password, please click here.* *Please do not reply to this email; if you require further*	*ACCESS THE LINK AFTER EMAIL REMINDER* DOMINO: Questionnaire Set Three: Incomplete TO: DOMINO TEAM *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Site: XXXXX* *Contact patient to discuss.* *SEE ADDITIONAL EMAILS REQUIRED AT BOTTOM OF TABLE – POINT 2*

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
		information please click domino@anzbctg.org *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	*information please click domino@anzbctg.org* *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	
Eight	*ONLY GENERATED WHEN A PARTICIPANT HAS SUBMITTED QUESTIONNAIRE SET* *Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Three Submitted* *Dear DOMINO study coordinator,* *For information. The following patient has completed DOMINO Questionnaire Set Three.* *Patient Initials: XXXX*	*ONLY GENERATED WHEN A PARTICIPANT HAS SUBMITTED QUESTIONNAIRE SET* *Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Three Submitted* *Dear DOMINO study participant,* *Thank you for taking the time to complete Set Three of the DOMINO Study Questionnaires. This email confirms receipt of your responses.*	NIL	NIL

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	Date of Birth: XXXX *Registration ID Number: XXXX* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Kind regards,* *The ANZBCTG DOMINO Study Team*	*We will contact you in <<Month, year>> (about 12 months after you originally registered for DOMINO), at which time we will ask you to complete the final set of DOMINO questionnaires.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Thank you again for your ongoing support of the DOMINO Study* *The ANZBCTG DOMINO Study Team*		
Nine	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Request for Data - Post-Treatment*	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Four Available* *Dear DOMINO study participant,*	*ONLY GENERATED IF PARTICIPANT EXITS THE SITE WITHOUT SUBMITTING SET THREE OR DOES NOT ACCESS THE LINK*	*ONLY GENERATED IF PARTICIPANT EXITS THE SITE WITHOUT SUBMITTING SET THREE OR DOES NOT ACCESS THE LINK AFTER EMAIL REMINDER*

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	Dear DOMINO study coordinator, *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Please login to the DOMINO website and enter Post-Treatment Data:* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Kind regards,* *The ANZBCTG DOMINO Study Team*	*Thank you for your ongoing support of DOMINO. Please follow of the below steps to access Set Four of the DOMINO Study Questionnaires.* *Click here (to take you to the DOMINO website) and enter your DOMINO user name and password:* • *LOGIN – your email address* • *Password* *If at any time during the study you forget your password, please click here.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Thank you again for your interest in the DOMINO Study.*	*Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Four Reminder* *Dear DOMINO study participant,* *We noticed that you did not complete Questionnaire Set Four. Please try to login within by <<date>> to answer the questionnaires.* *To complete the questionnaires click here (to take you to the DOMINO website) and enter your DOMINO user name and password.* • *User Name – your email address* • *Password* *If at any time during the study you forget your password, please click here.* *Please do not reply to this email; if you require further*	DOMINO: Questionnaire Set Four: Incomplete TO: DOMINO TEAM *Patient Initials: XXXX* *Date of Birth: XXXX* *Registration ID Number: XXXX* *Site: XXXXX* *Contact patient to discuss*

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
		The ANZBCTG DOMINO Study Team	*information please click domino@anzbctg.org* *Thank you again for your interest in the DOMINO Study.* *The ANZBCTG DOMINO Study Team*	
Ten	*ONLY GENERATED WHEN A PARTICIPANT HAS SUBMITTED QUESTIONNAIRE SET* *Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Four Submitted* *Dear DOMINO study coordinator,* *The following patient has completed DOMINO Questionnaire Set Four.* *Patient Initials: XXXX* *Date of Birth: XXXX*	*ONLY GENERATED WHEN A PARTICIPANT HAS SUBMITTED QUESTIONNAIRE SET* *Subject Line: ANBCTG: ANZ 1301 (DOMINO): Questionnaire Set Four Submitted* *Dear DOMINO study participant,* *Thank you for taking the time to complete the final set (Set Four) of the DOMINO Study Questionnaires. This email*	NIL	NIL

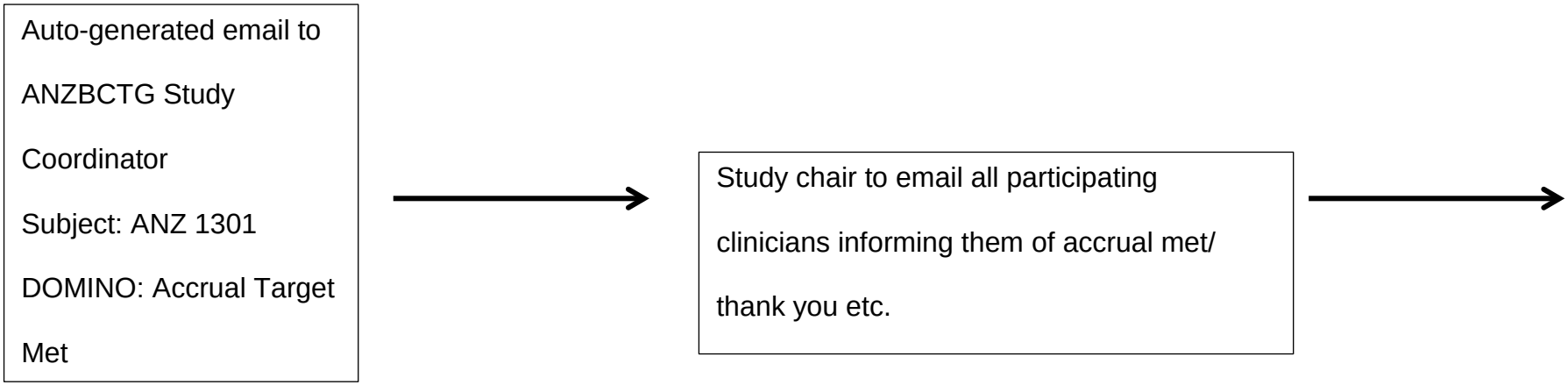
Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
	Registration ID Number: XXXX *This email marks the end of the data collection requirements for this patient. We will contact you to clarify any data queries. On behalf of the DOMINO Study Chair, Dr Nicholas Zdenkowski and the ANZBCTG DOMINO Study Team, we would like to thank you for your support of this Study.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org* *Kind regards,* *The ANZBCTG DOMINO Study Team*	*confirms receipt of your responses.* *This email marks the end of your participation in this study. On behalf of the DOMINO Study Chair, Dr Nicholas Zdenkowski and the ANZBCTG DOMINO Study team, we would like to sincerely thank you for your support of this Study.* *We plan to publish the results of this study in peer reviewed scientific/medical journals, in presentations at conferences and other professional forums. It is usual for a number of years to pass before the results of this type of study are available.* *Please do not reply to this email; if you require further information please click domino@anzbctg.org*		

Appendix 10.4: Participant reminders related to Papers Two and Three

Time point	Email to Study Coordinator,	Primary Email to Participant	Secondary/ Reminder emails to participant	Tertiary/ Reminder emails to ANZBCTG
		Thank you again for your participation in the DOMINO Study. *The ANZBCTG DOMINO Study Team*		

Appendix 10.4: Participant reminders related to Papers Two and Three

1. ONLY TRIGGERED AFTER 50(+) patients have been registered to the Study AND who have submitted responses to both Questionnaire set one and two.



Auto-generated email to Study Investigators

Subject: ANZ 1301 DOMINO STUDY Investigator Survey

Dear DOMINO Study Investigators,

Thank you for taking the time to assist in the recruitment of patients to the ANZ 1301: DOMINO Study. As you are aware, we have reached our target accrual of 50 evaluable participants. To assist in the analysis of the feasibility and utility of the DOMINO Decision Aid it would be greatly appreciated if you would complete this short Questionnaire.

Dr Zdenkowski may contact you by telephone to obtain more detailed information.

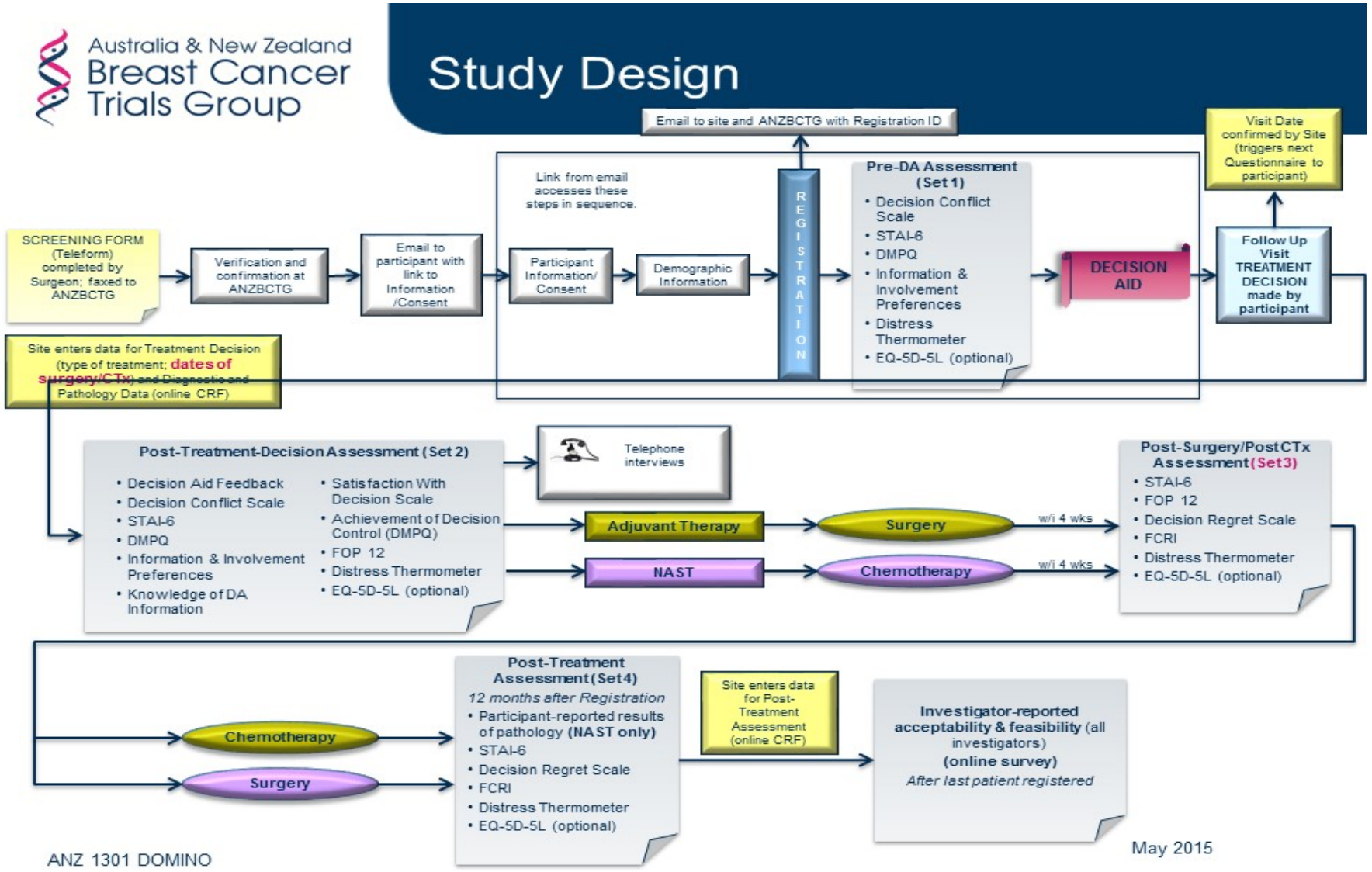
Kind regards,

Dr Nicholas Zdenkowski

ANZ 1301 DOMINO Study Chair

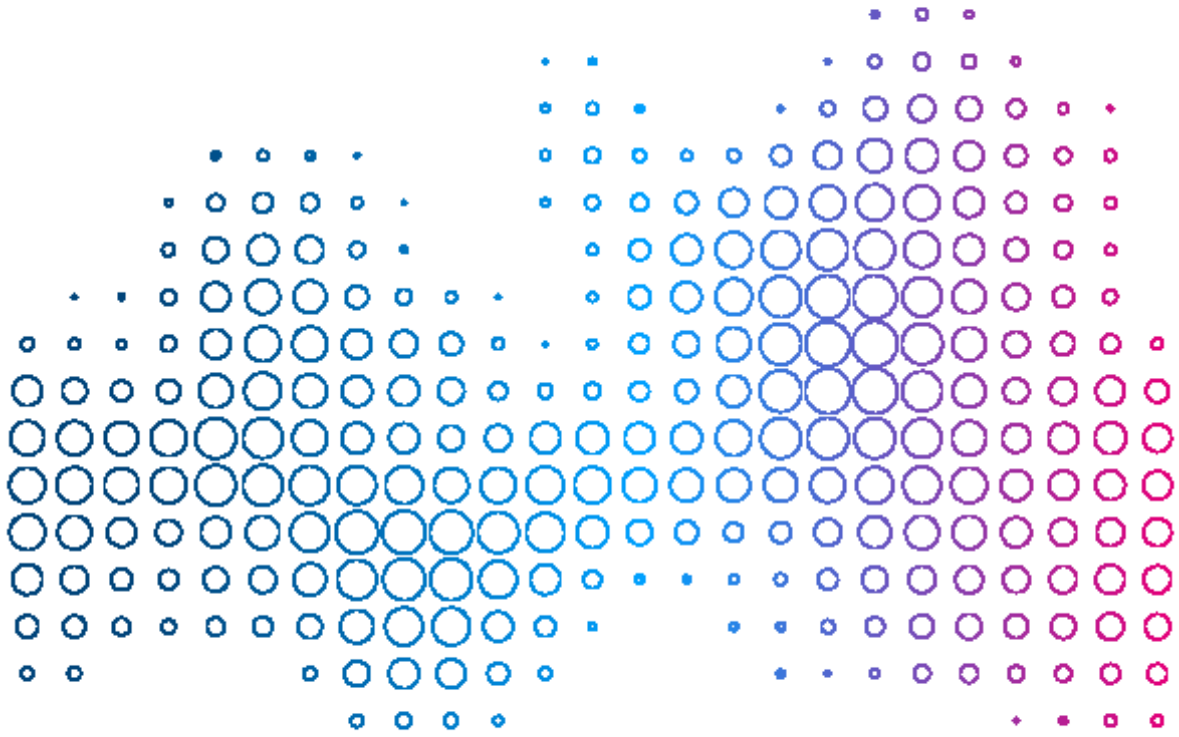
2. Site payment triggered after ALL data (Treatment Decision and Diagnostic and Pathology Data) has been entered by site AND the patient has submitted Questionnaires Set One and Two.

Appendix 10.5: Study scheme for intervention trial related to Papers Two and Three



Appendix 10.6: Decision aid related to Paper Three

A guide for women who are considering breast cancer treatment with chemotherapy and/or hormonal therapy before surgery



Australia & New Zealand Breast Cancer Trials Group

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- Introduction 1
- What type of breast cancer do I have? 2
- What treatments might be given for my breast cancer? 3
  - Surgery 3
  - Radiotherapy 3
  - Chemotherapy 3
  - Targeted therapy 3
  - Hormonal therapy 3
- How soon do I need to have treatment? 4
- What are my options for the timing of chemotherapy and surgery? 4
- Why might I choose to have treatment before surgery? 5
  - Reducing the size of the tumour so you can have breast conserving surgery rather than a mastectomy 6
  - Reducing the size of the cancer to make surgery easier so that less breast tissue needs to be removed 7
  - Planning surgery 7
  - Taking part in a breast cancer clinical trial 7
  - Observing the effect of the chemotherapy 7
  - Chances of the tumour disappearing completely 9
  - Prognosis (How likely is the cancer to return?) 10
  - Some other issues with having therapy before surgery 11
  - What if I can't have surgery? 11
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- Notes 21

Introduction

Over the last thirty years there have been significant improvements in the treatments available to women diagnosed with breast cancer. More treatment options are available to help cure more women of their cancer, and to keep women alive and well for longer. Treatment has also become more complicated, may be offered at different times and may continue for many months. Whenever possible, your treatment will be planned to best fit your personal situation and preference. Your treatment team is here to help you through this difficult time and to answer questions that you may have. This booklet is designed to help with some of those questions.

In certain situations, doctors may offer treatment with chemotherapy or **hormonal (systemic) therapy *before* surgery.** You have been given this booklet, called a 'Decision Aid', because your doctor thinks that this option may be suitable for you.

The purpose of this decision aid is to help women to choose whether to have chemotherapy or hormonal therapy ***before*** surgery (neoadjuvant) or ***after*** surgery (adjuvant). After reading the information, you may wish to weigh up reasons for and against having neoadjuvant therapy using this decision aid. You can then discuss your thoughts with your doctor and make a decision.

As well as using this decision aid, you might like to talk to your doctor(s), family and friends and read other information that you may have. You may find resources from the Australia and New Zealand Breast Cancer Trials Group, the Cancer Council, Cancer Australia, the Breast Cancer Network Australia (BCNA) and others to be valuable. These resources will give you extra information about breast cancer that you may find useful to help your decision about whether to have systemic therapy before or after surgery. A resource list is available at the end of this booklet along with space for you to make notes.

To summarise, this decision aid booklet is for women who have recently been diagnosed with breast cancer, for whom chemotherapy or hormonal therapy before surgery (neoadjuvant therapy) might be a treatment option.

What type of breast cancer do I have?

There are several different types of breast cancer. It is important to know which type you have when thinking about the pros and cons of treatment prior to surgery. Your doctor will be able to give you information about your type of breast cancer. There is also an explanation in the glossary on page 18. You may wish to mark which type you have, as a reminder (just tick the box that describes your cancer).

The main types of breast cancer are:

- Hormone receptor (HR) oestrogen and/or progesterone positive (ER+/PR+), HER2 negative (HER2-)
- Hormone receptor (HR) oestrogen and/or progesterone positive (ER+/PR+), HER2 positive (HER2+)
- Hormone receptor (HR) oestrogen and progesterone negative (ER-/PR-), HER2 positive (HER2+)
- Hormone receptor (HR) oestrogen and progesterone negative (ER-/PR-), HER2 negative (HER2-)(triple negative)

Women with any of these types of cancer may be offered chemotherapy, surgery and radiotherapy. If you have hormone receptor positive breast cancer, you may also be offered hormone blocking medication such as tamoxifen, anastrozole (Arimidex®) or letrozole (Femara®). Similarly, if you have HER2 positive breast cancer, you may be offered a drug called trastuzumab (Herceptin®).

Your doctor may take into account other factors when offering treatment options, including the grade of the tumour (how much tumour cells look like normal cells), stage of the tumour (describes the size and location of cancer), and whether there are cancer cells in the lymph nodes under your arm.

You can make notes about the important features of your cancer here:

What treatments might be given for my breast cancer?

Your doctors and nurses will explain the details about the exact treatments that you could receive. There are usually two types of breast cancer treatment: Local and Systemic.

LOCAL TREATMENTS: Treat cancer cells in the breast area only

Surgery

Surgery involves removing any visible cancer. The whole breast can be removed (a mastectomy) or just the cancer and the area around it (a lumpectomy, or breast conserving surgery). You would also have a procedure to check whether the lymph nodes (glands) in your armpit have any cancer in them. This may be done as a sentinel node biopsy at the same time as your breast operation. If there is cancer in the lymph node(s) that were removed, you may also have an operation to remove some more lymph nodes from under the arm (axillary dissection). Sometimes a second operation is needed because some cancer has been left behind in the breast. Having chemotherapy before surgery does not make this more or less likely to occur.

Radiotherapy

If you have breast conserving surgery, then you are likely to be offered radiotherapy. You may also be offered radiotherapy after a mastectomy, depending on the size of the cancer, whether any lymph nodes are involved, or other factors that your doctors think are important. Radiotherapy kills cancer cells in the area it is aimed at and is similar to the rays that are used when you have a chest X-ray.

SYSTEMIC TREATMENTS: Using drugs that can reach all parts of the body

Chemotherapy

Chemotherapy is a medicine that is given to kill cancer cells throughout the body. For breast cancer, it is usually given intravenously (though a drip or injection into the vein) every 1-3 weeks, for a total of 12-24 weeks. There are many different types of chemotherapy, and your doctor will be able to describe the risks and benefits of the treatments that are most suitable for you.

Targeted therapy

Targeted therapy, such as trastuzumab (Herceptin®), is given to women with HER2 positive breast cancer. This type of treatment works by targeting the HER2 receptors on the tumour cells, stopping the cells from dividing and growing. They are usually given intravenously (through an IV drip) once every three weeks for a year in total, including any trastuzumab that you might receive before surgery.

Hormonal therapy

Hormonal (endocrine) therapy is a tablet that is taken every day, for women with oestrogen (ER) and/or progesterone (PR) receptor positive breast cancer. It works by interfering with the signal that oestrogen sends to cause this type of breast cancer to grow. Hormonal treatments are usually given for 5 years or longer.

Why might it be necessary to have chemotherapy or hormonal therapy?

Chemotherapy and hormonal therapy are given to some women with early breast cancer, to reduce the chance that the cancer will return in the future.

How soon do I need to have treatment?

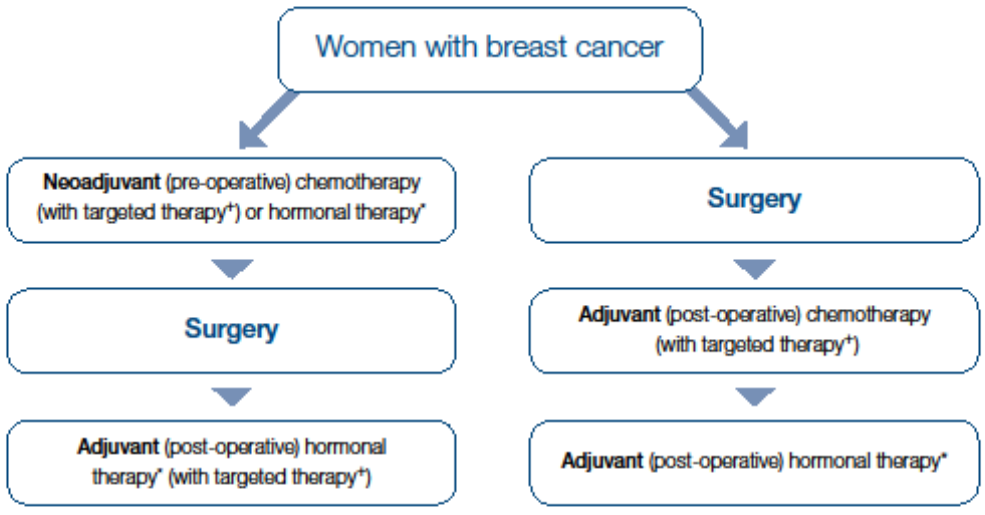
You might think that treatment for breast cancer needs to start within a very short time. However, research has shown that it takes several years for the majority of breast cancers to grow to a size that can be detected on mammogram. Therefore in most situations there is no harm in taking up to several weeks to make a decision about which treatment is right for you. After you have made a decision, surgery or chemotherapy may take days to a couple of weeks to commence, depending on local scheduling at the hospital where you are planning to have treatment. Again, there is no evidence to suggest that waiting those few weeks makes any difference to the success of your treatment.

What are my options for the timing of chemotherapy and surgery?

Neoadjuvant: This means you will start with chemotherapy, targeted therapy or hormonal therapy, and then have surgery, usually after several months of treatment. Hormonal therapy or targeted therapy (such as trastuzumab) may also continue after surgery. You may also require radiotherapy, which is usually given after surgery. This option does not usually mean that you will receive more therapy or receive treatment for a longer time, just that the timing is different.

Adjuvant: This means you will have surgery first. You will then be offered further therapy, including chemotherapy, targeted therapy, hormonal therapy and radiotherapy depending on the stage and type of cancer you have.

Figure 1. Your options for the sequence of treatments



+ Targeted therapy eg. trastuzumab is for HER2 positive breast cancer
* Hormonal therapy is for hormone receptor positive breast cancer

Neoadjuvant therapy (treatment begins before surgery) has been commonly used around the world for the last 15 years, and is increasingly used in Australia. Breast cancer clinical trials have shown that chemotherapy given to women before surgery is just as effective as having chemotherapy after surgery in terms of the cancer coming back (recurrence), and survival.

Being offered neoadjuvant therapy does not mean that your cancer is worse than cancer treated with adjuvant therapy. Neoadjuvant therapy has in the past been given to women who have larger breast tumours than average, but more recently this type of treatment has been given to women with moderately sized tumours.

Regardless of which treatment you choose, your doctor will ensure that you receive the best possible care.

NEXT, we describe the pros and cons of neoadjuvant therapy, and then the pros and cons of adjuvant therapy.

Why might I choose to have treatment before surgery?

There are several reasons why your doctor might have raised the possibility of treating your cancer with chemotherapy and/or hormonal therapy before it is removed surgically. These reasons include:

- To reduce the size of the tumour so that you can have a lumpectomy (rather than a mastectomy - removing the whole breast);
- To reduce the size of the tumour so that a smaller operation is possible;
- To be eligible to participate in a neoadjuvant clinical trial;
- To give time for more information to become available, such as the results of genetic testing, which can influence the type of surgery and treatment you may choose to have;
- To be able to see or feel the effectiveness of chemotherapy on the cancer;
- To give you a better idea of your prognosis (the chance of your cancer coming back).

These reasons are explained in the following pages. There are other reasons why your doctor may have suggested treatment before surgery, and your doctor will explain these to you, if relevant.

There is space provided for you to make notes at the end of this booklet. If you think of a question or have a concern or comment please write them in the back of the booklet as soon as possible so that you can take this list with you to your next visit.

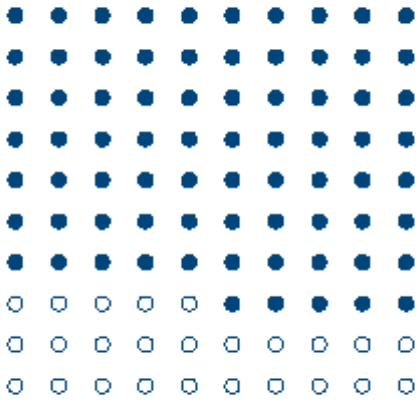
Reducing the size of the tumour so you can have breast conserving surgery rather than a mastectomy

Your surgeon may have told you that you need a mastectomy (removal of the entire breast). This may be due to the size of the tumour, the type of breast cancer, the size of your breast, or for other reasons.

Neoadjuvant therapy (chemotherapy or hormone therapy before surgery) can reduce the size of the cancer in some patients, so that they may safely have breast conserving surgery (removal of only the part of the breast containing the tumour). The breast cancer is more likely to shrink if it is triple negative or hormone receptor negative/HER2 positive and thus women with these types of breast cancer are more likely to be able to have breast conserving surgery after neoadjuvant therapy.

If you were going to need a mastectomy as initial treatment, but you choose chemotherapy or hormonal therapy before the surgery, you have around a 25% chance of having breast conserving surgery after these treatments. In other words, 25 out of every 100 patients treated in this way will be able to avoid a mastectomy, but 75 in every 100 patients will still require a mastectomy. The diagram below shows this.

Figure 2. If each of the 100 dots below is a woman who was going to need a mastectomy, then after neoadjuvant therapy about 25 women will be able to have breast conserving surgery (empty circles). About 75 women will still need to have a mastectomy (shaded circles).



Even if your surgeon has told you that you can have breast conserving surgery now, before chemotherapy is given, then neoadjuvant therapy may shrink the cancer further. This may mean that less breast tissue will need to be taken and your breast is more likely to retain its natural shape.

Reducing the size of the cancer to make surgery easier so that less breast tissue needs to be removed

If scans (ultrasound or MRI) or physical examination show your tumour is more than 2cm in size, then neoadjuvant chemotherapy might shrink the tumour enough so that less breast tissue needs to be removed at the time of surgery.

Planning surgery

In some cases, it may be worthwhile to delay surgery on the breast. You may wish to delay surgery if:

- you are waiting for the results of **genetic testing**. If you are offered genetic testing, and are found to have an inherited breast cancer gene, then you may wish to consider having a double mastectomy (both breasts removed) to reduce your risk of developing breast cancer again. Having the results before surgery means that you can have one operation, rather than two;
- **breast reconstruction** is planned, and you wish to allow time for both your breast cancer surgeon and your reconstruction surgeons to be available to perform their specific surgeries at the same time;
- you wish to delay decisions about surgery, and **take one decision at a time**;
- your doctors feel that it is important to start chemotherapy first because your cancer appears to be fast-growing.

Research has shown that if chemotherapy is required, you will get the same outcomes if you have it before surgery, as having it afterwards. If surgery is delayed for any reason, you might want to get the chemotherapy over and done with and have surgery afterwards.

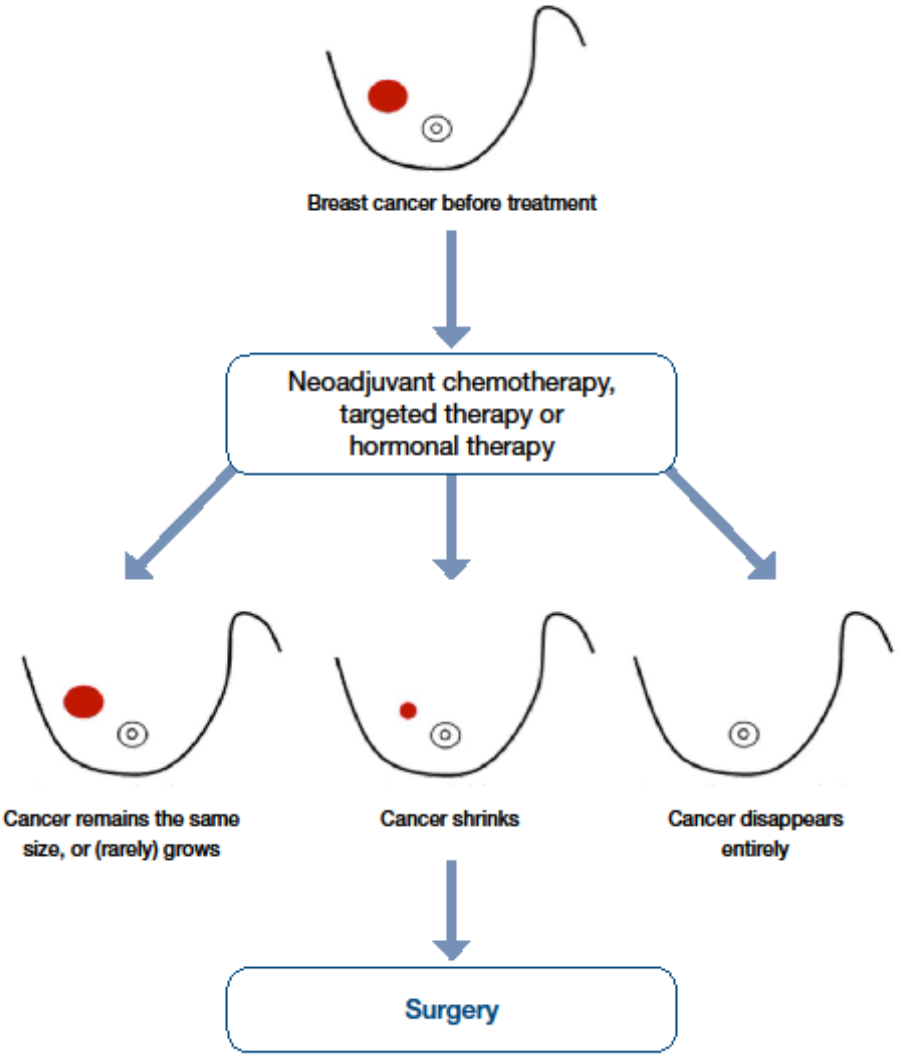
Taking part in a breast cancer clinical trial

In some situations, neoadjuvant therapy is given as part of a clinical trial (research study). Your doctors will discuss this option with you if there is a trial available that is suitable for you. This may involve a new drug, or a new way of using currently available therapies. For more information about breast cancer clinical trials, visit the Australia and New Zealand Breast Cancer Trials Group website at **www.anzbctg.org** and/or the Australia and New Zealand Clinical Trials Registry at **www.anzctr.org.au.**

Observing the effect of the chemotherapy

If you have chemotherapy or hormonal therapy before surgery, it is possible to check whether the chemotherapy is shrinking your cancer. This occurs for about 90% of women (90 out of every 100 cases treated in this way). **If you have surgery first, there is no way of knowing whether the cancer has shrunk in response to the treatment, because there is no cancer left in the breast to observe.** The reason this is important is discussed below.

Figure 3. Possible results of neoadjuvant chemotherapy.



Chances of the tumour disappearing completely

As shown above, there is a chance that neoadjuvant therapy will **completely clear the cancer** from your breast and from the lymph nodes under the arm. In that case, you should still have an operation, as otherwise the cancer may grow back. Your doctor may organise for a special metal 'clip' to be injected into the breast cancer before you start or during the course of neoadjuvant chemotherapy so that your surgeon knows where the cancer was and can remove tissue from that area.

The number of patients with **no cancer visible** on surgery after neoadjuvant chemotherapy varies depends on the type of breast cancer:

Figure 4.

Hormone receptor (HR) positive, HER2 negative: 1 out of every 10 women

Hormone receptor (HR) positive, HER2 positive: 3 out of every 10 women

Hormone receptor (HR) negative, HER2 positive: 5 out of every 10 women

Hormone receptor (HR) negative, HER2 negative (triple negative): 3 out of every 10 women

If each of these dots is one woman, the open circles show the number of women (out of 10) who do not have any tumour visible at the end of chemotherapy.

Prognosis (How likely is the cancer to return?)

There is no difference in survival following a diagnosis of breast cancer if you have chemotherapy before or after surgery. If you have chemotherapy or hormonal therapy before surgery, your cancer may shrink. In some cases, the cancer can disappear entirely. Whether or not this happens tells us something about your chances of doing well. If chemotherapy completely clears the cancer from your breast and lymph nodes, you will have gained some "good news" – that your breast cancer is responding to the treatment and is less likely to come back. On the other hand, if your cancer doesn't shrink, or even grows, you will have gained some less good or even "bad" news – that your breast cancer is not so responsive and is *more* likely to appear elsewhere in your body.

The following information is about women who are alive and free of cancer five years after being diagnosed with breast cancer. For some women the cancer comes back before 5 years, for some it comes back after 5 years, and for most women it never comes back. However, the statistics are often described using the 5 year mark.

For women who have had neoadjuvant chemotherapy, the prognosis depends on the type of cancer:

- Hormone receptor positive, HER2 negative: **85 out of every 100** women whose cancer has **disappeared entirely** are alive and free of breast cancer 5 years after diagnosis, compared with **75 out of 100** women whose cancer **did not disappear entirely.**
- Hormone receptor positive, HER2 positive: **90 out of every 100** women whose cancer has **disappeared entirely** are alive and free of breast cancer 5 years after diagnosis, compared with **65 out of 100** women whose cancer **did not disappear entirely.**
- Hormone receptor negative, HER2 positive: **85 out of every 100** women whose cancer has **disappeared entirely** are alive and free of breast cancer 5 years after diagnosis, compared with **50 out of every 100** women whose cancer **did not disappear entirely.**
- Triple negative: **85 out of every 100** women whose cancer has **disappeared entirely** are alive and free of breast cancer 5 years after diagnosis, compared with **50 out of every 100 women** whose cancer **did not disappear entirely.**

The chance of your cancer disappearing completely also depends on which type of cancer you have. This is explained in the following pages.

If the cancer does not shrink or disappear during chemotherapy, it means your cancer is more resistant to the treatment that you were given. It does not mean that the cancer will definitely come back. If you have a hormone positive cancer, not all the work is done by the chemotherapy, hormone blocking treatment is an important part of the treatment of this type of breast cancer.

Even if the cancer cannot be seen on scans and cannot be felt by you or your doctor after neoadjuvant therapy, surgery is still recommended to make sure that all cancer is removed. Looking at the cancer under the microscope after surgery can also give you additional information on the chances that your cancer will return.

Some other issues with having therapy before surgery

There is no increase (or decrease) in problems with surgery

Having chemotherapy and/or hormone therapy before surgery does not increase or decrease the chance of having problems from surgery, such as an infection or delayed wound healing.

Radiotherapy

If you have breast conserving surgery, radiotherapy is usually offered. If you have a mastectomy, radiotherapy may or may not be needed. A good response to neoadjuvant therapy does not mean that radiotherapy can be avoided.

What if the cancer does not get smaller?

As discussed above, there is a chance that the cancer may not seem to be getting any smaller during neoadjuvant therapy. This can cause worry that the treatment is not working. If the cancer does not get any smaller, it does not necessarily mean that the chemotherapy is not working, and you and your doctor may decide to continue with chemotherapy as planned.

In some cases you may still be able to feel a lump in your breast after you have started neoadjuvant therapy. What you can feel or see may only be scar tissue and no cancer is left. On the other hand, even if the cancer can no longer be felt, there is still a possibility that some cancer cells remain. So what we can see and feel from the outside does not tell the whole story. Scans and pathology are needed to make a decision on whether the treatment is working.

What if the cancer gets bigger?

Some people might worry about their cancer getting larger or spreading elsewhere, while receiving treatment prior to surgery. It is uncommon for this to happen. It happens in about 3% (3 in 100) of patients, and in almost all these patients (90%) surgery can still be successfully performed to remove the cancer, with outcomes remaining the same as if they had had surgery before adjuvant treatment. Figure 5 shows this risk.

What if I can't have surgery?

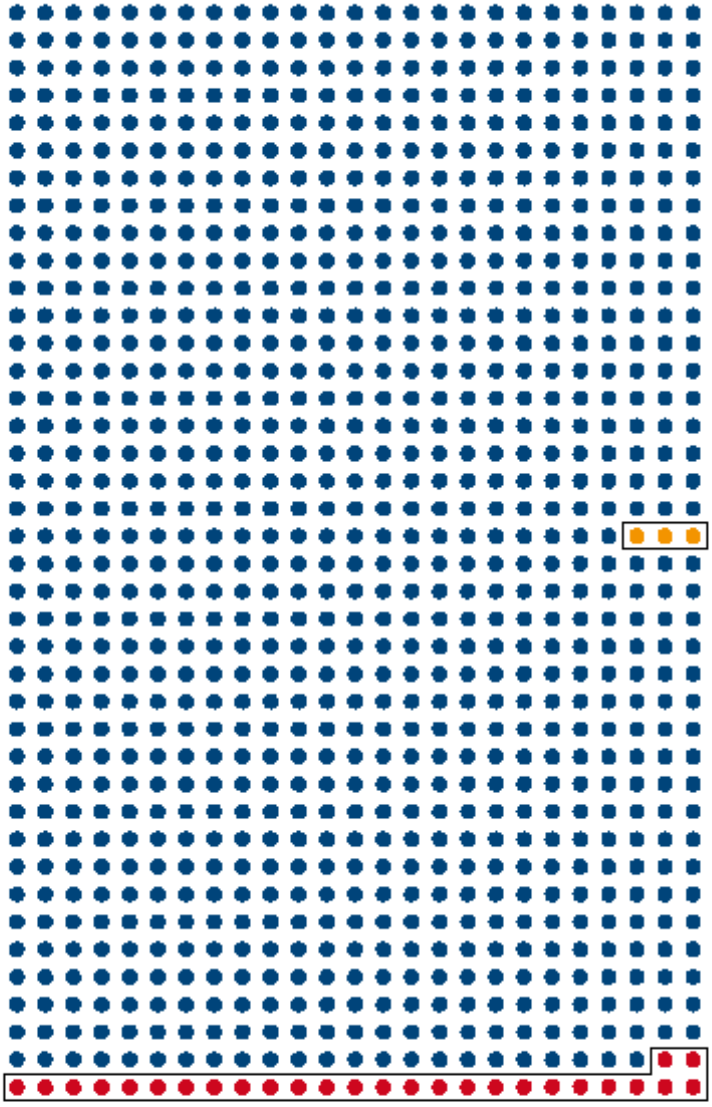
Less than 3 in every 1,000 patients (0.3%) who have neoadjuvant therapy before surgery are not then able to have surgery because the cancer became too large, or because cancer became visible elsewhere in the body (metastatic breast cancer).

In the rare situations that this occurs, it means that surgery would not have cured the cancer anyway, even if an operation was done first. This is because there was already cancer that had spread beyond the breast and lymph nodes, which would not have been completely removed by surgery and chemotherapy.

Your doctor will check regularly with physical examination and scans such as ultrasound or MRI to see whether the cancer is smaller, larger or the same size. If it does grow, your surgery may be moved to an earlier time, before your planned neoadjuvant therapy is finished.

Figure 5. The chance of cancer growing whilst receiving chemotherapy (3%).

Of 1000 people who have neoadjuvant therapy (the blue dots), 30 will have their cancer grow while having treatment (the red dots). 27 of these 30 people are almost certainly still able to have surgery aimed at cure. 3 out of every 1000 (0.3%) would not be able to have surgery, however surgery would not have cured these 3 if done before chemotherapy.



The pros and cons of adjuvant therapy (surgery first)

The chance of the cancer coming back over time is the same if you have chemotherapy first or surgery first.

If an operation is possible now, then you may prefer to have surgery first, and then make a decision about any other treatments such as chemotherapy and radiotherapy, once surgery is complete.

Advantages of surgery first

Information about the cancer

A possible advantage of having surgery first is that you may have more precise knowledge of the type and stage of the cancer before decisions are made about any further treatment. If the cancer is removed in an operation before chemotherapy is given, the pathologist can look at the cancer cells under a microscope and provide information about it. This helps you and your doctors to make decisions about the best treatment options for you. Occasionally this suggests that chemotherapy is not required after all, because the pathologist can see the whole cancer, rather than just a small part of it. The presence of cancer in the lymph nodes near the breast is one of the most useful predictors of prognosis (whether the cancer is likely to return) and it also guides whether radiotherapy is needed. If neoadjuvant chemotherapy (chemotherapy before surgery) has made the cancer shrink or disappear from the breast or lymph nodes, then some of that information may no longer be available.

Immediate removal of the cancer

Some women may be uncomfortable leaving the cancer in place for several months whilst receiving chemotherapy. The idea that the cancer is still in their body can cause some women to feel more anxious and stressed. There is a possibility of anxiety about whether the cancer is growing or not. If the cancer is removed first, then the small chance that it might grow is taken away.

Radiotherapy

If you have a mastectomy, then you are less likely to need radiotherapy after surgery. Radiotherapy might still be needed in certain situations, such as if there is cancer in your lymph nodes under the arm, or if your cancer is large. If you have breast conserving surgery, then radiotherapy is usually offered.

Many women in Australia have surgery first

Having surgery first is common, particularly for small breast cancers where breast conserving surgery is already possible, or in cases where chemotherapy may not be needed. Some women might prefer having a treatment that many others have. The use of neoadjuvant therapy is not rare, but it is less common than having surgery first.

Disadvantages of surgery first

Higher chance of needing a mastectomy

A possible disadvantage of having surgery first is that you may need a mastectomy which could have been avoided if you had neo-adjuvant therapy to shrink the cancer.

No way to see if systemic therapy is working

Another disadvantage is that you will not be able to see the effect that the chemotherapy or hormonal therapy is having on your cancer and so you may have less information about the chance of your cancer coming back. This is discussed in detail in the sections about neoadjuvant therapy titled 'Observing the effect of chemotherapy' and 'Prognosis'.

Infection after surgery

Sometimes after surgery, an infection may develop in the breast, or the wound may be slow to heal, which could delay the start of chemotherapy. While it is usually OK to wait for a short period before starting chemotherapy, it is generally recommended to start within 2-3 months to give the chemotherapy a chance to work. In other words, if an infection causes a delay of more than 2-3 months between surgery and starting chemotherapy, the chemotherapy may be less effective.

Remember:

Being offered treatment prior to surgery does not necessarily mean that there is anything unusual or worse about your type of breast cancer. Neoadjuvant therapy was previously given for larger breast tumours, but more recently this type of treatment is being given to women with moderately sized tumours.

Treatment prior to surgery is commonly used around the world, and is increasingly used in Australia. Having chemotherapy before surgery is just as effective as having chemotherapy after surgery in terms of the chance that the cancer will come back (recurrence) and survival.

The decision to have neoadjuvant or adjuvant therapy is one that you, your surgeon and your medical oncologist can make together. Your doctors will ensure you get the best care regardless of the decision you make.

Arriving at a treatment decision

The previous pages have outlined the main options available to you now. The following steps may help you to make a decision whether or not to have chemotherapy or hormonal therapy before surgery.

The decision-making process may be easier if you follow these seven steps:

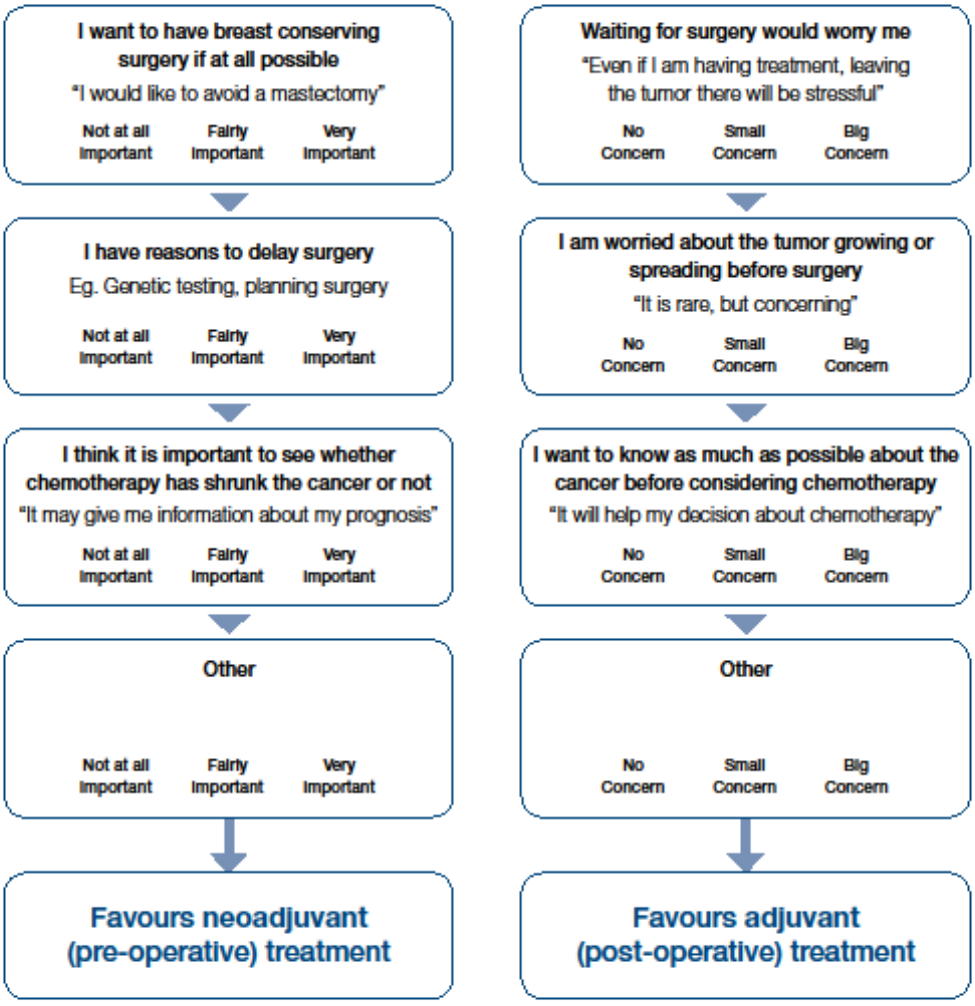
1. Understand your diagnosis and your risk of breast cancer recurring (coming back) as fully as you can.
2. Understand your options for treatment and the risks and benefits of these options.
3. Review the pros and cons of those options.
4. Assess the importance to *you* of the pros and cons.
5. If you are offered neoadjuvant treatment through a clinical trial, prioritise the pros and cons of the trial for *you* (and your family).
6. Get more information from your doctor or breast care nurse if you are unsure of anything or have more questions.
7. Discuss your preferred treatment option with your surgeon, medical oncologist, family doctor, your family and other significant people in your life.

You have already gone through steps 1-3. To help you complete steps 4-7, and come to the decision that suits you best, we have prepared a worksheet on the following page.

Worksheet

After reading this booklet you may feel you understand more about treatment options for your breast cancer. You may wish to weigh up the positives and negatives, to help you work out which treatment option is right for you. You may not come to a decision now, but this may assist you at your next visit with your medical oncologist or surgeon.

This page lists reasons that are relevant to the decision about whether to receive chemotherapy or hormonal therapy, either before or after surgery for your breast cancer. Indicate which issues are important to you. That will help you work out which way you are leaning.



Any further questions? Write down any questions you want to ask your surgeon or medical oncologist (there is more space at the end).

Which way are you leaning? Circle the star which best indicates whether you are leaning towards neoadjuvant therapy or adjuvant therapy. The closer the star is to either option, the more certain you feel about that option.

Which way are you leaning?

Neoadjuvant therapy ★ ★ ★ ★ ★ ★ ★ ★ ★ ★ **Adjuvant therapy**

What happens now?

Your treating doctor, often your surgeon, will have brought up the possibility of neoadjuvant therapy. Your doctor has given you this document to help you find out more about the option of receiving neoadjuvant therapy to assist you to make a decision about whether it is right for you.

Your doctor and other health care professionals (such as a breast care nurse) will continue to support you through the decision-making process, and will be able to answer any questions you might have. You may be referred to see a medical oncologist to discuss the matter further. A referral to a medical oncologist does not mean that you must proceed with treatment before surgery. Neoadjuvant therapy may be recommended as the preferred option, it may be presented to you as a "genuine choice" for you to make, or your medical oncologist may recommend against it, with immediate surgery being the preferred option.

Once you and your doctor(s) have made a decision, treatment will be arranged for you.

Glossary

Adjuvant: treatment that is given after surgery, with the intent of cure

Chemotherapy: Anti-cancer medicine that is usually given through an intravenous (IV) drip

Clinical trial: Research that is testing a new way of treating a disease

Decision aid: a document that contains information to help people make a decision about medical treatment

Early breast cancer: breast cancer that is only in the breast and lymph nodes under the arm on the same side of the body

Endocrine or hormonal therapy: tablets that are taken daily for at least 5 years for hormone receptor positive breast cancer, such as tamoxifen, anastrozole (Arimidex®) or letrozole (Femara®)

HER2 receptor: a protein on the surface of cells that helps them grow and divide

HER2 positive (HER2+) breast cancer: a type of breast cancer that has a larger number of HER2 receptors on the cells than usual. It can be treated with drugs such as trastuzumab (Herceptin®)

Hormone receptor: either the oestrogen receptor or progesterone receptor, which indicates that hormonal treatments such as tamoxifen may be used

Hormone receptor positive breast cancer (ER+/PR+): a type of breast cancer that has hormone receptors on the cells. These receptors are special proteins that the hormones estrogen and progesterone bind to, causing the cancer to grow. Hormonal therapy can be used for this type of breast cancer

Inflammatory breast cancer: breast cancer that affects a large area of the breast, but may not be felt as a distinct lump. It is a less common type of breast cancer; your doctor will be able to tell you if you have this type.

Local therapy: Treatment that affects part of the body, eg. surgery or radiotherapy

Metastatic (secondary or advanced) breast cancer: breast cancer that has spread beyond the breast and lymph nodes, to other parts of the body, such as bones, liver or lungs

Neoadjuvant: treatment that is given before an operation to remove the breast cancer

Pathological complete response (pCR): when no cancer can be seen by the pathologist in the breast or lymph nodes that have been surgically removed, after neoadjuvant chemotherapy or hormonal therapy has been given

Systemic therapy: Treatment that affects the whole body, eg. chemotherapy or hormonal therapy

Triple negative breast cancer: breast cancer that does not have oestrogen (ER), progesterone (PR), or HER2 receptors on its surface

Further information and support

Australia and New Zealand Breast Cancer Trials Group: **www.anzbctg.org**

Australian New Zealand Clinical Trials Registry: **www.anzctr.org.au**

Breast Cancer Network Australia: **www.bcna.org.au**
Phone 1800 500 258

Cancer Australia: **www.canceraustralia.gov.au**
Phone 1800 624 973

Cancer Council **www.cancercouncil.com.au**
Phone 131 120

Macmillan Cancer Support: **www.macmillan.org.uk** (United Kingdom based information)

Local contact information:

Notes

Full title: Decision aid for women considering having chemotherapy or hormonal therapy prior to surgery for breast cancer

This document has been developed by researchers of the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) and the Patricia Ritchie Centre for Cancer Care and Research, with funding support from the HCF Research Foundation, and the fundraising and education department of the ANZBCTG, the Breast Cancer Institute of Australia (BCIA). It has been endorsed by the ANZBCTG Consumer Advisory Panel. The Breast Cancer Network Australia (BCNA) have provided input into content.

1st edition, December 2014.

Australia & New Zealand
Breast Cancer
Trials Group

Appendix 10.7: Participant invitation, information statements, consent forms and reminders related to Papers Four and Five

Invitation to participate in the Research Project:

Who decides about medical care?
Comparing patient, surrogate and provider perspectives

Version #2, dated 26/11/2014

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

We would like to invite you to participate in a study being conducted at Calvary Mater Newcastle Hospital that is currently recruiting people who have been diagnosed with cancer and their support persons. Researchers and clinicians from the University of Newcastle, Hunter Medical Research Institute, Calvary Mater Newcastle Hospital and the Cancer Council NSW are involved in this study. The research team does not have any personal information about you. We will only receive information that you provide directly to us.

We often plan for different life events such as weddings, childbirth and retirement. Rarely do we have conversations about how we want to be cared for at the end of our lives. Having conversations about health, financial or legal matters can be difficult for patients, their families and doctors. However, these conversations are important as they can help make sure that people are able to choose how and where are looked after, sort out unfinished business and know what to expect at the end of life. Having these conversations can help with difficult last-minute decisions when a person may no longer be able to have their say.

The questions we are asking have nothing to do with the current state of health or care of the patient you are supporting. We are simply interested in your opinion and your experiences. Some of these questions may be difficult for you to think about, but your views about these kinds of conversations can help us develop ways to make communication more open and effective. If you do have questions or feel distressed, we recommend that you discuss this with your doctor. You can also contact the Cancer Helpline 13 11 20. This service is staffed by cancer nurses who provide information and support to people with cancer and their families.

You are under no obligation to participate in this study. However, your participation would be greatly appreciated. If you would like further information, please contact Dr Amy Waller on 1800 084 755 (free-call).

Thank you for considering this invitation.

Rob Sanson-Fisher
Laureate Professor of Health Behaviour
University of Newcastle
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Rob.Sanson-Fisher@newcastle.edu.au

Appendix 10.7: Participant invitation related to Papers Four and Five (Calvary Mater Newcastle)

Complaints about this research: This project has been approved by Hunter New England's Human Research Ethics Committee, Reference No. 14/11/19/4.04. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Manager, Research Ethics and Governance, Hunter New England Human Research Ethics & Governance Unit, Locked Bag 1, New Lambton NSW 2305, Australia, telephone (02) 49214950, email: hnehrec@hnehealth.nsw.gov.au.

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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Information Statement for the Research Project:

Who decides? Comparing patient, surrogate and provider perspectives on end of life care
V2: 26/11/2014

You are invited to participate in the research study identified above. The study is being conducted by L/Prof Rob Sanson-Fisher, Dr Amy Waller and Ms Annika Ryan. Dr Charles Douglas from the School of Medicine and Public Health, University of Newcastle; and Dr Nicholas Zdenkowski from Department of Medical Oncology, Calvary Mater Newcastle Hospital. The research team does not have any personal information about you. We will only receive information that you provide to us.

Why is the research being done?
People should be able to be as involved in decisions about their personal life, financial matters or medical care. Having conversations about these issues can be difficult. However, these conversations are important as they can help make sure that people are able to have a say about the care they receive, and to know what to expect at the end of life. Having these conversations earlier can also help with difficult last-minute decisions when a person may no longer be able to have their say. This study aims to explore how involved people want to be in decisions about end of life care, and whether people's families and doctors are aware of these preferences. **The questions we are asking have nothing to do with your current state of health or your current care. We are simply interested in your opinion.** This study will help find ways to improve communication about these issues with cancer patients and their families.

Who can participate in the research?
We are seeking people that are 18 years or older who have been diagnosed with cancer and are attending an outpatient oncology clinic. We are also seeking people's support person and their oncologist to participate in the study, as they may be involved in these discussions. Your support person is "*someone who is likely to be involved in making important decisions about your care".* Asking support persons and oncologists will help us to understand whether people know how these discussions and decisions may happen; and their attitudes towards being involved in these discussions.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you. If you do decide to participate, you may withdraw from the project at any time without giving a reason and have the option of withdrawing any data that identifies you. Before deciding whether or not to take part, you might want to talk about it with a relative, friend, your doctor or other health care professional.

What would you be asked to do?
If you agree to participate you will be asked to complete two surveys, three months apart. The surveys can be completed using pen and paper. We would also like you to pass on a study package to your support person if you think they would like to participate in the study. **We will not share your responses with your support person or your health care team.**

How much time will it take?
Each survey will take about 15-20 minutes to complete. Some people may find these questions stressful or difficult to answer. You may want to complete the survey while a friend or relative is present. However, we ask that you do not compare your responses with the person you support if possible, as we want to get their opinions on some of the issues we are asking you about in this survey.

What are the risks and benefits of participating?
We cannot promise you any benefit from participating in this research. We do expect that the results of this research will help to highlight how care can be improved for future patients. There may be some inconvenience due to the time taken to complete the survey. It is also possible that participation may cause you to reflect on your cancer care and may raise questions about your cancer. As the survey involves end of life issues, reflecting on this topic may cause you some distress. If you do have questions or feel distressed, we recommend that you discuss this with your treatment team. You can also contact the Cancer Helpline 13 11 20. This service is staffed by cancer nurses who provide information and support to people with cancer and their families.

How will your privacy be protected?
If you choose to participate your privacy will be protected. Your doctor will not have access to your responses and your treatment will not be affected by participating in the study. Information collected will be de-identified upon receipt. If you provide your name and contact information it will be stored separately from your survey data, and will only be able to be re-linked by the ID code. Any identifying information will be stored securely in a password protected file on the University of Newcastle server. This information will only be accessed by the researchers unless you consent otherwise, except as required by law. Data will be retained for at least 7 years in a locked filing cabinet and password protected files at the University of Newcastle. De-identified data may be made available for secondary analysis, however separate ethics approval will be sought beforehand. Where data is used for further analysis, it will not contain any identifying information.

How will the information collected be used?
The information collected may be presented at national and international conferences and published in scientific journals. Only group data will be presented in any reports of publications arising from this research. In this way, no individual will be identifiable and your privacy will be protected. At the end of the study we can send you a summary of the key findings of the project.

What do you need to do to participate?
Please read this Information Statement and be sure you understand all its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the researcher, whose details are below. If you would like to participate, please sign the consent form and complete the survey and post it to the research team.

Further information
If you would like further information, please contact Dr Amy Waller on 1800 084 755 (free-call).

Thank you for considering this invitation.

Rob Sanson-Fisher
Laureate Professor of Health Behaviour
University of Newcastle

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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Support Person Information Statement:

Who decides? Comparing patient, surrogate and provider perspectives on end of life care
V2: 26/11/2014

You are invited to participate in the research study identified above. The study is being conducted by L/Prof Rob Sanson-Fisher, Dr Amy Waller, Dr Charles Douglas from the School of Medicine and Public Health, University of Newcastle; and Dr Nicholas Zdenkowski from Department of Medical Oncology, Calvary Mater Newcastle Hospital. The research team does not have any personal information about you. We will only receive information that you provide to us.

Why is the research being done?
People should be able to be as involved in decisions about their personal life, financial matters or medical care. Having conversations about these issues can be difficult. However, these conversations are important as they can help make sure that people are able to have a say about the care they receive, and to know what to expect at the end of life. Having these conversations earlier can also help with difficult last-minute decisions when a person may no longer be able to have their say. This study aims to explore how involved people want to be in decisions about end of life care, and whether people's families and doctors are aware of these preferences. **The questions we are asking have nothing to do with the health of the person you support. We are simply interested in your opinion.** This study will help find ways to improve communication about these issues with cancer patients and their families.

Who can participate in the research?
We are seeking people that are 18 years or older who have been diagnosed with cancer and are attending an outpatient oncology clinic. We are also seeking people's support persons and their oncologist to participate in the study. **You have been nominated by a patient as their support person.** Asking support persons and oncologists as well as patients will help us to understand whether people know how these discussions and decisions may happen; and their attitudes towards being involved in these discussions.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you. If you do decide to participate, you may withdraw from the project at any time without giving a reason and have the option of withdrawing any data that identifies you. Before deciding whether to take part, you might want to talk about it with a relative, friend, your doctor or other health care professional

What would you be asked to do?
If you agree to participate you will be asked to complete two surveys, three months apart. The surveys will be mailed to you and contain a reply paid envelope for the survey return. **We will not share your responses with the person you support or their health care team.**

How much time will it take?
Each survey will take about 15-20 minutes to complete. Some people may find these questions stressful or difficult to answer. We ask that if possible you do not compare your responses with the person you support, as we want to get their opinions on some of the issues we are asking you about in this survey.

What are the risks and benefits of participating?
We cannot promise you any benefit from participating in this research. We do expect that the results of this research will help to highlight how care can be improved for future patients and their care givers. There may be some inconvenience due to the time taken to complete the interview. It is possible that participation may cause you to reflect on your loved one's cancer care and may raise questions about their cancer. As the survey involves end of life issues, reflecting on this topic may cause you some distress. If you do have questions or feel distressed you can contact the Cancer Helpline 13 11 20. This service is staffed by cancer nurses who provide information and support to people with cancer and their families.

How will your privacy be protected?
If you choose to participate your privacy will be protected. Your loved ones doctor will not have access to your responses and their treatment will not be affected by participating in the study
Information collected will be de-identified upon receipt. This means that a unique identification code (ID) will be stored with your interview transcripts. If you provide your name and contact information it will be stored separately from your survey data, and will only be able to be re-linked by the ID code. Any identifying information will be stored securely in a password protected file on the University of Newcastle server. This information will only be accessed by the researchers unless you consent otherwise, except as required by law. Data will be retained for at least 7 years in a locked filing cabinet and password protected files at the University of Newcastle. De-identified data may be made available for secondary analysis, however separate ethics approval will be sought beforehand. Where data is used for further analysis, it will not contain any identifying information.

How will the information collected be used?
The information collected may be presented at national and international conferences and published in scientific journals. Only group data will be presented in any reports of publications arising from this research. In this way, no individual will be identifiable and your privacy will be protected.
At the end of the study we can send you a summary of the key findings of the project.

What do you need to do to participate?
Please read this Information Statement and be sure you understand all its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the researcher, whose details are below. If you would like to participate, please sign the consent form and complete the survey and post it to the research team.

Further information
If you would like further information, please contact Dr Amy Waller on 1800 084 755 (free-call).

Thank you for considering this invitation.

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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Information Statement for the Research Project:
How would you like to decide? Patients' preferences for making cancer treatment decisions

You are invited to participate in the research study identified above. The study is being conducted by L/Prof Rob Sanson-Fisher and Anne Herrmann from the School of Medicine and Public Health, University of Newcastle; and Dr Nicholas Zdenkowski from the Department of Medical Oncology, Calvary Mater Newcastle Hospital and the Breast & Endocrine Centre Gateshead.

Why is the research being done?
People should be able to be involved in decisions about their medical care. Deciding between different treatment options can be particularly difficult for patients and their doctors. This study aims to explore how people would like to make treatment decisions with their doctor. **The questions we are asking have nothing to do with your current state of health or your current care. We are simply interested in your opinion.** This study will help find ways to improve doctor-patient-communication about cancer care.

Who can participate in the research?
We are seeking people that are 18 years or older; who have been diagnosed with breast cancer; and are attending the Breast & Endocrine Centre in Gateshead.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you. It will not impact the care or treatment you receive. If you do decide to participate, you may withdraw from the project at any time without giving a reason and you have the option of withdrawing any data that identifies you.

What would you be asked to do?
If you agree to participate you will be asked to complete the survey included with this information sheet. The survey can be completed using pen and paper. This will take approximately 5 minutes. Your doctor is happy for you to complete it while you are waiting for your consultation. After you have completed the survey please return it by sealing it in the reply paid envelope and putting it in the box located in the waiting room. You can also take the survey home, complete and return it using the supplied reply paid envelope.

How much time will it take?
Each survey will take about 5 minutes to complete.

What are the risks and benefits of participating?
We cannot promise you any benefit from participating in this research. We do expect that the results of this research will help to highlight how care can be improved for future patients. There may be some inconvenience due to the time taken to complete the survey. It is also possible that participation may cause you to reflect on your health care and may raise questions about your cancer. As the survey involves issues regarding your healthcare, reflecting on this topic may cause you some distress. If you do have questions or feel distressed, we recommend that you discuss this with your treatment team. You can also contact the Cancer Helpline 13 11 20. This service is staffed by cancer nurses who provide information and support to people with cancer and their families.

How will your privacy be protected?
If you choose to participate your privacy will be protected. Your doctor will not have access to your responses and your treatment will not be affected by participating in the study. Information collected will be de-identified upon receipt. This information will only be accessed by the researchers. Printed copies of the data will be retained for at least 7 years in a locked filing cabinet at the University of Newcastle. Electronic files will be password protected. De-identified data may be made available for secondary analysis, however separate ethics approval will be sought beforehand.

How will the information collected be used?
The information collected may be presented at national and international conferences and published in scientific journals. Only group data will be presented in any reports or publications arising from this research. In this way, no individual will be identifiable and your privacy will be protected.

What do you need to do to participate?
Please read this Information Statement and be sure you understand all its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the researcher, whose details are below. If you would like to participate, please sign the consent form and complete the survey and return it to the research team.

Further information
If you would like further information, please contact Anne Herrmann on 1800 084 755 (free call).

Thank you for considering this invitation.

Rob Sanson-Fisher
Laureate Professor of Health Behaviour
University of Newcastle

Complaints about this research: This project has been approved by Hunter New England's Human Research Ethics Committee, Reference No. 14/11/19/4.04. The study has also been authorised by the Breast & Endocrine Centre Gateshead. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Manager, Research Ethics and Governance, Hunter New England Human Research Ethics & Governance Unit, Locked Bag 1, New Lambton NSW 2305, Australia, telephone (02) 49214950, email: hnehrec@hnehealth.nsw.gov.au.

☐☐☐☐☐☐

Patient Consent Form
Who decides? Comparing patient, surrogate and provider perspectives on end of life care
Version 2: 26/11/2014

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

The Research Team: Laureate Professor Rob Sanson-Fisher, Dr Amy Waller, Dr Charles Douglas, Dr Nicholas Zdenkowski, A/Prof Frans Henskens, Ms Natalie Dodd

Please tick (✓) ONE BOX to indicate if you would like to take part in the study.

☐ **Yes, I agree to participate in the above research project and give my consent freely**

- I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.
- I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.
- I consent to completing two questionnaires.
- I understand that my personal information will remain confidential to the researchers.
- I have had the opportunity to have questions answered to my satisfaction.
- I would like to receive a summary of the project results ☐ Yes ☐ No

Title *(please circle one)*: Mr / Mrs / Miss / Ms / Dr / Other _____		
Name:		
Postal Address:		
Suburb:	State:	Postcode:
Phone:	Signature:	Date:

Please tick (✓) ONE BOX to indicate if you consent to the Research Team sending a survey to your oncologist.

☐ Yes, I give permission for the Research team to send a survey to my oncologist.

☐ No, I do not give permission for the research team to send a survey to my oncologist.

☐☐☐☐☐☐☐

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Support person Consent Form
Who decides? Comparing patient, surrogate and provider perspectives on end of life care
Version 2: 26/11/2014

The Research Team: Laureate Professor Rob Sanson-Fisher, Dr Amy Waller, Dr Charles Douglas, Dr Nicholas Zdenkowski, A/Prof Frans Henskens, Ms Natalie Dodd

Please tick (✓) ONE BOX to indicate if you would like to take part in the study.

☐ **Yes, I agree to participate in the above research project and give my consent freely**

- I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.
- I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.
- I consent to completing two questionnaires.
- I understand that my personal information will remain confidential to the researchers.
- I have had the opportunity to have questions answered to my satisfaction.
- I would like to receive a summary of the project results ☐ Yes ☐ No

Title *(please circle one):* Mr / Mrs / Miss / Ms / Dr / Other _____		
Name:		
Postal Address:		
Suburb:	State:	Postcode:
Phone:	Signature:	Date:

Version 1
3-month survey letter

<date>

Dear <name>,

RE: Who decides about medical care

We wish to thank you for agreeing to take part in the above-mentioned study a few months ago and since returning the baseline survey. We realise that some of these questions may have been difficult for you to think about, but your views about these kinds of conversations will help us develop ways to make communication more open and effective.

We would also like to thank you for agreeing to complete another survey after 3 months (which is now enclosed with this letter). Completion of this survey is of course voluntary, and your answers will be kept confidential. **If you decide to complete this survey, please return it to us in the reply-paid envelope provided** at your earliest convenience. If you have any questions about the survey or the study, please call our research team on 1800 084 755 (free-call).

We appreciate your valuable contribution to this study. However, if you decide that you no longer want to take part, please telephone us on 1800 084 755, or simply disregard this letter.

Thank you again for your help.

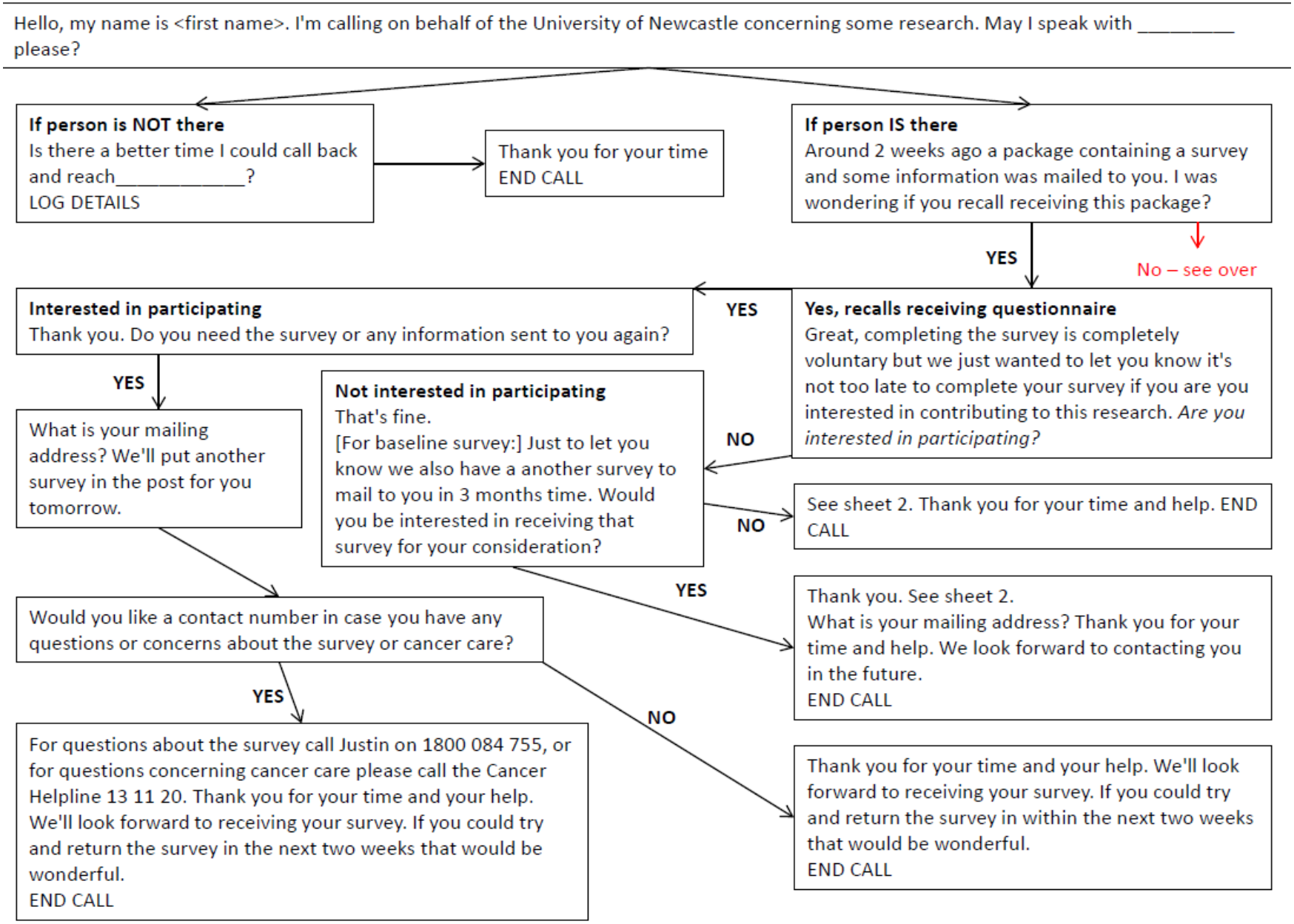
Yours sincerely,

Rob Sanson-Fisher
Laureate Professor of Health Behaviour
University of Newcastle

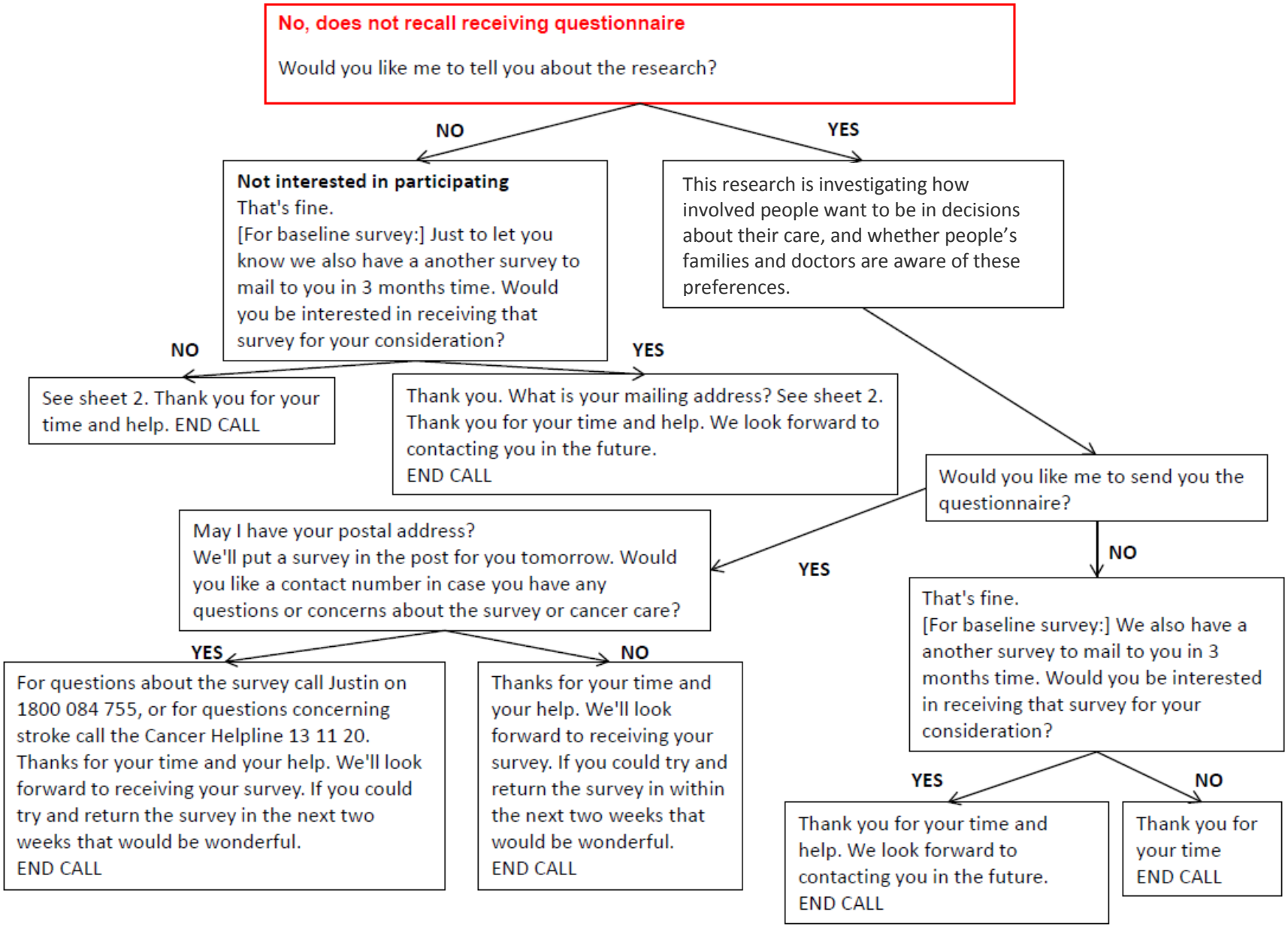
Research Team:
L/Prof Rob Sanson-Fisher, Dr Amy Waller, Mr Justin Walsh and Ms Judy Hollingworth. Dr Charles Douglas from the School of Medicine and Public Health, University of Newcastle; and Dr Nicholas Zdenkowski from Department of Medical Oncology, Calvary Mater Newcastle Hospital.

Complaints about this research: This project has been approved by Hunter New England's Human Research Ethics Committee, Reference No. 14/11/19/4.04. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Manager, Research Ethics and Governance, Hunter New England Human Research Ethics & Governance Unit, Locked Bag 1, New Lambton NSW 2305, Australia, telephone (02) 49214950, email: hnehrec@hnehealth.nsw.gov.au.

Appendix 10.7: Participant reminders related to Papers Four and Five



Appendix 10.7: Participant reminders related to Papers Four and Five



SHEET 2

As we are always trying to improve how we conduct our research could I ask you what barriers have prevented you from participating today? For example, other people have said:
The survey looked too long
They are too busy
They don't feel well enough
That they were not interested in the research

Yes

No

That's fine. Thank you for the time you have given me today. It has been a great help.

Appendix 10.8: STROBE checklist related to Paper Four

STROBE (Strengthening The Reporting of OBservational Studies in Epidemiology) Checklist

A checklist of items that should be included in reports of observational studies. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Section and Item	Item No.	Recommendation	Reported on Page No.
Title and Abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/Rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study Design	4	Present key elements of study design early in the paper	4-7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	N/A
		Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	N/A
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	4-5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	N/A
		Case-control study—For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-7

Section and Item	Item No.	Recommendation	Reported on Page No.
Data Sources/ Measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	4-7; 11-12
Study Size	10	Explain how the study size was arrived at	4-7
Quantitative Variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical Methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	7-8
		(*c*) Explain how missing data were addressed	7-8
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed	N/A
		Case-control study—If applicable, explain how matching of cases and controls was addressed	N/A
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7-8
		(b) Give reasons for non-participation at each stage	7-8
		(c) Consider use of a flow diagram	N/A
Descriptive Data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7-8
		(b) Indicate number of participants with missing data for each variable of interest	7-8
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome Data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	N/A
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	N/A
		Cross-sectional study—Report numbers of outcome events or summary measures	7-9

Section and Item	Item No.	Recommendation	Reported on Page No.
Main Results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-8
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other Analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8
Discussion			
Key Results	18	Summarise key results with reference to study objectives	7-9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11-12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	9-12
Other Information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Appendix 10.9: Data coding manual related to Papers Four and Five

CODING GUIDE – Subsample 1: Patients recruited from Calvary Mater Newcastle

Question	Variable label	Code	Option	Coding rules
Patient ID	Patient ID			
Number of combination	Combination		See attached	
ABCD combination	ABCD comb		See attached	
Which of the scenarios below would you like most?	DCE_MOST			If more than one scenario selected or the same scenario selected for most and least preferred, code as missing*
Which of the scenarios below would you like least?	DCE_LEAST			If more than one scenario selected or the same scenario selected for most and least preferred, code as missing
1. Are you male or female?	Q1_Gender	1 2	Male Female	If >1 selected code as missing

2. What is your date of birth?	Q2_DOB		Date	
Age	Age			
3. What type of cancer do you have?	Q3_Diagnosis	1 2 3 4 5	Breast Prostate Lung Colorectal Other	If >1 selected, code as missing 'Other' answers should be coded separately in Excel spreadsheet
4. Where are you in your cancer journey?	Q4_Stage	1 2 3 4	treatment follow-up incurable treatment l incurable no treatment	If >1 selected, code as missing
5. What is your postcode?	Q5_Postcode			
6. What country were you born in?	Q6_Country	1 2	Australia Other	If both selected, code as missing 'Other' answers should be coded separately in Excel spreadsheet
7. Are you of Aboriginal or Torres Strait Islander origin?	Q7_ATSI	1 2 3 4	No Aboriginal Torres Strait islander Both	If >1 selected code as missing
8 How would you rate your overall quality of life?	Q8_QoL	1-10	1-10 scale	If >1 selected choose higher

* missing data to be coded as 99

CODING GUIDE – Subsample 2: Support persons recruited from Calvary Mater Newcastle

Question	Variable label	Code	Option	Coding rules
Support person ID	SP ID			
Number of combination	Combination		See attached	
ABCD combination	ABCD comb		See attached	
Which of the scenarios below would you like most?	DCE_MOST			If more than one scenario selected or the same scenario selected for most and least preferred, code as missing*
Which of the scenarios below would you like least?	DCE_LEAST			If more than one scenario selected or the same scenario selected for most and least preferred, code as missing
1. Are you male or female?	Q1_Gender	1 2	Male Female	If >1 selected code as missing
2. What is your date of birth?	Q2_DOB		Date	
Age	Age			
3. What is your postcode?	Q3_Postcode			

4. What country were you born in?	Q4_Country	1 2	Australia Other	If both selected, code as missing*, 'Other' answers should be coded separately in Excel spreadsheet
5. Are you of Aboriginal or Torres Strait Islander origin?	Q5_ATSI	1 2 3 4	No Aboriginal Torres Strait islander Both	If >1 selected code as missing
6. What is your relationship to the person with cancer?	Q6_Relationship	1 2 3 4 5 6 7	Spouse/partner Parent Brother/sister Daughter/son Other relative Paid live in carer Other	If >1 selected choose higher
7. Do you live with the person with cancer?	Q7_Living with patient	1 2	Yes No	
8. On average how much time do you spend caring for the person diagnosed with cancer per week?	Q8_Caring time	1 2 3 4 5	Less than 20 hours 20-40 hours More than 40 hours Unsure Do not provide any care	
9. How would you rate your own overall quality of life?	Q9_SPQoL	1-10	1-10 scale	If >1 selected choose higher

10. How would you rate the overall quality of life of the person you support?	Q8_PatientQoL	1-10	1-10 scale	If >1 selected choose higher

* missing data to be coded as 99

CODING GUIDE – Subsample 3: Patients recruited from Breast & Endocrine Centre Gateshead

Question	Variable label	Code	Option	Coding rules
Patient ID	Patient ID			
Number of combination	Combination		See attached	
ABCD combination	ABCD comb		See attached	
Which of the scenarios below would you like most?	DCE_MOST			If more than one scenario selected or the same scenario selected for most and least preferred, code as missing*
Which of the scenarios below would you like least?	DCE_LEAST			If more than one scenario selected or the same scenario selected for most and least preferred, code as missing

1. Are you male or female?	Q1_Gender	1 2	Male Female	If >1 selected code as missing
2. What is your date of birth?	Q2_DOB		Date	
Age	Age			
3. Do you have private health insurance?	Q3_PHI	1 2	Yes No	
4. Do you have a health care card?	Q4_HC	1 2	Yes No	
5. What type of cancer do you have?	Q5_Diagnosis	1 2 3 4 5	Breast Prostate Lung Colorectal Other	If >1 selected, code as missing 'Other' answers should be coded separately in Excel spreadsheet
6. What stage was your breast cancer when it was first diagnosed?	Q6_Cancer at diagnosis	1 2 3	Early Progressed Don't know	If >1 selected, code as missing
7. How long ago were you diagnosed with breast cancer?	Q7_Time since diagnosis		Months	
8. Do you have a support person?	Q8_SP	1 2 3 4 5	No Yes, my spouse/partner Yes, my parent Yes, my child Yes, other	

9. Where are you in your cancer journey?	Q9_Stage	1 2 3 4	treatment follow-up incurable treatment I incurable no treatment	If >1 selected, code as missing
10. Have you been diagnosed with a type of cancer other than breast cancer?	Q10_Cancer other BC	1 2 3 4 5	Breast Prostate Lung Colorectal Other	If >1 selected, code as missing 'Other' answers should be coded separately in Excel spreadsheet
11. What is your postcode?	Q11_Postcode			
12. What country were you born in?	Q12_Country	1 2	Australia Other	If both selected, code as missing 'Other' answers should be coded separately in Excel spreadsheet
13. Are you of Aboriginal or Torres Strait Islander origin?	Q13_ATSI	1 2 3 4	No Aboriginal Torres Strait islander Both	If >1 selected code as missing
14. What is your marital status?	Q14_Marital	1 2 3 4	Married Living with a partner Divorced or widowed Single or never married	
15. What is the highest level of education you have completed?	Q15_Edu	1 2	Year 10 Higher School Certificate	

		3 4 5 6	Trade or vocational training Bachelor degree Postgraduate degree Other	
16. How would you rate your current quality of life?	Q16_QoL	1-10	1-10 scale	If >1 selected choose higher

* missing data to be coded as 99

Appendix 10.10: PRISMA checklist related to Paper Six

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	NA
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6-7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Additional file 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8-9
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8-9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9-10
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	NA
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	NA

Page 1 of 2

Appendix 10.10: PRISMA checklist related to Paper Six

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Additional file 2, data extraction sheet
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	NA
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	NA
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	17

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

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