INDIVIDUAL DIFFERENCES IN SHARED DECISION-MAKING: DOES DECISION-MAKING CAPACITY AFFECT COLLABORATIVE PATIENT-PROVIDER INTERACTIONS?

A Dissertation

Presented to

The Faculty of the Department

of Psychology

University of Houston

In Partial Fulfillment

Of the Requirements for the Degree of

Doctor of Philosophy

By

David P. Sheppard

August, 2019

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ABSTRACT

Background: Medical decision-making can have important implications for patients and families. Shared decision-making (SDM) interventions aim to promote collaboration in patient-provider interactions by building a consensus about preferred treatments, and these show small effects for improving patient-reported outcomes. However, no studies have examined whether individual differences in decision-making moderate the effectiveness of SDM for improving patient decisional conflict after making medical decisions.

Method: 89 University of Houston undergraduate students were randomized into an SDM group aimed at maximizing patient-provider collaboration or a control group with minimal collaboration during a simulated medical decision. Participants rated their perceived decisional conflict using the Decisional Conflict Scale. Participants also completed a series of well-validated self-report and performance-based measures of decision-making capacity. Statistical models included moderated multiple regression with terms including each decision-making capacity measure, group status, and the interaction between each decision-making capacity measure and group status predicting decisional conflict.

Results: There was no significant group difference between the SDM and control groups for perceived decisional conflict (Cohen's d=.26). Controlling for gender and its interaction with group, multiple regressions revealed *main effects* of two aspects of decision-making (i.e., decision-making reasoning, self-reported decisional control/thoroughness) that were associated with lower decisional conflict. Across measures of decision-making capacity, there were no statistically significant interactions between decision-making and SDM group on decisional conflict (all ps > .05).

Conclusions: Findings suggest individual differences in some aspects of decision-making capacity are associated with decisional conflict, but they do not modulate the effects of SDM on perceived decisional conflict among healthy young adults. The current study was limited by design (i.e., healthy participants, simulation of medical decisions) and sample size. Future studies might nevertheless examine whether decision-making capacity alters SDM effectiveness for patient-reported outcomes in clinical populations with prevalent decision-making impairment who are confronting real-world medical decisions.

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CHAPTER 1

INTRODUCTION

It is estimated that the total national health expenditure for the United States was $3.2 trillion in 2015 (National Center for Health Statistics, 2016). To reduce costs, medical models and legislation alike have addressed the roles that patients and providers play in making decisions to undergo potentially costly medical treatments (Institute of Medicine, 2001; Patient Protection and Affordable Care Act, 2010). Moreover, decision-making in the midst of medical situations can have lasting and life-altering implications for patients and their families, including affecting quality of life, longevity, physical health, cognitive impairments, emotional changes, and financial health (Hunink et al., 2014). For example, an individual with a brain tumor who is expected to live fewer than 2 years may face the decision of whether or not to enroll in a clinical trial of a novel chemoradiation regimen while considering the possible side effects (e.g., memory impairment, nausea, fatigue), financial cost, time burden, and potential increase in lifespan, all in the context of a highly emotional decision. Given these complexities, investigations into general medical decision-making within medical populations (e.g., cancer, HIV) have described some of the important factors that are critical for making medical decisions, including literacy, health literacy, and neurocognitive functioning (Doyle et al., 2016; Goggins et al., 2014; Reyna, Nelson, Han, & Pignone, 2015). Critically, these factors have important impacts on health outcomes including medication adherence, quality of life, retention in care, and mortality (Krull et al., 2011; Lescure et al., 2011; Halverson et al., 2015; Jacks et al., 2015).

While medical models invariably integrate patient autonomy and decision-making as the critical final step for medical decisions, the extent to which providers play an

authoritarian, informative, or passive role earlier in this process varies, and this can have significant influence on the choices that patients make (Charles, Gafni, & Whelan, 1999). In the above example, a provider may provide a patient with information about the benefits and risks of enrolling in the chemoradiation trial, and then continue to provide information while the patient chooses to enroll or forgo the clinical trial (informative). Conversely, the provider may provide his or her own recommendation using current medical knowledge and then ask the patient whether he or she agrees to enroll (authoritarian). Shared decision-making (SDM) is defined as an approach in which the clinician and patient collaboratively discuss treatment options in the context of the patient's preferences, resources, and values to arrive at a mutually agreed-upon medical decision (Charles, Gafni, & Whelan, 1997). In this regard, SDM is considered a potentially useful model for minimizing consequences of treatments that patients perceive as most problematic (e.g., side effects, cost) and maximizing the aspects of treatments that are most important to patients (e.g., quality of life, longevity/mortality). While there has been support for SDM effectiveness at improving patient autonomy in medical decisions (Shay & Lafata, 2015), the limited research on this topic has not adequately identified specific SDM processes or patient characteristics that might affect SDM effectiveness (Légaré et al., 2014). Identifying critical SDM activities and individual differences in patient characteristics (i.e., individual differences in decision-making capacity or neurocognitive functioning) may allow for a better understanding of how these factors affect treatment adherence or other critical health outcomes during collaborative patient-provider medical decisions.

Decision-Making and Medical Outcomes

Decision-making in medical contexts is described as a patient—while under the care of a provider—exercising autonomy as an independent participant directing medical decisions (Beauchamp, 1994). Of course, there are a multitude of complex situations and medical populations in which the capacity to meet these decision-making demands are limited. For example, individuals with incipient dementia show gradual declines in their ability to understand consent information, which can eventually lead to decisional impairment (Okonkwo et al., 2008; Tallberg, Stormoen, Almkvist, Eriksdotter, & Sundström, 2013). In more severe cases, individuals with intellectual disabilities oftentimes require proxies to make medical decisions due to lack of capacity to make decisions themselves (Cantor, 2005). Another issue often encountered in medical contexts is the impact of mental illness, as either individual mental health decisions or as comorbidities that impact the medical decisions for other diseases (Ganzini, Lee, Heintz, Bloom, & Fentz, 1994). In these instances, decisional capacity can be limited due to: (1) specific symptoms of a mental health disorder (e.g., psychosis, severe depression), (2) specific mechanisms of indifference, ambivalence, or indecisiveness, (3) difficulties communicating, or (4) lack of insight that they are ill or need treatment (Van Staden & Krüger, 2003). Finally, even in cases of only mild or no observed cognitive limitations, patients' medical decisional process can be made difficult due to ambiguity of information, varying interpretations of evidence, the emotional saliency of decisions, and weighing potentially equally important outcomes depending on patient values (e.g., quality of life vs. life expectancy). For example, a patient faced with the decision of whether to undergo a chemoradiation clinical trial may understand that their decision will only marginally increase their life expectancy (if at all) at the expense of severe

possible side effects. In each of these instances, there are a number of important health outcomes and consequences that may result should a patient be limited in their medical decision-making.

Specific health outcomes that have been associated with impaired medical decision-making include poorer medication adherence (DiMatteo, 2004; McGrady, Brown, & Pai, 2016), lower health-related quality of life (Kaplan, 1991), and even higher rates of mortality (Boyle, Wilson, Yu, Buchman, & Bennet, 2014). Given the importance of decision-making in the context of medical settings, particularly in the context of important health outcomes such as disability and mortality, there have been recent movements to maximize the potential roles and autonomy of patients in the decision-making process. As such, improving patient decision-making processes through improved patient-provider communication as in SDM may specifically ameliorate decision-making limitations in populations with decreased decisional capacity. In parallel, SDM may also increase patient autonomy during instances of particularly complex medical decisions, which may be particularly important for individuals within clinical populations that commonly have subtle alterations in cognitive or physical functioning but in the context of retained decisional capacity.

Shared Decision-Making

In order to address some of the important issues of decision-making within medical populations, SDM has been implemented using a variety of methodologies across a multitude of medical settings and clinical populations. SDM is broadly defined as patient-provider interactions during which a mutually agreed-upon medical decision is made using both the patient's preferences, resources, and values in addition to the provider's knowledge of

treatment benefits and risks (Charles et al., 1997). In a review surveying SDM studies across different disease populations, Shay and Lafata (2015) found that the most commonly studied medical population within SDM was cancer (36% of studies), followed by mental health (13%), diabetes (13%), serious injury (8%), heart disease (5%), and HIV (5%). One of the most common applications of SDM involves the utilization of decision aids, which include written materials, instructional videos, electronic media, or other interactive guides to assist patients when making informed decisions about medical treatments. Decision aids often include information about treatments such as the likelihood of experiencing benefits or side effects, relative effectiveness of treatments, the specific strengths and skills of the health care team, cost, and burden on daily functioning. Another common implementation of SDM includes the training of medical providers in communication skills or in other interpersonal effectiveness skills in order to maximize patient values and preferences in the decision-making process (Shay & Lafata, 2015). While surveys of SDM studies have revealed that there is no single definition of SDM across studies examining its effectiveness (Makoul & Clayman, 2006), SDM ultimately requires collaborative alliance and communication between patients (i.e., values, preferences) and providers (i.e., medical knowledge; Charles et al., 1997).

While limited in number, studies examining the effectiveness of SDM broadly support its use in clinical settings. A Cochrane Collaborative review (Légaré et al., 2014) of 39 studies examining SDM showed small but reliable effects (mean Cohen's $d = 0.21$) of SDM on improving patients' reports of health decision outcomes compared to usual care. A systematic review of SDM randomized controlled trials showed that over half of SDM studies showed significant effects of SDM for improving outcomes such as treatment

adherence, patient satisfaction, and well-being (Joosten et al., 2008). Studies attempting to identify specific outcomes improved through SDM have shown that SDM interventions are most commonly effective when improving affective-cognitive outcomes (i.e., patient satisfaction, anxiety about the illness, decisional conflict, confidence in decision, knowledge), but less so for behavioral (e.g., enacting treatment decisions, medication adherence) or health (e.g., overall health, quality of life, depressive symptoms, physiological measures) variables (Shay & Lafata, 2015). Taken together, these reviews suggest that there are small-to-moderate effects (Cohen's *d* effect size range .03 to .50) of SDM on patient satisfaction with the decision-making process, while there is there is weaker evidence for SDM effects on behavioral (e.g., mediation adherence) or well-being (e.g., health, quality of life) outcomes (Cohen's *d* effect size range .02 to .24; Légaré et al., 2014). Nevertheless, there exists the possibility that individual patient differences may modulate the effectiveness of SDM in clinical settings.

Given the relatively small effect of SDM on patient outcomes, there have been a number of investigations attempting to describe characteristics of individual patients who may disproportionately benefit from SDM. For example, data from individual studies and meta-analyses have shown that patient variables that have an impact on the effectiveness of SDM include literacy, education, socioeconomic status, social support, and numeracy (Durand et al., 2014; Smith, Nutbeam, & McCaffery, 2013; Schoenthaler, Schwartz, Wood, & Steward, 2012). A critical finding supported by a meta-analysis of individual differences in SDM (and may serve to direct the present study's hypotheses) is that individuals with low education, literacy, and socioeconomic status are disproportionately aided by SDM for improving knowledge, informed choice, participation in decision-making, decision self-

efficacy, preference for collaborative decision making, and reduced decisional conflict (Durand et al., 2014). In other words, individuals from lower socioeconomic and educational backgrounds are more likely to benefit from SDM. However, a review by Smith et al. (2013) showed that even among individuals low in health literacy, certain basic aspects of health literacy (acquisition of knowledge, ability to extract/interpret information, weigh options/outcomes) are critical for participating in SDM. This suggests that benefits from SDM may not extend to individuals with severely impaired basic comprehension skills necessary for understanding decision aids, such as reading ability and basic numeracy. As such, given that SDM may not benefit individuals at the very lowest levels of basic literacy (i.e., illiterate individuals) or those who do not have medical decision-making capacity (i.e., severe dementia), it is critical for studies to consider variability of patient factors in the normal range (as opposed to those with frank impairment) and their effects on SDM effectiveness. Parallel evidence of an effect of health literacy in SDM comes from multiple studies showing that higher numeracy patients prefer a more active role in decision-making processes (Galesic & Garcia-Retamero, 2011; Hanoch, Miron-Shatz, Rolison, Omer, & Ozanne, 2015), suggesting that individuals high in the component processes of health-decision making may not prefer a provider who works in the framework of SDM. Finally, recent theoretical models have included general patient factors such as self-efficacy to suggest that these characteristics are important for patients to participate in SDM (Makoul & Clayman, 2006). In all, it is hypothesized that health literacy, literacy, and self-efficacy all play critical roles in describing individual differences that can affect both general decision-making and SDM. Nevertheless, as mentioned previously, there indeed is limited research concerning other specific individual differences that might impact the effect sizes associated

with the effectiveness of SDM improving health, behavioral, and patient satisfaction outcomes.

Consistent with previous calls in the literature to find "active" elements of complex patient-centered interventions (Dwamena et al., 2012; Légaré et al., 2014), there is a need for studies that determine the possible moderating or mediating effects of individual differences in decision-making capacity on the association between SDM and important health outcomes. Quite surprisingly, even though "decision-making" is contained within the phrase "shared decision-making," there have been no investigations to date explicitly examining the effects of individual differences in decision-making capacity (as measured by health-related decision-making tasks) or neurocognitive functioning (including tasks sensitive to brain areas important for decision-making) on SDM effectiveness. As such, a primary aim of the currently proposed study is to assess whether individual differences in decision-making capacity moderate the effect of simulated SDM on participants' decisional conflict. Decisional conflict has been defined as (1) uncertainty in choosing options, and (2) feeling uninformed and unclear about how personal values inform a choice (O'Connor, 1995). Critically, decisional conflict is the most commonly studied outcome variable across SDM studies (Légaré et al., 2014), in part because it is easily assessed with validated scales, and because it considers patient-reported mechanisms (e.g., extent to which patient values were part of a decision) that are actively targeted by many SDM interventions.

Medical Decision-Making and Neuropsychology

The theoretical reasons for including SDM in the medical decision-making model are based on the concept that evidence-based medicine is most effective when it is combined

with patient values and preferences. A movement towards implementing SDM into clinical and research practice for neuropsychologists is in line with broader expectations for care providers, such as Section 3506 of the Patient Protection and the Affordable Care Act (2010) and commentaries on the role of SDM in medicine (e.g., Lee & Emanuel, 2013) calling for evidence-based decision aids to be used reliably across health programs and settings. In parallel, according to the American Medical Association (AMA) Code of Medical Ethics (Riddick, 2003), medical providers are required to discuss with patients the evidence-based benefits, risks, and costs of appropriate treatment alternatives (including forgoing treatment), and to consider patient's resources and needs (e.g., values). Previous statements made by the American Psychological Association have defined evidence-based psychological practice (EBPP) as making clinical decisions collaboratively with patients using the best clinical evidence while considering patient values (APA Presidential Task Force on Evidence-Based Practice, 2006). Relatedly, Chelune (2010) proposed that evidence-based clinical neuropsychological practice (EBCNP) should adopt the same core features of the medical model including clinical expertise along with best research evidence but *in the context of individual patient needs*. Thus, Chelune (2010) proposed that neuropsychologists strive for 3 primary goals in order to deliver EBCNP: (1) provide clinical outcomes that are defined by changes in status, performance, or another objectively defined endpoint, (2) analyze data that can be readily applied by clinicians, and (3) utilize statistical analyses that allow for group-level findings to be readily applied to *individual neuropsychological cases*. In the interim years since Chelune's (2010) proposal for EBCNP, there have been few successful studies that have directly addressed these goals. However, one possible process of increasing evidence-based practice in neuropsychology is to adopt practices with demonstrated

effectiveness in the medical literature and applied medical settings, particularly those that meet individual patient needs. As such, SDM remains a potentially fruitful avenue for exploring the extent to which neuropsychological researchers and providers might be able to gather evidence-based intervention or assessment outcomes towards the ultimate goal of improving individual case outcomes.

Cognitive Correlates of Medical Decision-Making

Although there are no studies that have directly examined the cognitive architecture of SDM, we do have a better understanding about health decision-making and its neuropsychological correlates, which may inform hypothesis development for the current study. Previous theoretical models of decision-making may be drawn from the broader psychological literature including analytic decision theory (Von Neumann & Morgenstern, 1944) and information integration theory (Anderson, 1968). More recent studies have demonstrated that specific neurocognitive functions among clinical populations are particularly relevant to difficult health decisions. For example, a number of studies have found that the cognitive domains of executive functions, memory, and speed of information processing are particularly important component processes of decision-making among medical populations (Iudicello et al., 2013; Muhlert et al., 2015). Among these domains, executive functions appear to be the most widely studied and supported neurocognitive domain showing associations with decision-making (e.g., Muhlert et al., 2015).

In his model of frontal lobe functions, Stuss (2011) specifically describes the inherent difficulty assessing decision-making from a neuropsychological perspective, noting that individuals with damage to the ventromedial prefrontal cortex (an area often associated with

poorer real-world decision-making; Denburg et al., 2007) often perform within normal limits on traditionally used neuropsychological measures. Nevertheless, component executive functions that are proposed to be particularly important for decision-making include categorization of alternative decisions, selecting critical information to be recalled, and strategy application (Brand, Labudda, & Markowitsch, 2006). Other tasks of executive function thought to be sensitive to ventromedial prefrontal cortex dysfunction include those employed in a number of studies examining "risky" decision-making (e.g., gambling tasks, delayed discounting) among medical populations. For example, individuals infected with Hepatitis C virus (HCV) have been observed to choose smaller immediate rewards over larger delayed rewards (Huckans et al., 2011), potentially highlighting altered decision-making styles in this clinical population. Broadly, there appears to be support for increased risky decision making among disease populations with fronto-striatal involvement, including Parkinson's disease (Evens, Hoefler, Biber, & Lueken, 2016), HIV disease (Hardy, Hinkin, Levine, Castellon, & Lam, 2006), multiple sclerosis (Muhlert et al., 2015), traumatic brain injury (TBI; Sigurdardottir, Jerstad, Andelic, Roe, & Schanke, 2010), and Wilson's disease (Ma et al., 2013). These patient populations with executive dysfunction have been shown to benefit from rehabilitative techniques aimed at improving executive functions (Levine et al., 2000). While it remains to be determined whether SDM interventions could in the future generalize to remediating decision-making impairments in populations with executive dysfunction, the current study seeks to examine whether individual differences in decision-making generally alter the effectiveness of SDM.

By way of example, HIV disease provides a model population in which medical decisions are commonly made for engaging in medical care or adhering to medications

(Gardner, McLees, Steiner, del Rio, & Burman, 2011), and the disease itself can confer neurocognitive dysfunction, which can result in poorer decision-making capacity (Doyle et al., 2016). HIV-associated neurocognitive disorders (HAND) is associated with more severe HIV disease characteristics (Ellis et al., 2011), more medical comorbidities (e.g., cardiovascular disease; Wright et al., 2010), and decreased retention in care and health-related behaviors (Doyle et al., 2016; Jacks et al., 2015). Further, HAND commonly confers impairments in neurocognitive domains often considered critical for health-related decision-making, including executive functions, episodic memory, psychomotor speed, and attention (Brand, Labudda, & Markowitsch, 2006; Reger, Welsh, Razani, Martin, & Boone, 2002). Specific studies examining "risky" decision-making in HAND have shown poor decision-making in this population, and decision-making is associated with deficits in the domains of executive functions and learning (Iudicello et al., 2013). Doyle et al. (2016) found that health-related decisional capacity was impaired in individuals with HAND, and performances on the capacity measures were related to neurocognitive functions (e.g., episodic memory, risky decision-making) and health literacy. Taken together, these findings suggest that individuals with HAND show specific neurocognitive (e.g., executive functions, episodic memory) and health (e.g., health literacy) variables that are particularly important for making health-related decisions. Finally, these findings of cognitive correlates of decision-making in HIV are particularly applicable to SDM, as previous studies have demonstrated that higher levels of communication, trust, and collaboration between providers and patients are associated with better adherence to anti-retroviral treatments (Heckman, Catz, Heckman, Miller, & Kalichman, 2004; Schneider, Kaplan, Greenfield, Li, & Wilson, 2004), and lower mortality rates (Ironson, Lucette, & McIntosh, 2015). As such, medical

populations such as HIV provide important data suggesting how neurocognitive variables could modulate or play a role in the SDM process.

While applied studies examining decision-making among medical populations have generally found that executive functions are primary, critical components of medical decision-making, theoretical models of decision-making have produced more comprehensive descriptions of the cognitive resources necessary for effective medical decision-making. To this end, a relevant model proposed by Brand et al. (2006) includes three primary neurocognitive domains necessary for decision-making. These neurocognitive abilities include: (1) episodic memory in order to learn and retain important information relevant to the decision (particularly in early and late stages of decision-making) and to recall previously experienced decision-making experiences, (2) categorizing alternative choices, strategy application, and selection of important information (e.g., executive functions), and (3) attention/working memory to attend to important information. As it pertains to SDM in previous studies, a critical component of medical decision-making capacity involves intact global neurocognitive functioning (e.g., mental status; Karlawish, 2008), while more complex medical-decisions can require intact memory, executive functions, and attention/working memory. Thus, it follows that since one crucial aspect of the collaborative patient-provider interactions in SDM is the patient's background and individual decision-making capacity, there is an important place for considering neurocognitive functioning and decision-making capacity in individuals participating in SDM with their provider.

Decision-Making Capacity

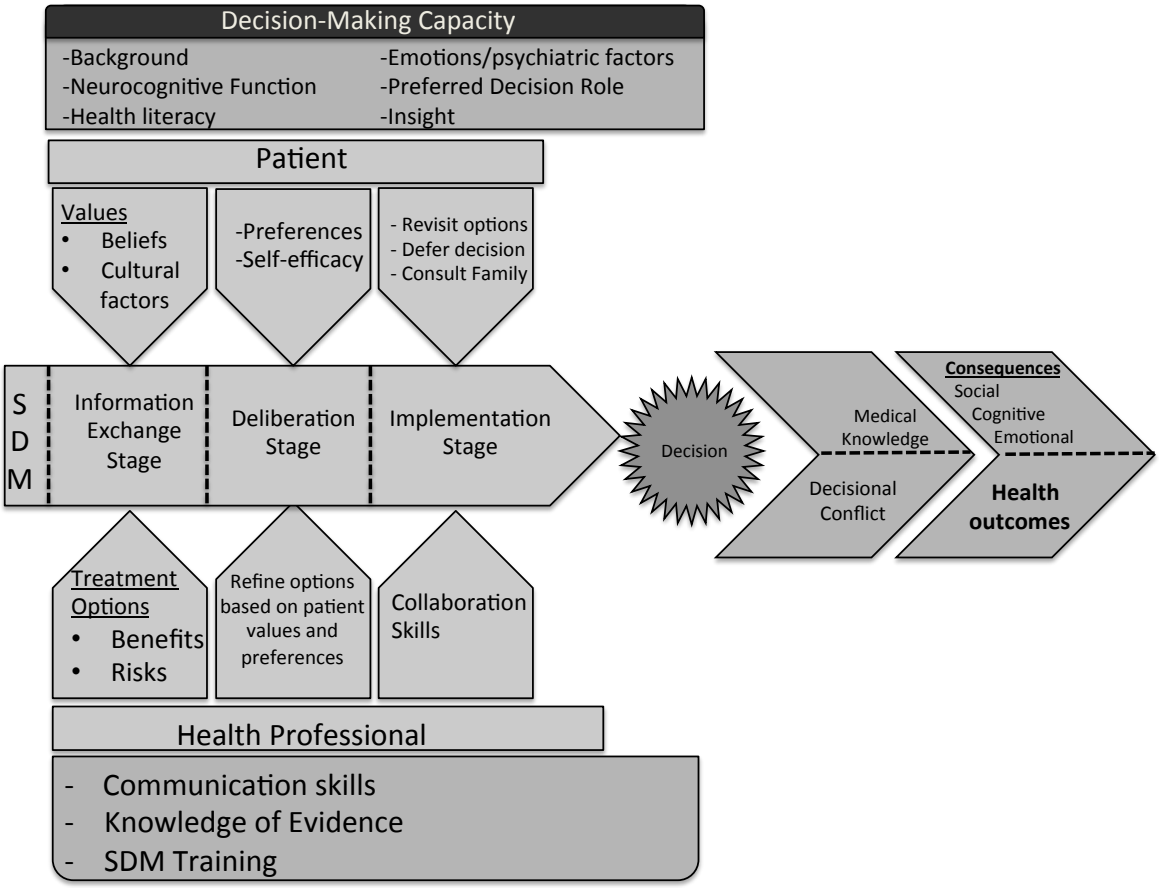
On a practical level, decision-making capacity has been defined in a theoretical model by Marson, Ingram, Cody, & Harrell (1995), which includes: (1) evidencing a treatment choice, (2) appreciating personal consequences of the choice, (3) providing rational reasons for treatment choice, (4) understanding treatment situation and choices, and (5) making a reasonable treatment choice. However, this definition has since been noted to be more closely descriptive of decisional *competency*, which is a related but not interchangeable term (Marson, Earnst, Jamil, Bartolucci, & Harrell, 2000). The key distinction between *capacity* and *competency* involves the type of patient status being assessed and who is doing the evaluation, wherein *capacity* denotes a clinical status as determined by a clinician while *competency* denotes a legal status as determined by a judge (Wyszynski & Garfein, 2005). Regarding assessment of each of these designations, there is considerable variability and discussion surrounding adequate measurement of clinical decision-making capacity. In the medical field, these decisions are most commonly left to medical providers to make clinical inferences to determine decision-making capacity. Nevertheless, there have been specific measures developed in an attempt to more reliably assess an individual's decision-making capacity, such as the Capacity Consent to Treatment (CCTI; Marson et al., 1995) and the Functional Inquiry (Pachet, Newberry, & Erskine, 2007). Another measure developed in research settings is the Modified UCSD Brief Assessment for Capacity to Consent (UBACC-T; Jeste et al., 2007), which attempts to standardize the difficult procedure for determining medical decision-making capacity or consenting to participate in research studies. Regardless, decision-making capacity remains a primarily clinical decision based on medical providers' integration of multiple sources of data (e.g., mental status, capacity to understand

spoken or written language) and semi-structured interviews such as Functional Inquiries. In research settings, studies commonly include individual measures of decision-making capacity as opposed to composite measures drawing from the cognitive and health literacy domains considered to be part of decision-making capacity.

While clinician assessments of patient medical decision-making capacity vary, many are based on the specific competency model of medical decision-making posited by Marson et al. (1995). For example, Dunn, Nowrangi, Palmer, and Saks (2006) proposed that medical decisions as related to capacity require the ability to understand information, to appreciate significance of evidence, and to apply evidence and information by choosing a clear and consistent choice. Building off these specific models, a composite conceptual model for medical decision-making capacity as constructed for the current proposal is presented in Figure 1, and includes variables commonly considered in medical-decision making models, but also incorporates these variables into a broad SDM model. This model serves as a general indicator of the decision-making correlates that are hypothesized to be required to adequately make health decisions in the real-world. In short, this model is presumed to operate within existing patient-provider communication and SDM schema such as that proposed by Charles et al. (1997), in which an individual's decision-making exists in in the context of the exchange of both information and treatment preferences by both physician and patient and agreement by both parties on the treatment to implement. Further, consistent with previous reports indicating the importance of individual differences in medical decision-making (i.e., Doyle et al., 2016), it is proposed that important patient-specific variables (e.g., literacy, health literacy, neurocognitive functioning, general self-efficacy) are part of the overall model contributing to effective SDM and its outcomes. This current model highlights

the need for a complete assessment of decision-making capacity within a patient in order to determine whether any of the individual factors falling underneath the umbrella of decision-making capacity might moderate the effectiveness of SDM with a treatment provider. For the proposed study, decision-making capacity as a variable will be constructed using a composite of measures theorized to draw from these many contributory components of capacity. In this regard, the present study adds to the previous body of literature by examining decision-making capacity using multiple measures of both health-related decision-making and risky decision-making, as opposed to individual measures of decision-making capacity.

Figure 1. Shared decision-making model.



Cancer: A Model of Medical Decision-Making

While SDM has been employed and investigated in numerous medical diseases, including diabetes, serious injury, heart disease, and HIV, the most commonly studied disease populations involve decisions regarding cancer treatment (Légaré et al., 2014; Shay & Lafata, 2015). Further, there are important disease-specific clinical and decision-making factors unique to cancer populations that make them particularly suitable for SDM implementation. For example, cancer patients often make decisions throughout the "cancer continuum," including prevention, screening, diagnosis, treatment, survivorship, and end of life stages (Reyna, Nelson, Han, & Pignone, 2015). The importance and gravity of medical decisions within this population also cannot be understated, with therapy or surgical intervention clinical trials often examining outcomes such as severe cognitive impairments (e.g., language or memory impairments; Gondi et al., 2014) or median mortality with average timelines as short as weeks to months (e.g., Shin et al., 2016). Additionally, a cancer diagnosis commonly presents with multiple treatment options, including surgical resection, radiation, chemotherapy, immunotherapy, or hormone therapies, (National Cancer Institute, 2017), from which multiple combinations of options may be presented to patients. Finally, cancer patients are of particular interest for examining possible individual differences in decisional capacity or neurocognitive performance due to the specific effects that cancer and treatment can have on these functions. For example, patients with brain tumors in the frontal lobe (particularly involving the ventromedial prefrontal cortex) evidence disadvantageous decision-making on the Iowa Gambling Task (IGT) compared to neurologically unimpaired controls (Mattavelli et al., 2012). These findings also can be found in non-CNS cancers treated with chemotherapy. For example, Chen et al. (2013) found that breast cancer patients

treated with the chemotherapy evidenced disadvantageous decision-making on the IGT compared to breast cancer patients not undergoing chemotherapy. Taken together, the frequency and importance of medical-decision making coupled with the decision-making impairments that can occur in cancer populations make them a particularly interesting group in which to determine how individual differences in decision-making capacity might affect the efficacy of SDM.

Conclusion

The presently reviewed neurocognitive architecture of health decisions, as well as the prevalence of decision-making problems that are observed in clinical populations with neurocognitive impairments, make examining neurocognition and decision-making abilities a particularly promising set of variables to examine as potential modulators of the effectiveness of SDM. Quite surprisingly, although SDM holds as a core tenet the decision-making of both patients and providers, there have been no investigations of how individual differences in decision-making capacity or neurocognitive functioning in patients affect SDM in any clinical or experimental population. To this end, the present study will propose to utilize an experimental paradigm using a hypothetical medical scenario with undergraduate students in order to test the effects of decision-making capacity on the efficacy of SDM.

As reviewed previously, there are a host of outcome variables (e.g., perceived role in medical decisions, decisional conflict, knowledge of treatments, behavioral outcomes, health outcomes) that have been examined as possible factors on which SDM may operate (see Taylor et al., 2013). Given the relatively small effect sizes describing the relationship between SDM and across these outcome variables, the present study will investigate how

SDM affects decisional conflict (i.e., feeling uncertain and uninformed about a decision), which is the most commonly studied outcome and is considered to be most immediately affected by a decision (e.g., not a long-term outcome; Légaré et al., 2014). Given the findings of a meta-analysis conducted by Durand et al. (2014) showing that SDM interventions provided a differential benefit to groups with lower literacy and socioeconomic groups (compared to their higher literacy and socioeconomic group peers), it is hypothesized that individuals with lower levels of decision-making capacity and neurocognitive function will receive a disproportionate benefit to decisional conflict compared to individuals with higher levels of decision-making capacity.

Should SDM be moderated by individual differences in decision-making capacity, there are multiple potential benefits that might subsequently be applied to the medical field or to specific populations. First, it is possible that individual differences in decision-making capacity or broader neurocognitive function represent an understudied patient factor that has previously been influencing suboptimal effectiveness of SDM in research to date. Thus, the current study could provide evidence for a specific patient-factor to be considered in future studies of SDM, and may even lead to specific subpopulations of patients (e.g., those with low decision-making capacity) that may differentially benefit from SDM. This may in turn provide clinical and economic incentives for researchers and providers alike to choose groups that might receive structured decision-making interventions and leave other groups to undergo more traditionally implemented authoritative or passive interventions. Second, should it be determined that SDM is of particular benefit to individuals with specific decision-making or neurocognitive dysfunction, it is possible these data could provide the impetus for specific disease populations, such as those that evidence executive dysfunction

associated with fronto-striatal pathway or ventromedial prefrontal cortex involvement, to be specifically targeted for SDM interventions. For example, future studies may wish to specifically study glioblastoma patients with frontal lobe tumors and executive dysfunction to determine whether these individuals might be particularly aided in their decision-making process to elect or forgo an early phase therapy trial instead of standard of care. These possible benefits to research and clinical medicine highlight the importance of studying individual differences in decision-making capacity in SDM.

Hypotheses.

The primary hypothesis for the current study was that decision-making capacity scores would moderate the effect of SDM on decisional conflict such that the effect of SDM on decisional conflict is stronger in individuals with relatively *low* decision-making capacity. In other words, SDM was hypothesized to be strongly related to decisional conflict among individuals with poor individual decision-making capacity, but SDM would not be associated with decisional conflict among individuals with high individual decision-making capacity. In order to determine whether decision-making capacity is a unique moderator of the SDM and decisional conflict relationship, the current study also sought to determine whether other possible moderators (i.e., global neurocognitive functioning, executive functions, general health literacy, general self-efficacy) affect the relationship between SDM and decisional conflict. Specifically, it was predicted that global neurocognitive functioning, executive functions, general health literacy, and general self-efficacy would have numerically smaller moderating effect sizes relative to that of decision-making capacity. Finally, it was predicted that exploratory analyses using alternative outcome measures (i.e., memory for symptom and treatment information, perceived collaboration between participant and provider) would

show similar effects to the current primary hypotheses. Specifically, it was predicted that decision-making capacity also would moderate the effect of SDM on memory for treatment information such that SDM disproportionately benefits individuals with lower decision-making capacity for retaining treatment information. However, it was predicted that individuals with lower decision-making capacity would have lower reported perceived collaboration with providers, regardless of SDM condition.

CHAPTER 2

METHOD

Participants

The study sample consisted of a group of younger adults (age range 18 - 45) recruited from the undergraduate research participant pool at the University of Houston. All participants provided signed consent before participating in the study, and the Institutional Review Board at the University of Houston approved all procedures for the study (STUDY00000406). All participants received 2 credit hours per hour of participation in the study. Inclusion criteria for analyses included being between the ages of 18 and 50, a registered University of Houston student, native or bilingual proficiency in English language fluency and comprehension, and capacity to provide consent to participate. Exclusion criteria included self-reported history of major neurological problems (e.g., head injury with loss of consciousness greater than 30 minutes, seizure disorders, multiple sclerosis, etc.), severe psychiatric conditions (e.g., bipolar disorder, psychosis), and active drug or alcohol use disorder as measured by a self-reported comorbidity checklist.

A total of 98 participants were recruited and participated in the study from March 2018 to November 2018, which was 121% of the original enrollment target. Of the 98 participants, 5 participants were excluded for having an effort index > 0 on the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS; Randolph, Tierney, Mohr, & Chase, 1998; Silverberg, Wertheimer, & Fichtenberg, 2007), 3 participants were excluded for failing to adequately respond to quality-check reverse-coded items on the self-report outcome measure (1 of these also was an outlier on the experimental group check measure), and 1 participant was excluded due to losing data for the outcome measure and decision-making capacity measures, resulting in a total of 89 individuals in the total study sample used for all analyses. Participants were randomly assigned into the shared decision-making group (SDM; n = 45) or the autocratic decision-making group (control; n = 44).

Procedure

All participants were tested in one 2-hour evaluation session while seated in an examination room with the examiner.

Assessments and Measures

The following two sections describe the study measures that were administered to assess the health-related and risk-taking aspects of decision-making. For health-related decision-making, both performance- and report-based tasks were chosen due to their relatedness to health-decisions. Examples of such tasks included participants being administered a vignette, asked to make a health-related decision and answer questions about the possible decision option(s) (performance-based) or asked to rate their perceived typical role in real-world health decision (report-based), and it is considered that these directly comprise the construct of decision-making capacity for medical decisions. Risk taking

measures, while not explicitly part of medical decision-making, were considered for the purposes of this study to be a related construct that may play an important role in determining individual differences in medical decision-making. Further, studies in clinical populations (e.g., HIV) have shown risk-taking and health decision tasks to be related and associated with small-to-medium effect sizes ($\rho = .24$; Doyle et al., 2016). Risk-taking measures are described below and include risk/reward gambling tasks and delayed gratification vs. immediate gain tasks. As such, the proposed decision-making composite included in this study was hypothesized to represent (1) health-related decision-making capacity and (2) extent of response style regarding risky decisions, such that higher scores represent better health-related decision-making capacity *and/or* less risky decision-making. Component aspects of medical decision-making (e.g., numeracy, health literacy, mood) were not planned to be included in the proposed decision-making composite variable since the proposed performance-based measures were hypothesized to draw from these more elementary components when performing or reporting preferred medical decision-making.

Health-Related Decision Measures.

Participants were administered the Modified UCSD Brief Assessment for Capacity to Consent (UBACC-T), which was developed by Jeste et al. (2007) and adapted to contain treatment appraisal content (Burton et al., 2012). The UBACC-T involves a scenario using an imaginary situation in which a friend asks participants to share advice making an important medical decision. After making their decision, participants were asked to provide additional information about the scenario (e.g., alternatives to treatment) and details surrounding justification for their decision on 10 questions relating to the medical scenario (score range 0-19, sample range = 7-19), with higher scores reflecting better performance.

Participants completed a modified version of the Decisional Conflict Scale Hypothetical Medication Scenario (DC-MED; O'Connor, 1995) described by Doyle et al. (2016). Participants were presented with a brief hypothetical scenario in which they have been experiencing mild problems with memory and paying attention. Participants were presented with four different medication options, each with different rates of success at improving symptoms, severities of side effects, and cost. Given the primary outcome of the currently proposed study (decisional conflict), the current version was adapted to have a single best medical decision. Given a high rate of correct responses across the sample (98% identified the correct choice), total scores included participant responses to 3 questions regarding the efficacy, side effects, cost, and color of pill shown during the medication decision. Possible scores range from 0-14, with higher scores representing better recall of treatment information (sample range = 2-12).

All participants completed a modified version of the Decision-Making Competence Assessment Tool (DMCAT; Finucane & Gullion, 2010). The DMCAT is a performance-based decision-making task comprised of three subscales surrounding medical and nutritional decisions: (1) comprehension, (2) dimension weighting, and (3) consistency of decisions. In the interest of time, the original DMCAT was modified from its original version (50 items) to 14 items by using only complex problems (i.e., removing simple problems) and using only items involving health content (i.e., removing financial items). The DMCAT thus has a range of 0-14, with higher scores indicating better comprehension and consistency in decision-making (sample range = 3-14).

Risk-Taking Decision Measures.

The Iowa Gambling Task (IGT; Bechara, Damasio, Damasio, & Anderson, 1994) requires assessing rewards and risks, uncertainty, implicit rule learning, and response to feedback performance on a computerized task of simulated monetary gains/losses. Participants were asked to maximize profits over 100 trials while drawing cards from 4 decks of cards: 2 decks with high immediate gains and occasional higher penalties, and 2 other decks with low immediate gains and occasional low penalties. Total IGT scores reflected the total number of choices from advantageous decks minus the total number of choices from disadvantageous decks only among items 21 through 100 (NB. the first 20 trials have been shown to have low validity for risky decision making and are considered to reflect exploratory behavior rather than decision-making style, Dunn, Dalgleish, & Lawrence, 2006), such that scores are indicative of poor decision-making (total score range = -80 to 80, sample range = -50 to 68).

The Decision Making Questionnaire (DMQ; French, West, Elander, & Wilding, 1993) is a 21-item scale that assesses individuals' control, confidence, and thoroughness in the decision making process. Of the 7 subscales from this instrument, 3 of the subscales were excluded in the current study since they presented possible criterion contamination with the decisional conflict outcome, had limited relevance risky decision-making, and also showed the lowest associations with everyday functioning in the original validation study (French et al., 1993). The subscales (items) that were excluded include social resistance (i.e., "Do you like to consult with others?"), principled ("How often are your decision governed by your ideals regardless of practical difficulties?"), and instinctiveness ("Do you rely on 'gut feelings' when making decisions?"). Thus, the measure used in the current study included 14

items from 4 subscales (i.e., thoroughness, control, hesitancy, optimizing) and examples of items include “Do you make decisions without considering all of the implications?” and “Do you take the safe option if there is one?” and had a possible range of 14-84 with higher scores representing “better” decision making control and thoroughness (sample range = 43-73).

Participants were administered the Monetary Choice Questionnaire (MCQ; Kirby, Petry, & Bickel, 1999), a self-reported measure of delayed discounting during which participants are asked to make forced-choice decisions based on hypothetical monetary gains that can be obtained immediately (i.e., tonight) of relatively smaller amounts or later (e.g., in 25 days) for varying amounts. Items were scored using a scoring program (Kaplan, Lemley, Reed, & Jarmolowicz, 2014), which provided a *k* value that was used for analyses. Higher overall *k* values represent relatively steep discounting wherein small amounts of delay substantially affect reward value (possible range of *k* is 0 to ∞ but practical range is 0 to 0.50, Wileyto, Audrain-McGovern, Epstein, & Lerman, 2004; sample range 0-0.13). In previous studies, higher k values have been associated with obesity, drug abuse, and gambling behaviors (see Odum, 2011).

One measure, the Game of Dice Task (GDT; Brand et al., 2005), was unable to be included in the final data analysis due to a proportion of the collected data being lost. As was proposed, the remaining six decision-making capacity measures were considered for inclusion into a composite score for each participant by computing sample-based Z-scores for each measure listed below and then using the arithmetic mean of these measures to create a composite decision-making score. However, as shown in Table 3 and discussed further in the results, only 2 of the 6 total decision-making capacity measures were significantly correlated with each other, with 14 of the 15 pair-wise spearman r_s values failing to reach statistical

significance at $\alpha = .05$, and the mean r_s value was small (i.e., .04). Therefore, a composite approach to data analysis is not appropriate because it would be comprised of unrelated measures and an unreliable measure of decision-making capacity. Accordingly, I used an approach for analysis whereby individual decision-making capacity measures were tested in separate moderation models. Given the increased risk of Type I error with this alternate approach, the critical α was adjust using false discovery rate (Benjamini & Hochberg, 1995).

Executive Functions Assessment.

All participants were administered the Color-Word Interference and Trail Making (switching) subtests from the Delis Kaplan Executive Function System (D-KEFS; Delis, Kaplan, & Kramer, 2001) as well as the Paced Auditory Serial Addition Task (PASAT; Gronwall, 1977) in order to assess executive functions and create an executive functions composite score for use in hierarchical multiple regressions. Due to time limitations, these measures were administered in a manner inconsistent with standardized administration procedures (i.e., without administering preceding tests as performed in normative data collection), and as such all tests were analyzed using raw scores (as opposed to age-adjusted scaled scores). Each of the 3 raw scores were converted into a sample-based Z-score. For each participant, the arithmetic mean of these 3 Z-scores was derived to create an executive function composite score (mean $r_s = 0.51$).

The Color-Word Interference test of the D-KEFS measures a participant's ability to inhibit an overlearned verbal response (i.e., reading printed words) in order to generate a conflicting response of naming the dissonant ink color in which the words are printed (Delis, Kaplan, & Kramer, 2001). The outcome variable of this measure is total time to complete the task (sample range 29 – 92). The Trail Making (switching) test of the D-KEFS requires

participants to connect numbers and letters in alternating, ascending sequence, and is a measure of cognitive flexibility, working memory, visual scanning, and motor speed. Total time to complete is the outcome variable (sample range 34 – 173). The PASAT is a measure of working memory and speed of information processing that involves participants' ability to add pairs of digits by adding each digit to the digit immediately preceding it. For the current study, digit presentation rates of every 3.0" and 2.4" were used. 50 items were presented for each interval set with a max score of 49 on each set. Thus, scores could range from 0-98 with higher scores representing better working memory and speed of information processing. Total correct responses across all 98 items were summed (sample range 27 – 97) and converted to a sample-based Z-score for each participant.

Neuropsychological Assessment.

All participants were administered the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS; Randolph et al., 2014) as a global indicator of neurocognitive functioning. Given the study's hypotheses (i.e., that decision-making capacity moderates the effect of SDM on decisional conflict, while global cognitive functioning does not), RBANS scores were derived using sample-based Z-scores in a manner similar to that of the decision-making capacity composite. Specifically, sample based Z-scores were generated for individual raw score each of the 12 RBANS subtest scores (list learning, story memory, figure copy, line orientation, picture naming, semantic fluency, digit span, coding, list recall, list recognition, story recall, figure recall) and the arithmetic mean of these sample-based Z-scores were derived for each participant (mean r_s = . 23)

General Health Literacy.

The Rapid Estimate of Adult Literacy in Medicine Reading Test (REALM; Davis et al., 1993) was administered as an assessment of both single-word reading for assessing literacy/generalized intelligence as well as a health literacy assessment. The list was comprised of 66 words commonly used in healthcare settings that participants were asked to read aloud (scores range 0-66, sample range 53 – 66). Participants also were administered Newest Vital Sign (NVS; Weiss et al., 2005), which is a quick screening test for health literacy commonly employed in primary health settings. Participants are asked to examine health-related information from a nutritional label and answer 6 questions based on the information (score range 0 – 6, sample range 2 – 6). Participants also were administered the Expanded Numeracy Scale (ENS; Lipkus, Samsa, & Rimer, 2001) which is a measure of participants' ability to understand and use numeric information. The ENS is comprised of 8 (score range 0-8, sample range 2 – 8) items and involves participants responding in multiple choice or short answer format to each item regarding numerical judgments and understanding numerical information. Finally, participants completed the Brief Health Literacy Screen (BHLS; Chew, Bradley, & Boyko, 2004), which is a 3-item self-report questionnaire measuring perceived capacity to perform health-related tasks, including understanding written health information. The BHLS utilizes a Likert-type scale on each item (range 0-4; 0 = none of the time to 4 = all of the time), with higher scores reflecting poorer self-reported capacity to perform health tasks (score range 0 – 12, sample range 0 – 10). Given lack of correlations among general health literacy scores with the exception of REALM and NVS, which were significantly related ($r_s = .35$, $p < .001$), raw scores were used for all moderation analyses. A single composite was made for the REALM and NVS (since these measures

were correlated) by converting raw scores into a sample-based Z score and computing the arithmetic mean of these 2 Z-scores for each participant. To account for multiple comparisons, an FDR adjustment to α for the 5 (REALM, NVS, ENS, BHLS, REALM/NVS) composite scores used for moderation model interaction terms.

General Self-Efficacy.

All participants completed the General Self-Efficacy Scale (GSE; Schwarzer & Jerusalem, 1995) as a measure of self-perceived self-efficacy for managing and coping with daily hassles and adaptation to experiencing stressful life events. The GSE is a 10-item scale with example items including "I can always manage to solve difficult problems if I try hard enough." and "I can usually handle whatever comes my way." Participants rated each item from "Not true at all" to "Exactly true" and scores for each item range from 1 to 4. Total scores range from 10 to 40 (sample range = 22 – 40), with higher scores representing better management and coping for stressful life events/problems.

Psychosocial Factors.

Participants also completed a modified version of the Beliefs Related to Medication Assessment (BERMA; McDonald-Miszczak, Maris, Fitzgibbon, & Ritchie, 2004), which was modified to assess only for the 25-item "Dealing with Doctors" subscale. Participants rated agreement with statements using a Likert-type scale (range 1-5, 1= "strongly disagree" and 5 = "strongly agree), with higher scores indicating better interactions with healthcare providers (score range 25-125, sample range 54 – 115); total scores were used from this measure. The Control Preference Scale (CPS; Degner, Sloan, & Venkatesh, 1997) was administered as a measure of preferred role in treatment decision processes in order to determine if there were any group differences on preferred role (e.g., shared versus individualized decisions) in real-

world decision-making. Participants were asked to choose 1 of 6 possible options that differ in the degree to which the participant prefers to participate in their own medical decision (e.g., "I prefer to make the final treatment decision", "I prefer that my doctor and I share responsibility for deciding which treatment is best for me," "I prefer to leave all treatment decisions to my doctor"). Participants were asked to choose their most preferred role in the treatment process of the 6 response options. Preferred roles were assigned a value from 1 to 6 (score range 1 – 6, sample range 1 – 4) with an individuals score representing their top-rated preferred role. On this measure, lower scores indicated a preference for an active role and higher scores indicated a preference for passive medical decision-making. For descriptive purposes (see Table 1), criteria proposed by Degner et al. (1997) were applied to this continuous variable to categorize individuals into "passive", "collaborative, or "active" roles in medical decision-making.

Cancer Knowledge.

Participants provided (1) self-reported history of cancer and (2) history of cancer in a family member that were used as adjunct binary variables of familiarity with cancer diagnoses. A questionnaire developed de novo for the proposed study was administered to participants as an assessment of cancer treatment knowledge (Cognitive Effects of Cancer Treatment Questionnaire; CECT-Q). This 12-item true/false questionnaire assessed familiarity with the content of the SDM task, and was used as a quality control (i.e., possible covariate) measure to ensure that the randomized groups do not differ in their familiarity with the content discussed during the SDM task (i.e., cancer treatment and possible neurocognitive sequelae of cancer treatments). Sample items included: "Chemotherapies can cause patients to experience slowed processing speed and memory impairments" (TRUE)

and "Surgery to remove a brain tumor always immediately improves a patient's memory" (FALSE). Possible scores range from 0 to 12, with higher scores representing more knowledge of cancer and cancer treatment effects on cognition. Across the sample, the CECT-Q was found to have adequate internal consistency (Kuder-Richardson Formula 20 = 0.71), scores ranged from 0 to 12, and the distribution was normally distributed (Shapiro-Wilk W = 0.98, p = .166). However, scores on the CECT-Q were not significantly associated with any health-related tasks (all ps > .10) or self-reported family history of cancer (F[1,87] = 0.01, p = .927, Cohen's d = .04).

Mood Assessment.

All participants completed the Profile of Mood States (POMS; McNair, Lorr, & Droppleman, 1981) as a measure of affective distress, which involves 65 items of emotional or physical states that participants rate from having experienced a given state "not at all" to "extremely" over the week prior to the evaluation (range 0 to 4, 0 = "not at all" and 4 = extremely), with higher scores indicating relatively higher mood disturbance (range -32 to 200, sample range -18 – 102).

Shared Decision-Making.

The experimental SDM task included a mock patient-provider interaction, with participants being instructed to imagine they were in a situation during which they are at a doctor's visit discussing treatment options with their medical provider (examiner). Participants were instructed to imagine that they have been undergoing cancer treatment over the past year, and while they are now in remission from cancer, recent cognitive testing shows that they have impairments on neuropsychological functioning (i.e., problems paying attention, impaired memory, difficulties with organization). This approach was taken to

increase the possible clinical relevance given the limitations inherent in using a sample of health undergraduate students. All participants were informed that they can be referred to a physician who will prescribe them medications or to a psychologist who will provide a brain training computer program, both aimed at improving their thinking skills (NB. participants ultimately decide whether they would choose the medication, brain training computer program, *neither* treatment, or *both* treatments). While one participant disclosed previous personal health history significant for cancer diagnosis (see above self-reported comorbidity checklist), this participant was not be excluded from the current study. Participants were randomly assigned to one of 2 groups: (1) a shared decision-making (SDM) group with the examiner and participant working collaboratively to reach a treatment decision using decision aids (SDM group), and (2) an autocratic decision-making "treatment as usual" (control) condition wherein the participant was informed that the provider typically chooses one of the treatment options (i.e., the medication), and that while the provider wrote up their prescription they could look over other treatment options. Participants in both groups were provided identical decision aids with information covering specific values (i.e., treatment side effects, treatment cost, treatment daily routine) that they were asked to use to inform their decision. However, decision aids were used collaboratively between the mock provider and the participant in the SDM group, but the participant was left to review the decision aids alone in the control group. In the SDM group, the mock provider and participant reviewed the decision aids in a way that specifically addressed participant's actual real-world values to guide their decision of choosing the medication, brain training computer program, both treatments, or neither treatment. In the control group, the participants examined identical decision aids as presented in the SDM group, but were told that a treatment option has been

selected for them by the provider but that they are able to make their final decision. Both groups made a decision after reviewing their respective materials.

At the conclusion of the task, participants in both groups rated their decisional conflict using the Decisional Conflict Scale (DCS; O'Connor, 1995). The DCS consists of 16 questions regarding self-efficacy and decisional conflict using Likert-type scale responses (range 0-4; 0 = strongly agree, 4 = strongly disagree), with higher values indicating less confidence in health-related decision (total score range 0-64, sample range = 0 - 42); total scores of the DCS were included for analyses. In the current sample, the DCS had high internal consistency (Cronbach's $\alpha = 0.88$). The DCS is the primary outcome of the current study due to the fact that it is the most commonly utilized outcome measure across studies of SDM (Légaré et al., 2014). However, as part of outcomes of exploratory analyses, participants also were administered outcome measures assessing perceived role in their decision and health knowledge gained. Participants completed the 9-item Shared Decision Making Questionnaire (SDM-Q-9), which asks participants to rate the collaborative interaction during the SDM process using Likert-type scale responses (range 0-5; 0 = completely disagree, 5 = completely agree). Raw responses were transformed to be on a 0-100 scale (sample range 11 – 100), such that 0 indicates the lowest level of SDM and 100 indicates the highest SDM (Kriston et al., 2010). In addition to considering the SDM-Q-9 as a hypothesized study outcome, this measure also was considered as a SDM/control group manipulation check since it is a validated measure used in studies assessing the quality of SDM interventions (Légaré et al., 2014). As a measure of possible gains in knowledge after SDM task exposure, a de novo 10-item multiple-choice response questionnaire also was administered and included questions assessing recall of information regarding treatment

options and their side effects, cost, regimen complexity, and effectiveness using a multiple-choice format, with higher scores indicating better recall of information (scores range 0-10, sample range 7 – 10).

Data Analysis

The proposed moderation model for the primary hypothesis included a multiple regression with a continuous decisional conflict score predicted by categorical SDM/control group (focal predictor), continuous decision-making capacity (moderator), and their interaction term. To address the study hypotheses that decision-making capacity would serve as a significant moderator of group status predicting decisional conflict, while executive function, global neurocognitive functioning, health literacy, and general self-efficacy would have numerically smaller moderating effect sizes, the primary model was repeated in separate multiple regressions with the only difference being the moderator of interest. This statistical approach was informed by the primary hypothesis assessing the specificity of decision-making capacity as a moderator of SDM interventions and decisional conflict, as opposed to the *independent* moderating effect of decision-making capacity over and above related constructs (e.g., executive functions). In other words, alternative approaches such as including multiple moderation terms in a single model (e.g., SDM x executive functions, SDM x decision-making capacity), hierarchical regression, or inferiority testing would only be more appropriate if the primary hypothesis was examining the moderating effect of decision-making capacity that is independent from (e.g., accounting for) other constructs of cognition, health literacy, or self-efficacy. Moreover, limited power due to a relatively small sample size also informed the decision not to use models with multiple moderation terms in a single regression. The current analytic approach also was repeated for exploratory analyses

examining separate outcome variables of memory recall of treatment information and perceived collaboration with the provider.

As noted in the results, measures comprising composite variables of decision-making capacity and health literacy were not significantly or reliably related with other measures within these proposed composites, and thus these composite scores were not deemed valid. As such, an alternative approach was taken by testing 6 separate moderation models using each decision-making capacity measure as a unique moderator in each model. Given that this approach using multiple separate tests increased type I error rate due to multiple comparisons, all significance testing was conducted by adjusting the critical alpha using false discovery rate (FDR; Benjamini & Hochberg, 1995). FDR adjusts the critical α for each null hypothesis test by dividing α (determined for the current study to be α=.05) by the n^{th} test conducted (e.g., 1^{st}… 6^{th}; $\alpha_1 = .05$… $\alpha_6 = .008$), and then rank ordering the *p* values of the 6 tests conducted to be compared to the rank ordered FDR α values. FDR is less stringent than family-wise error correction approaches (e.g., Bonferroni correction) as it adjusts for Type I error with relatively less inflation of Type II error rate (Shaffer, 1995). This approach also was taken for the 4 health literacy measures each considered as moderators. All models were constructed in Mplus version 8 using maximum likelihood estimation and 95th percentile bootstrap confidence intervals. All findings were interpreted through examining whether the bootstrapped 95% CI of unstandardized estimates from moderation models contained zero, but false discovery rate determinations of significance for decision-making capacity variables (i.e., the primary hypotheses) were determined using the model results exact *p* value. 90% CI (critical α = .10) of unstandardized estimates are reported as trend-level findings and noted as such. Probing of significant interaction terms was performed using guidelines provided by

Aiken and West (1991) by conducting a simple slope analysis through rescaling the moderator at 3 levels: -1.0 SD (low), 0.0 SD (normal), +1.0 SD (high) levels of each moderator. In addition, Johnson-Neyman plots for trend-level interaction terms are provided. Johnson-Neyman plots represent simple slopes of the relationship between DCS scores on group (SDM = 1, control = 0, such that simple slope values < 0 indicate lower [better] DCS scores in the SDM group compared to the control group) across levels of each moderator of interest.

Consistent with Yzerbyt, Muller, and Judd (2003), possible covariates were included based on the results of a data-driven covariate selection process. Variables in Table 1 were included as covariates if they were related to any two of the three variables in each mediation model (i.e., focal group predictor, moderator, and decisional conflict) at a critical alpha of 0.10, *and* were significant independent predictors of decisional conflict in a model containing only possible covariates. Additionally, any variables that specifically related to the focal variable of group status and the outcome of decisional conflict were included along with their interaction term with group status. Among variables in Table 1, gender, race/ethnicity, POMS total mood disturbance, BERMA, family history of cancer, and GPA were significantly related to DCS scores. Among these, gender (included in all models), BERMA (included in models with UBACC-T, DMQ), and family history of cancer (included in models with UBACC-T, DMQ) were related to select moderator variables and were included in models assessing these moderators. Only gender was significantly related to both decisional conflict (outcome) and differed across the SDM and control groups (focal predictor), and as such gender was the only covariate that also included its interaction term with group status in each moderation model.

For exploratory analyses using separate outcomes (recall of treatment information and perceived collaboration during SDM, the moderation models (i.e., those conducted for the outcome of DCS) were replicated in an identical manner as those performed with the DCS outcome. Specifically, models examining treatment recall and perceived collaboration on the SDM-Q-9 were examined with each moderator including: (1) separate decision-making capacity raw scores with critical α corrected by FDR, (2) EF composite scores, (3) RBANS composite scores, (4) separate health literacy raw scores with critical α corrected by FDR, and (5) GSE raw scores.

In the entire sample dataset, a total of .01% of data cells were missing. Missing items within a scale for each participant were given prorated scores from remaining completed items. If an entire score from a measure was missing for a participant, these scores were imputed using mean imputation. Among primary variables (i.e., moderators, primary DCS outcome scores), only 5 cases were missing (1 case for MCQ, 2 for DMQ, 2 for DC-MED) that were imputed (total < .01% mean imputed; no DCS outcome scores were mean imputed). Outliers > 3.0 SD away from the mean of each variable were windsorized (Tabachnick & Fidell, 2019), which included a total of 20 (< .01%) cases windsorized (3 [< .01%] among primary moderator and outcome variables). All variables were screened for normality using the Shapiro-Wilk test of normality; non-normally distributed variables (p < .05) were examined using Wilcoxon rank-sum tests for examining for examining univariate relationships presented in Tables 1 and 2. For regression moderation models, a 95% CI bootsrapping approach was used to account for non-normally distributed data. Of the 18 variables presented in Table 3, 14 were non-normally distributed (Shapiro-Wilk W range

0.72 - 0.98, all *p*s < .05), and so correlations between study variables were examined using Spearman r_s associations (see Table 3).

CHAPTER 3

RESULTS

Sample Characteristics

As shown in Table 1, SDM and control groups were broadly comparable across demographic, health, and mood variables. However, random assignment resulted in there being a higher proportion of men in the control group (n = 15; 34% of control sample) than in the SDM group (n=6; 13.3 % of SDM sample; $\chi^2[1]=5.45$, p =.020, Odds ratio = 3.4 [1.2, 9.7]). There were no differences between the SDM and control groups in education, familiarity with cancer as measured by the novel CECT-Q, preferred role in real-world medical decisions, or healthcare provider status (all ps $> .10$).

Table 1. Demographic, health, and mood variables within the shared decision-making (SDM) and autocractic decision-making (control) groups.

Variable	SDM Group (n=45)	Control Group (n=44)	*p*	Cohen's *d*
Age	22.4 (6.1)	22.3 (4.6)	.610	.01
Gender (% male)	13.3	34.1	.020	.67
Race/Ethnicity			.763	
African-American (%)	20.0	18.2		.06
Asian (%)	28.9	38.6		-.24
Caucasian (%)	18.2	15.6		.10
Hispanic (%)	18.2	28.9		-.33
Other (%)	6.7	6.8		-.01
Education (years)	13.7 (1.2)	14.1 (1.2)	.130	-.32
Mother's Highest Education (years)	13.8 (2.8)	14.3 (3.3)	.144	-.15
Grade Point Average (self-reported)	3.3 (0.4)	3.3 (0.4)	.957	.00
CECT-Q (of 12)	5.9 (2.1)	5.5 (3.0)	.434	.15
Family History of Cancer (% yes)	60.0	59.1	.930	.02
BERMA Dealing with Doctors Scale	87.3 (16.1)	88.3 (13.9)	.774	-.06
Control Preferences Scale Preferred Role (%)			.520	
Passive	4.4	2.3		.38
Collaborative	28.9	20.5		.25
Active	66.7	77.3		-.29
Healthcare Provider Status (% with provider)	80.0	68.2	.233	.34
No. Visits with Provider Last Year	2.0 (2.0)	2.0 (3.4)	.909	.00
Healthcare Insurance Status (% insured)	82.2	86.4	.591	-.17
POMS Total Mood Disturbance	29.2 (27.3)	30.5 (28.6)	.990	-.05

Note. Data represent mean (standard deviations) or valid population % values. CECT-Q = Cognitive Effects of Cancer Treatment Questionnaire; BERMA = Beliefs Related to Medication Assessment; POMS = Profile of Mood States.
*Categorical variable Cohen's *d* values represent converted odds ratio values.

SDM and Control Group Performances on Study Variables

As shown in Table 2, the SDM group scored significantly higher on the manipulation check variable Shared Decision-Making Questionnaire-9 ($Z = 5.71$, $p < .001$, Cohen's $d = 1.54$). At the univariate level, there was no significant difference and a small-to-medium effect size between the SDM and control group reporting on the primary outcome Decisional Conflict Scale ($Z = 1.05$, $p = .294$, $d = -.26$). Among measures considered as potential

moderators (i.e., decision-making capacity, neurocognitive functioning, executive functions, general health literacy, self-efficacy measures), only the DC-MED differed between the SDM and control groups, such that SDM group had significantly higher DC-MED memory scores than the control group ($F[1, 87] = 4.54$, $p = .036$, $d = .45$).

Table 2. Decisional conflict, decision-making capacity, global neurocognitive, executive functions, health literacy, general self-efficacy, and exploratory study outcome measure performances across the shared decision-making (SDM) and autocratic decision-making (control) groups.

Variable	SDM Group (n=45)	Control Group (n=44)	*p*	Cohen's *d*
Decisional Conflict				
Decisional Conflict Scale (of 100)	11.5 (9.9)	14.3 (11.5)	.292	-.26
Decision-making Capacity Measures (Sample-based Z)	0.04 (0.44)	-0.02 (0.49)	.594	.13
Health-related (Sample-based Z)	0.14 (0.69)	-0.14 (0.64)	.047	.42
UBACC-T (of 19)	15.0 (2.5)	14.6 (2.4)	.523	.16
DMCAT (of 14)	9.4 (2.0)	8.9 (2.2)	.233	.24
DC-MED (of 13)	7.2 (2.1)	6.3 (1.8)	.037	.46
Risk-taking (Sample-based Z)	-0.07 (0.55)	0.11 (0.59)	.140	-.31
Iowa Gambling Task (range -80 to 80)	13.3 (22.5)	14.3 (31.9)	.861	-.04
Monetary Choice Questionnaire (Overall *k)*	0.03 (0.04)	0.02 (0.02)	.274	.32
Decision Making Questionnaire (range 14 – 70)	56.7 (6.0)	57.2 (6.6)	.723	-.08
Global Neurocognitive Functioning (Sample-based Z)	0.02 (0.53)	-0.02 (0.53)	.724	.08
RBANS Total (age-adjusted standard scores)	93.6 (14.1)	93.1 (14.5)	.868	.03
Executive Functions (Sample-based Z)	-0.03 (0.82)	0.03 (0.79)	.793	-.07
D-KEFS Trail Making Switching (seconds)	82.7 (31.9)	79.8 (29.0)	.793	.10
D-KEFS Color Word Interference (seconds)	48.4 (12.3)	47.9 (12.2)	.761	.04
PASAT (of 98)	68.4 (16.8)	69.0 (15.2)	.970	-.04
General Health Literacy (Sample-based Z)	-0.06 (0.63)	0.06 (0.59)	.342	-.20
REALM (of 66)	61.8 (3.6)	62.3 (3.4)	.657	-.14
Expanded Numeracy Scale (of 8)	6.2 (1.7)	6.2 (1.6)	.973	.00
Newest Vital Sign (of 6)	4.3 (1.3)	4.6 (1.3)	.273	-.23
Brief Health Literacy Screen (of 12)	3.3 (2.6)	3.0 (2.0)	.797	.13
Self Efficacy				
General Self Efficacy Scale (range 10 - 40)	31.3 (4.3)	31.7 (4.2)	.789	-.09
Exploratory Study Outcomes				
Memory for Treatment Options (of 10)	9.1 (0.9)	9.1 (1.0)	.712	.00
SDM-Q-9 (of 100)	83.3 (10.3)	57.3 (21.5)	<.001	1.54

Note. Data represent mean (standard deviations) or valid population % values. UBACC-T = UCSD Brief Assessment of Capacity to Consent; DMCAT = Decision-Making Competence Assessment Tool; DC-MED = Decisional Conflict Scale Hypothetical Medication Scenario; RBANS = Repeatable Battery for the Assessment of Neuropsychological Status; D-KEFS = Delis-Kaplan Executive Function System; PASAT = Paced Auditory Serial Addition Test; REALM = Rapid Estimate of Adult Literacy in Medicine; SDM-Q-9 = Shared Decision-Making Questionnaire-9.

Associations Between Decisional Conflict Scale Scores and Moderator Variables

As shown in Table 3, across the entire study sample the primary study outcome DCS did not significantly correlate with any decision-making capacity, neurocognitive

functioning, executive functions, or self-efficacy scores, and the effect sizes were small (all *p*s > .05, r_s range .04 – .20). The DCS was significantly associated with a single measure of general health literacy, such that higher decisional conflict reported on the DCS was significantly associated with poorer self-reported health literacy (r_s = .35, p < .001), and the DCS showed a trend-level association with DMQ scores with a small effect size (r_s = -.20, p = .059), such that higher decisional conflict was associated with poorer decision-making thoroughness and control.

Associations Among Component Measures of the Decision-Making Capacity Composite

Critical to the current hypotheses, and as shown in Table 3, only 2 of the 6 decision-making capacity measures were significantly related to each other at α=.05, such that poorer delayed discounting as measured by Overall *k* from the MCQ was significantly associated with more risky decision-making on the IGT (r_s = -.22, p = .043). DC-MED scores showed trend-level associations with UBACC-T scores (r_s = .20, p = .062). Otherwise, 13 of the 15 remaining pair-wise spearman r_s associations failed to reach statistical significance and revealed small effect sizes (all *p*s > .10, r_s range .01 – .17). In light of these results, an exploratory factor analysis (EFA) was conducted to determine whether one or more latent factors could be identified from 5 decision-making observed variables (NB. low reliability among items [Cronbach's α = 0.26] in the DC-MED resulted in this observed variable being excluded). Results of the EFA showed adequate-to-poor model fit for a one-factor solution (χ^2[5]=5.98, p = .309; RMSEA = .05, CFI = .70, TLI = .39, SRMR = .06), and examination of factor loadings revealed that only one observed measure loaded onto this factor (DMCAT; factor loading = 1.03, all other loadings <.16). The two-factor solution fit statistics were unstable due to the model having 1 degree of freedom (χ^2[1]=0.00, p = .997; RMSEA = .00,

CFI = 1.0, TLI = 4.1, SRMR = .000), and each factor had only one measure that significantly loaded (Factor 1: MCQ Overall *k* loading = 1.04, Factor 2: DMCAT loading = .55; all other factor loadings <.35). As such, it was determined that the current sample size and correlations between measures were inadequate to determine one or more reliable decision-making latent factors. In light of these findings, the proposed data analysis plan to combine all 6 decision-making capacity measures into a single composite score using sample-based Z scores was determined to be inadequate. Instead, the primary hypothesis was investigated by conducting 6 separate regression moderation models, correcting for Type I error by adjusting critical α using false discovery rate (FDR), with each model having a separate moderator comprised of a single decision-making capacity raw score (see Table 4). Broadly, using Fisher's transformation Z tests there was no significant difference between control and SDM groups in average r_s associations between decision-making capacity measure scores and DCS outcome scores (Fisher's Z = 0.18, p = .857; mean r_s in control = -.02, mean r_s in SDM = -.06).

Table 3. Spearman r_s correlations among decision conflict, decision-making, global neurocognitive, executive functions, health literacy, general self-efficacy, and exploratory outcome (memory for treatments, Shared Decision-Making Questionnaire-9) measures.

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.	17.	18.
1. DCS Total Score	--																	
2. UBACC-T	-.15	--																
3. DMCAT	-.09	.09	--															
4. DC-MED	-.08	.20	.16	--														
5. IGT	.13	.05	.17	-.03	--													
6. MCQ Overall k	-.04	-.03	.09	.12	-.22*	--												
7. DMQ	-.21	.01	.14	-.09	.03	-.03	--											
8. RBANS Total	.07	.19	.11	.37**	.03	-.04	.05	--										
9. D-KEFS Trails	.04	-.24*	-.14	-.18	-.11	-.10	-.06	-.43**	--									
10. D-KEFS CWI	-.11	-.18	-.31*	-.17	-.29*	-.01	-.12	-.44**	.44**	--								
11. PASAT	.14	.17	.16	.16	.11	.12	.23*	.56**	-.49**	-.60**	--							
12. REALM	-.08	.06	-.03	.04	.09	.08	-.02	.32*	-.10	-.19	.29*	--						
13. ENS	-.05	.14	.18	.11	.15	.04	-.06	.14	-.17	-.21	.25*	.04	--					
14. NVS	-.10	.19	.12	.25*	.07	-.07	-.02	.54**	-.42**	-.42**	.42**	.35*	.20	--				
15. BHLS	.35**	-.01	-.08	-.09	-.10	.03	-.23*	-.14	-.06	-.11	-.07	-.16	-.14	-.07	--			
16. GSE	.17	.22*	.20	-.12	-.04	-.08	.46**	.13	-.17	-.10	.17	.20	-.03	.13	-.25*	--		
17. MFT	-.22*	.14	.26*	.14	.04	.23*	.04	.24*	-.17	-.22*	.14	.17	.05	.31*	-.11	-.04	--	
18. SDM-Q-9	-.32*	.11	-.06	.15	-.20	.12	.07	-.10	.10	.18	-.14	.09	.03	-.09	-.07	.13	-.06	--

Note. N = 89; DCS = Decisional Conflict Scale; UBACC-T = UCSD Brief Assessment of Capacity to Consent; DMCAT = Decision-Making Competence Assessment Tool; DC-MED = Decisional Conflict Scale Hypothetical Medication Scenario; IGT = Iowa Gambling Task; MCQ = Monetary Choice Questionnaire; DMQ = Decision Making Questionnaire; RBANS = Repeatable Battery for the Assessment of Neuropsychological Status; D-KEFS = Delis-Kaplan Executive Function System; PASAT = Paced Auditory Serial Addition Test; REALM = Rapid Estimate of Adult Literacy in Medicine; ENS = Expanded Numeracy Scale; NVS = Newest Vital Sign; BHLS = Brief Health Literacy Screen; GSE = General Self Efficacy Scale; MFT = Memory for Treatments; SDM-Q-9 = Shared Decision-Making Questionnaire-9.

* $p < .05$

** $p < .001$

Primary Hypothesis: Decision-Making Capacity Moderation Models

All overall models examining decision-making capacity measures as moderators were significant (all *p*s < .001). As shown in Table 4, across the 6 separate moderation models predicting DCS scores while adjusting for gender and its interaction with group status, there were significant main effects of DMCAT scores (*b* [95% CI] = -1.7 [-2.8, -0.4]) and DMQ scores (-0.5 [-0.9, -0.2]). Specifically, controlling for gender and its interaction with group status, for two people in the control group and differed by one unit on the DMCAT, the participant one unit higher on the DMCAT (better decision-making comprehension and consistency) was expected to have 1.7 fewer points of decisional conflict as measured by the DCS. For two people in the control group that differed by 1 unit on the DMQ, the participant one unit higher on the DMQ (more thorough and controlled decision-making) was expected to have 0.5 fewer units of decisional conflict on the DCS. Gender as a covariate was a significant independent predictor of DCS scores in each model (all 95% CIs did not contain 0) such that females reported lower levels of decisional conflict on the DCS. However, there were no significant gender x group interaction terms in any model (all 95% CIs contained 0).

Across the 6 separate moderation models while adjusting α using FDR, no interaction terms between any decision-making measure and group status significantly predicted DCS scores (*b* range -18.7 – 1.8, *p* range .088 – .995). Moreover, none of the 95% CIs (α = .05) for interaction terms between each decision-making capacity measure and group status were significant. A power analysis conducted *a priori* revealed that the proposed linear multiple regression analysis, given a hypothesized medium-to-large effect size f^2 of .21, α error probability = .05, in order to achieve power of 0.80 using the proposed 3 total predictors

would require a sample size of 80 participants in total. Current power analysis using sample means and standard deviations of each interaction term revealed that the average least significant number (LSN) of observations to observe significant interactions between decision-making capacity measures and group status was 1434 (range 118 - 6429). The interaction between DMCAT and group status was associated at a trend-level *(b* = 1.8, 90% CI [.03, 3.5]). However, as shown in Figure 2, Johnson-Neyman plot of the simple slopes and 95% CIs of group predicting DCS scores revealed that this trend was not significant at any observed level of observed DMCAT performances. In parallel, an exploratory probing of this trend-level interaction with simple slope analysis by rescaling the moderator at low (-1.0 SD), mean (0.0 SD), and high (+1.0 SD) levels of DMCAT performances revealed that the effect of group status on decisional conflict did not significantly differ across levels of DMCAT performances, even at $\alpha = .10$ (simple slope [90% CI] at -1.0 SD = -5.89 [-14.69, 2.77], mean = -2.88 [-11.26, 5.30], +1.0 SD = -.004 [-8.67, 8.69]). While not significant at $\alpha=.05$ or $\alpha=.10$, plotting these simple slope effect sizes indicate that at, on average, for individuals with a DMCAT score 1.0 SD below the mean (DMCAT = 7.0), those in the SDM group had DCS scores that were 5.89 points lower than the control group, while for individuals with DMCAT scores 1.0 SD above the mean (DMCAT = 11.3), those in the SDM group had DCS scores that were only .004 points lower than the control group.

Table 4. Mixed effects linear regression model results for separate moderation models, with each using a separate decision-making capacity measure as the moderator.

Predictor	*b*	SE	90% CI	95% CI	*p* [a]	Interaction term α (FDR)
UBACC-T	0.6	0.8	[-0.7, 2.0]	[-1.0, 2.2]	--	--
Group	14.4	15.1	[-11.5, 37.9]	[-16.3, 43.2]	--	--
UBACC-T*Group	-1.4	1.0	[-3.0, 0.4]	[-3.3, 0.7]	.170	.025
DMCAT	-1.7	0.7	[-2.8, -0.4]*	[-3.0, -0.1]**	--	--
Group	-19.9	11.2	[-37.5, -0.9]*	[-40.8, 2.7]	--	--
DMCAT*Group	1.8	1.0	[.03, 3.5]*	[-.3, 3.8]	.088	.008
DC-MED	-0.4	0.8	[-1.7, 1.0]	[-1.9, 1.3]	--	--
Group	-4.1	9.0	[-18.5, 10.8]	[-21.4, 14.3]	--	--
DC-MED*Group	-0.01	1.1	[-1.9, 1.8]	[-2.3, 2.2]	.995	.050
IGT	0.1	0.1	[-.02, .15]	[-.03, .16]	--	--
Group	1.9	7.8	[-11.8, 14.3]	[-14.3, 16.3]	--	--
IGT*Group	-0.1	0.1	[-0.2, 0.03]	[-0.2, .06]	.229	
MCQ	-0.3	96.5	[-154.1, 163.3]	[-178.7,194.2]	--	--
Group	-3.5	6.8	[-14.4, 8.1]	[-16.6, 10.3]	--	--
MCQ*Group	-18.7	100.8	[-191.5, 140.5]	[-226.7,164.8]	.853	.042
DMQ	-0.5	0.2	[-0.9, -0.2]*	[-1.0, -0.1]**	--	--
Group	-33.7	20.9	[-66.6, 2.1]	[-72.9, 8.6]	--	--
DMQ*Group	0.5	0.4	[-0.1, 1.0]	[-0.2, 1.1]	.165	.017

Note. FDR = False discovery rate; UBACC-T = UCSD Brief Assessment of Capacity to Consent; DMCAT = Decision-Making Competence Assessment Tool; DC-MED = Decisional Conflict Scale Hypothetical Medication Scenario; IGT = Iowa Gambling Task; MCQ = Monetary Choice Questionnaire; DMQ = Decision Making Questionnaire. Group is coded as: shared decision-making group = 1, control group = 0.

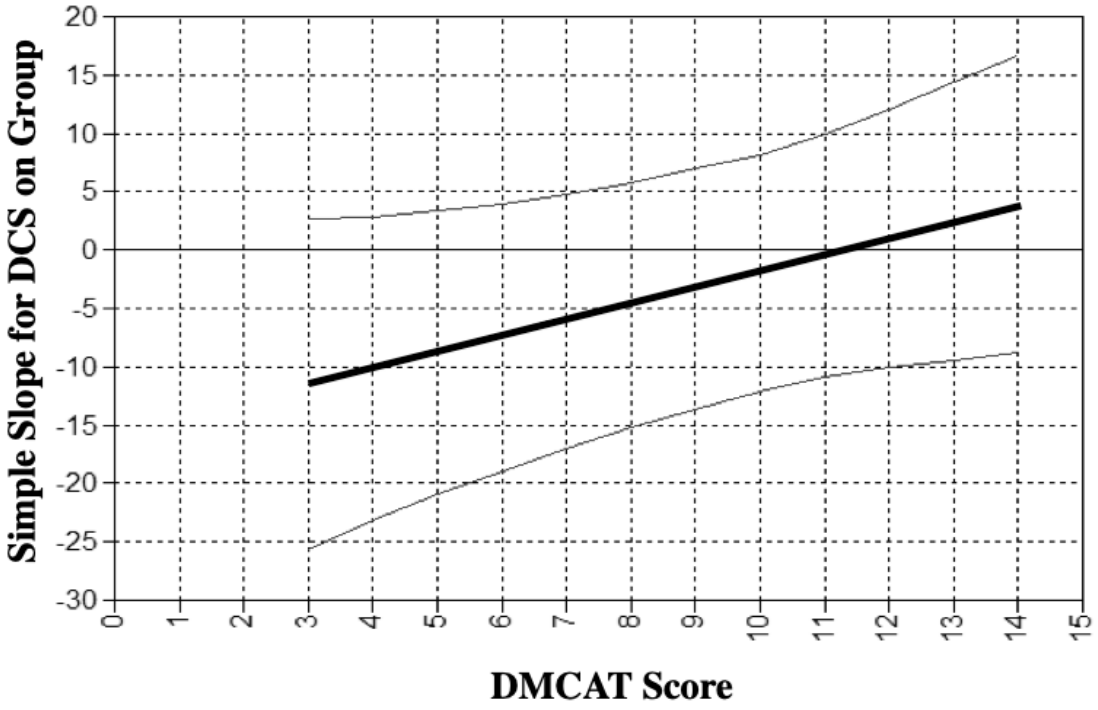
[a] *p* values are presented for interaction terms to be used in false discovery rate analyses to adjust for Type I error due to multiple comparisons. *p* values are from maximum likelihood model results using symmetric confidence intervals.

* 90% CI from bootstrap analysis does not contain 0.

**95% CI from bootstrap analysis does not contain 0.

***$p \leq$ FDR α

Figure 2. Johnson-Neyman plot of simple slopes (difference in Decisional Conflict Scale scores for shared decision-making group compared to control group) across observed levels of Decision-Making Competence Assessment Tool (DMCAT) scores.



Note. DCS = Decisional Conflict Scale; DMCAT = Decision-making Capacity Assessment Tool. Black line represents simple slope. Gray lines indicate 95% CIs for simple slope.

Executive Functions Moderation Model

The overall model with an executive functions composite serving as the moderator was significant ($\chi^2[6]=20.6$, $p = .002$). Adjusting for family history of cancer, gender, and gender x group interaction, main effects of group (b = -3.57 [-21.6, 13.4]), executive functions composite scores (b = 1.8 [-2.7, 6.0]), and the interaction between group x executive functions (b = -3.57 [-21.6, 13.4]) were not significant independent predictors of DCS scores. Only gender (b = -10.2 [-15.1, -4.3]) and family history of cancer (b = -7.0 [-

11.6, -2.2]) were significant predictors of DCS scores, such that being a woman or having a family history of cancer was associated with on average 10.2 and 7.0 fewer units on the DCS, respectively.

Global Neurocognitive Functioning Moderation Model

The overall model with RBANS total sample-based Z scores serving as the moderator was significant ($\chi^2[6]=22.7$, $p < .001$). Adjusting for family history of cancer, gender, and gender x group interaction, main effects of group (b = 1.3 [-18.9, 20.6]), RBANS scores (b = 5.5 [-0.2, 11.9]), and the interaction between group x RBANS (b = -3.1 [-11.6, 6.0]) did not reach statistical significance using 95% CIs. However, the main effect of RBANS scores was associated at trend-level with DCS scores (b = 5.5, 90% CI [0.6, 10.8]), such that for two people in the control group and who differed by one unit on the RBANS, the participant one Z score unit higher on the RBANS (better global neurocognitive functioning) was expected to have 5.5 points *higher* decisional conflict as measured by the DCS. Consistent with the model described above, both gender (b = -12.5 [-17.4, -6.6]) and family history of cancer (b = -7.6 [-11.8, -3.1]) were significant predictors of DCS scores in this model.

General Health Literacy Models

Given that only 2 of the 4 general health literacy measures were associated with on another (i.e., REALM and NVS), general health literacy measures (in addition to the REALM and NVS composite score) were treated as individual moderators in separate models with interaction term significance determined by comparing p values to FDR-adjusted α. All overall models were significant (all ps < .05). Across all models, adjusting for BERMA, family history of cancer, gender, and gender x group interaction, there were no significant main effects of group (all 95% CIs contained 0 and p > FDR α), main effects of health

literacy (all 95% CIs contained 0 and p > FDR α), or interaction terms between group x health literacy for each measure (all 95% CIs contained 0 and p > FDR α) predicting DCS scores.

General Self Efficacy Model

The overall model with the GSE scale serving as the moderator was significant ($\chi^2[6]=24.4$, $p < .001$). Adjusting for BERMA, gender, and gender x group interaction, *main effects* of group (b = -13.4 [-51.5, 24.8]), GSE scores (b = -0.17 [-1.20, 0.82]), and the group x GSE interaction (b = -0.25 [-0.86, 1.41]) were not significant independent predictors of DCS scores. Only gender (b = -9.3 [-14.7, -3.5]) and BERMA (b = -0.25 [-0.41, -.09]) were significant predictors of DCS scores, such that being a woman was associated with 9.3 fewer units of decisional conflict and for two people in the control group and who differed by one unit on the BERMA, the participant one unit higher on the BERMA was expected to have 0.25 points fewer decisional conflict as measured by the DCS.

Exploratory Analyses

Perceived SDM Collaboration and Recall of Treatment Information Outcomes.

The moderation models (i.e., those conducted for the outcome of DCS) were replicated using two other separate outcomes: (1) recall of treatment information and (2) perceived collaboration during SDM. These models were conducted using an identical analysis plan as used for the DCS outcome, such that separate models were run with each moderator, including: (1) 6 separate decision-making capacity raw scores with interaction term critical α corrected by FDR, (2) EF composite scores, (3) RBANS composite scores, (4) 4 separate health literacy raw scores with critical α corrected by FDR, and (5) GSE raw scores. At the univariate level, the SDM group had significantly higher reported perceived

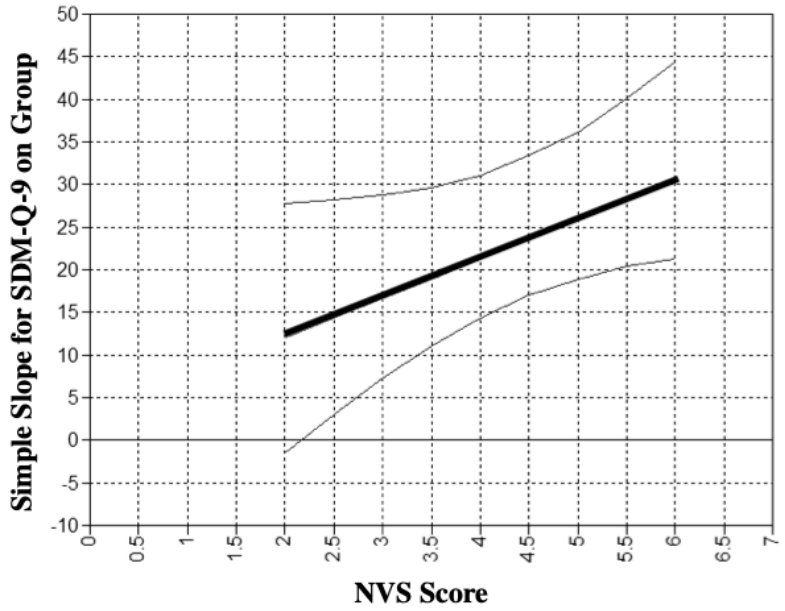
collaboration on the SDM-Q-9 (Z= 5.71, p < .001, d = 1.54), but there was no significant difference in recall of treatment information between SDM and control groups (Z = 1.05, p =.249, d = .00).

Main Effects and Moderators of SDM on Perceived SDM Collaboration.

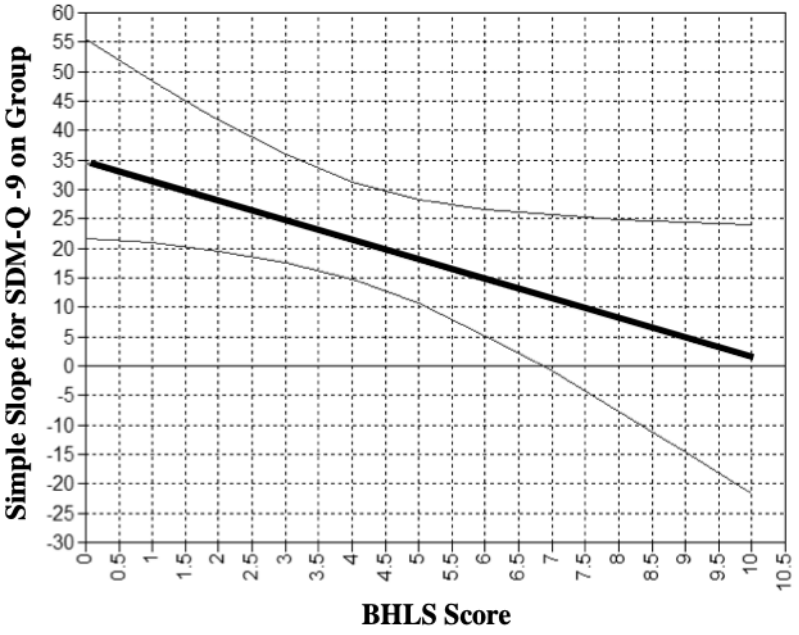
Across separate models, significant main effects of group status (SDM, control) predicting SDM-Q-9 scores were observed only in models containing the MCQ (b = 27.9 [16.3, 39.0]) and BHLS (b = 37.4 [24.2, 53.2]), such that SDM groups reported higher SDM collaboration with the provider compared to the control group in each model. Across all models, only RBANS was a significant independent predictor of SDM-Q-9 scores (b = -12.1 [-29.4, -2.6]), such that for two people in the control group and who differed by one Z score unit on the RBANS, the participant one unit higher on the RBANS (better global neurocognitive functioning) was expected to have 12.1 points *lower* perceived collaboration on the SDM-Q-9. Across models there were no significant main effects of any decision-making capacity measures, the executive functions composite, health literacy measures, or GSE scores (all 95% CIs contained 0 or p > FDR α). Across models, there were no interaction terms that reached statistical significance (all 95% CIs contained 0 or p > FDR α). However, examination of 90% CIs revealed that interaction terms for group x NVS (b = 5.1 [0.8, 9.2]) and group x BHLS (b = -3.6 [-6.6, -0.7]) reached trend-level significance. As shown in Figure 3, simple slope analyses at +/- 1.0 SD using 90% CI revealed that SDM resulted in higher perceived collaboration among individuals with higher health literacy measured by the NVS (SS at +1.0 SD = 29.7 [21.0, 42.5] versus SS at -1.0 SD = 17.2 [8.1, 28.9]) and among individuals with higher levels of self-reported health literacy ability (SS at -1.0 SD = 31.5 [21.0, 49.2] versus SS at +1.0 SD = 16.3 [8.2, 27.4]).

Figure 3. Johnson-Neyman plots of simple slopes (difference in Shared Decision-Making Questionnaire-9 scores for shared decision-making group compared to control group) across observed levels of (A) Newest Vital Sign (NVS) scores and (B) Brief Health Literacy Scale (BHLS) scores. (NB. higher BHLS scores represent poorer self-reported health literacy).

(A)



(B)



Note. SDM-Q-9 = Shared Decision-making Questionnaire-9; NVS = Newest Vital Sign; BHLS = Brief Health Literacy Screen. Black lines represent simple slope. Gray lines indicate 95% CIs for simple slope with regions of significance indicating CIs at levels of NVS that do not contain 0.

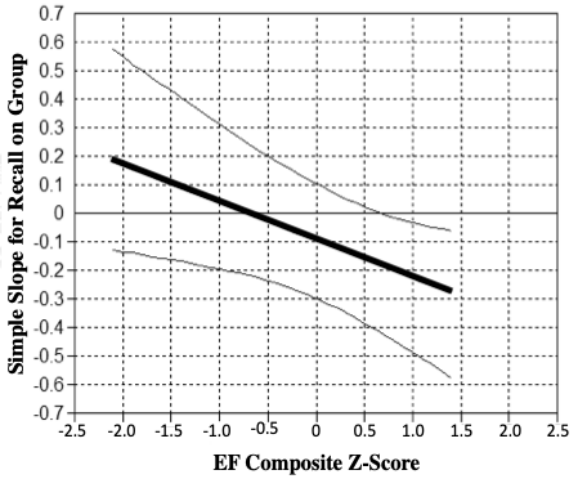
Main Effects and Moderators of SDM on Recall of Treatment Information.

Across separate models, there were no significant main effects of group status (SDM, control) predicting memory for treatment information (all 95% CIs contained 0 or $p >$ FDR α). Across all models, main effects of DMCAT scores ($b = 0.16$ [0.04, 0.26]) and executive functions (EF) composite scores ($b = 0.55$ [0.14, 0.97]) were significant predictors of recall for treatment information. For two people in the control group and who differed by one unit score unit on the DMCAT (one Z score unit on the EF composite), the participant one unit higher on the DMCAT (the EF composite) was expected to have 0.16 (0.55) units more recall of treatment information. Across models there were no significant main effects of any other decision-making capacity measures (i.e., UBACC-T, DC-MED, IGT, DMQ, MCQ), RBANS Z-scores, health literacy measures, or GSE scores (all 95% CIs contained 0 or $p >$ FDR α). Across all model interaction terms, only the group x EF composite interaction was significant ($b = -0.5$ [-1.0, -0.1]). Additionally, examination of 90% CIs revealed that interaction term for group x DMQ ($b = -0.07$ [-0.13, -.01]) and group x RBANS ($b = -0.8$ [-1.5, -0.1]) reached trend-level significance. As shown in Figure 4, computing simple slopes at +/- 1.0 SD revealed that being in the *control* group (compared to SDM group) resulted in disproportionately *higher* recall of treatment information among individuals with *high* EF composite scores (SS at +1.0 SD = -0.20 [-0.45, -0.02]), *high* RBANS scores (SS at +1.0 SD = -0.31 [-0.61, -0.04]), and *high* DMQ scores (SS at +1.0 SD = -0.59 [-1.22, -0.02]). In contrast, there was no difference in recall between SDM and control groups (all 95% CIs contain 0, with effect sizes trending in the direction of better recall for the SDM group compared to the control group), among individuals with low EF composite scores (SS at -1.0

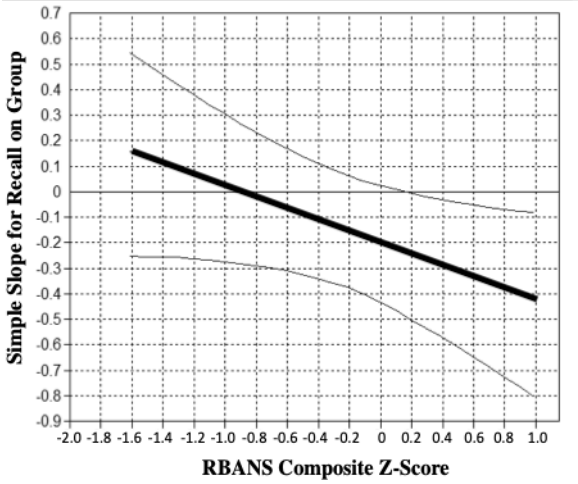
SD = .01 [-.21, .26]), low RBANS scores (SS at -1.0 SD = -.08 [-.32, .14]), and low DMQ scores (SS at -1.0 SD = 0.08 [-0.57, 0.73]).

Figure 4. Johnson-Neyman plots of simple slopes (difference in recall of treatment information scores for SDM group compared to control group) across observed levels of (A) executive function (EF) composite Z-scores, (B) Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) Z-scores, and (C) Decision-making Questionnaire (DMQ) scores.

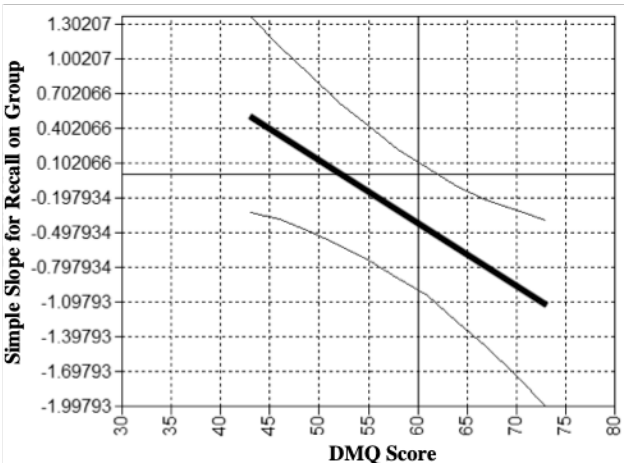
(A)



(B)



(C)



Note. EF = Executive functions; RBANS = Repeatable Battery for the Assessment of Neuropsychological Status; DMQ = Decision-making Questionnaire. Black lines represent simple slope. Gray lines indicate 95% CIs for simple slope with regions of significance indicating CIs at levels of NVS that do not contain 0.

CHAPTER 4

DISCUSSION

The aim of the current study was to examine whether the effectiveness of a shared decision-making (SDM) intervention for improving decisional conflict during a medical decision varies as a function of individual differences in decision-making capacity. Specifically, it was predicted that in a sample of healthy undergraduates participating in simulated SDM, individuals with lower decision-making capacity would benefit from SDM (report lower decisional conflict than an autocratic decision-making group), whereas among individuals with high decision-making there would be no effect of SDM intervention on decisional conflict. Contrary to hypotheses, findings indicated that none of six separate decision-making capacity measures played a statistically significant moderating role on SDM in the context of self-reported decisional conflict. The effect size of SDM improving decisional conflict across the sample was small (Cohen's d = -0.26), and this was generally true across levels of decision-making measure with effect sizes ranging from minimal to medium. Consistent with hypotheses, there were small effect sizes associated with moderators of executive functions, global neurocognitive functioning, health literacy, and general health literacy variables. Taken together, the currently observed lack of moderating variables on the relationship between SDM and decisional conflict may indicate that decision-making capacity does not play a role in altering the perceived decisional conflict associated with SDM interventions. Nevertheless, currently observed trend-level findings associated with small-to-medium effect sizes, in light of study design limitations and restricted statistical power, may serve to inform future studies examining moderators of SDM on decisional conflict.

Current Shared Decision-Making Intervention and Decisional Conflict

The current study utilized a SDM paradigm within a simulated medical decision of choosing among treatments to address cognitive symptoms associated with cancer. This was conducted among an undergraduate sample with the primary aim of the SDM intervention being: (1) to increase patient-provider collaboration and (2) include participant values in the decision. The SDM group had significantly higher scores than the control group on a validated measure of SDM collaboration (SDM-Q-9, $d = 1.54$), indicating that the current manipulation demonstrated sufficient fidelity. However, consistent with previous literature showing varying effectiveness or no effect of SDM interventions for improving health and well-being outcomes (Joosten et al., 2008; Shay & Lafata, 2015), these healthy undergraduate SDM and control groups did not differ in reported levels of decisional conflict (the primary outcome) after making the simulated decision. Specifically, the current study revealed a small effect size ($d = 0.26$) for the SDM group having lower reported decisional conflict, which is commensurate with the mean differences of patient-reported outcomes between SDM and control groups of randomized controlled trials of SDM (median Cohen's d = .21 [range 0.04 – 0.50]; Légaré et al., 2014). The lack of an effect of group status on decisional conflict also held true when including decision-making capacity measures in each model. Thus, while the SDM intervention did increase perceived collaboration between participant and provider, it did not have an effect on perceived decisional conflict associated with the decision.

Decision-Making Capacity Main Effects and Moderators

Adjusting for gender, analyses revealed two significant main effects of decision-making capacity measure performances predicting the outcome of decisional conflict.

Specifically, better performance on a measure comprised of dimension weighting, understanding decision information, and consistency of choices, as well as higher self-reported thoroughness and control in real-world decision-making, both predicted lower decisional conflict (associated with a small-to-medium effect sizes). These findings of better decision-making being associated with lower decisional conflict are consistent with previous literature reporting small-to-medium effects of decisional conflict being predicted by risky decision-making as well as by health knowledge when making medical decisions (Doyle et al., 2016; O'Connor, 1995). Nevertheless, there were no significant interactions between any decision-making capacity measure and group status in the current study. In other words, contrary to the primary hypothesis, the effect of group status (SDM, control) for affecting decisional conflict did not depend on level of decision-making capacity. These findings stand in contrast to previous literature suggesting that a pattern of individual differences across education, literacy, and socioeconomic status alter the effectiveness of SDM on decisional conflict (Durand et al., 2014). In the current study, despite there being significant differences in the proportion of gender between SDM and control groups (higher proportion of men in the control group), and significant main effect of gender on decisional conflict in each model, there were no significant gender by group interactions in any model.

There are several study design limitations that may explain why findings failed to support the original hypotheses. First, the current sample consisted of healthy undergraduate participants who were expected to have a restricted range of decision-making capacity differences. For example, in the current study the UBACC-T (a measure of health-related decision-making currently examined as a moderator with a possible range of 0-19) had a 25th quartile score of 13 and a minimum score of 7, whereas in a sample of HIV+ individuals with

HIV-associated neurocognitive disorders (HAND) reported by Doyle et al. (2016) individuals had a 25th quartile and minimum score of 11 and 4, respectively. Thus, the relatively restricted range in the lower end of the distribution across decision-making measure performances may have limited the inclusion of individuals who have truly "low" levels of decision-making capacity. As such, hypotheses regarding effects of low levels of decision-making may not have been fully addressed as tested in the current sample. Future studies should expand on the current design by utilizing clinical samples with expected difficulties with decision-making (e.g., incipient dementia, serious mental illness), or restrict healthy samples (e.g., undergraduate students) by including only individuals with lower levels of decision-making. Next, the current research design employed a simulated medical decision made in a laboratory. This is problematic given the many contextual factors that exist in real-world medical decisions not present in simulation, such as emotional side effects of decisions and non-provider interpersonal support, which can alter how individuals make decisions in the real-world (Evans et al., 2015; Janis & Mann, 1977). Moreover, the current findings may have been impacted by participant ability to abstract from a hypothetical scenario to real-world costs, side effects, and daily routines of treatments as it relates to decisional conflict. As such, having participants report decisional conflict based on a hypothetical vignette may have dampened any moderating effect of decision-making capacity that exists in the real-world. To this end, the current sample of healthy participants in a simulated medical scenario reported DCS scores (median [interquartile range] = 10.9 [3.9, 21.1]) that appear lower than those observed in studies using clinical samples for both vignette-based decisions (Doyle et al., 2016; median = 17 [8, 25]) and real-world medical decisions (Korteland et al., 2017, median = 24; cf. Taylor et al., 2016, median =10.9 [4.7,

25.0]). Thus, while decisional conflict did not appear to be limited to a ceiling effect, scores do indicate that decisional conflict in the current healthy sample using a simulation approach may have been relatively lower than levels of decisional conflict observed in most clinical studies. Future investigations should address these broad limitations affecting generalizability by testing decision-making capacity and its role on altering SDM effectiveness on decisional conflict within clinical populations. For example, future studies could include participants with greater variability in decision-making capacity (e.g., HAND, individuals with "chemobrain," typically aging older adults) or impaired decision-making capacity (e.g., dementia, serious mental illness).

In parallel with these limitations, there exist statistical limitations in the current design suggesting that the moderation analyses for the primary hypothesis may have been underpowered in this healthy undergraduate sample. While an *a priori* power analysis predicted a medium-to-large effect size at α error probability = .05 determined a sufficient sample size was 80 participants, power analysis using sample means and standard deviations of each interaction term revealed that the average least significant number (LSN) of observations to observe significant interactions between decision-making capacity measures and group status was 1434 (range 118 - 6429) across five of the interaction terms, with the remaining interaction term (DC-MED) requiring over 3 million cases to reach statistical significance. Given that the current analytic plan required responsible data pattern interpretation (e.g., use of α error probability false discovery rate for multiple comparisons), it is apparent that this approach coupled with a relatively small sample size resulted in insufficient power to detect a significant moderation of decision-making capacity on the effect of SDM on decisional conflict. Future studies could embed cognitive and health-

related decision-making measures into existing SDM paradigms in order to maximize sample sizes. In parallel, it would be beneficial to use effect sizes and patterns in the current data to choose decision-making capacity instruments that evidenced relatively larger moderating effect sizes (e.g., DMCAT). Findings also indicate that studies should choose decision-making instruments based on theoretical relevance to medical decisions (e.g., medical decision-making measures such as DMCAT and UBACC-T as opposed to risky decision-making capacity measures). Finally, given previous literature supporting SDM effectiveness differing across levels of literacy and education (Durand et al., 2014), the current hypotheses were focused on differential effectiveness of SDM interventions across levels of decision-making capacity. However, given the possible benefits of SDM at improving not only outcomes such as decisional conflict but also potentially at generalizing to decision-making strategies or self-efficacy, it is possible that decision-making capacity could itself be changed by SDM. Therefore, future studies may wish to use mediation analyses to determine whether SDM itself changes decision-making capacity and subsequently improves decisional conflict through this change.

As detailed above, the planned analyses did not support the primary study hypothesis. Nevertheless, there have been increasingly frequent dialogues in the social sciences concerning interpretation of findings using *p*-value cutoffs (e.g., $p = .05$) and a general trend towards emphasis on effect sizes (Gliner, Leech, & Morgan, 2002; Greenland et al., 2016). For example, a recent *Nature* publication by Amrhein, Greenland, & McShane (2019) *endorsed by over 800 international scientists* highlighted the potential pitfalls of limiting interpretation of results to statistical significance (e.g., they called for "confidence intervals" to be renamed "compatibility intervals" to avoid over-interpretation of the confidence in

significant findings). To be in line with this call in the literature, the results of the current study are considered to be most compatible with no important moderating effect of cognitive and health-related decision-making on SDM for decisional conflict. However, another compatible explanation born out in the data is that performances on certain individual measures of decision-making may have very small moderating influences on the effect of SDM on decisional conflict. As such, current findings also will be discussed using statistical evidence weighed against guidelines set forth by Thompson (2002) and Kazdin (1999), which together highlight the importance of considering practical significance (i.e., effect sizes) and clinical significance (i.e., real, genuine, meaningful changes affecting daily life).

Although effect sizes are interpreted cautiously, examination of compatibility intervals and effect sizes revealed that the DMCAT, a performance-based decision-making task comprised of three subscales (medical decisions using data tables, dimension weighting, consistency of decisions) surrounding medical and nutritional decisions, was a moderator of the association between SDM on decisional conflict at trend-level (i.e., lacks statistical significance). However, as concerns clinical significance, examination of simple slopes revealed that for individuals with a DMCAT score 1.0 SD below the mean, those in the SDM group had decisional conflict scores that were nearly six points lower than the control group, while among individuals with DMCAT scores 1.0 SD above the mean, those in the SDM group had functionally the same scores as those in the control group. These findings suggest that even in the context of the aforementioned limitations of using a healthy sample and a simulation design, participants with low levels of performance-based health decision-making appear to benefit from SDM for decisional conflict depending on their level of DMCAT performance. This effect was associated with a rate of nearly 2 decisional conflict scale

points for every point lower on the DMCAT. This clinical significance of 6 decisional conflict points, on average, between high- and low-performing DMCAT individuals is comparable to raw DCS score differences between clinical groups such as HIV+ individuals with HAND relative to HIV- individuals when making a simulated decision (Doyle et al., 2016; mean DCS difference = +7), and is over 3-times larger than the difference between groups of women who have and have not decided to have breast cancer screening (O'Connor, 1995; mean difference = +1.9). Concerning practical significance, these raw score differences were converted to estimated Cohen's *d* effect sizes using the sample's DCS scores standard deviation. Namely, the effect of SDM on decisional conflict for individuals with low DMCAT performances (i.e., 1.0 below the SD) was estimated to have a medium effect size (estimated Cohen's $d = .48$), while there was minimal effect of SDM on decisional conflict (estimated Cohen's $d = .00$) for individuals with high DMCAT performances (i.e., +1.0 SD). This medium effect size for SDM on decisional conflict among those with low DMCAT scores stands in contrast to effects reported in meta-analyses for SDM interventions across samples (mean Cohen's $d = 0.21$, range 0.04 - 0.50). Put another way, SDM eased decisional conflict in a subgroup of individuals at a magnitude that was over twice that reported *across* SDM studies, and is commensurate with effect sizes found in the strongest evidence for SDM benefits (across studies that don't consider moderators). Taken together, if one were to use only *p* values and confidence intervals for interpretation of this moderator, a practically and clinically significant effect of SDM on decisional conflict would be missed for a subgroup that would otherwise benefit from such interventions. Nevertheless, given recent concerns over replicability across psychological studies (Shrout & Rogers, 2018), it is important to consider not only this individual study result but also patterns of data across

measures and other studies. Indeed, five of the six decision-making capacity measures did not appear to have practical or clinical significance as moderators of the SDM on decisional conflict relationship. Thus it is not possible to rule out Type I error. Nevertheless, the present findings identify important design and theoretical considerations for future studies to include when examining decision-making capacity as a moderator of SDM interventions for improving decisional conflict.

While null hypothesis significant testing revealed no significant moderating effects of decision-making variables, considering the practical and clinical significance of the interaction between DMCAT scores and SDM group could impact future studies of decision-making capacity and its effects on SDM interventions. First, the current findings that individuals with *lower* DMCAT performances had more benefit from SDM compared to individuals with higher DMCAT score are consistent with previous literature showing that low education, literacy, and socioeconomic status are disproportionately aided by SDM for improving decisional conflict (Durand et al., 2014). As such, the reliability of this medium-sized effect is at least in part supported by previous findings and theory. Future studies may wish to enroll individuals with lower levels of education and socioeconomic status as well as individuals with poor decision-making capacity when examining SDM interventions and their effects on decisional conflict. In the current study sample, low DMCAT scores were not related to demographic, health, or psychosocial factors, suggesting that there were not other group-differences explaining this possible moderation of the DMCAT on SDM effectiveness for decisional conflict. One exception revealed by *post hoc* analyses within the SDM group was a trend-level finding that lower DMCAT scores were associated with lower BERMA dealing with doctor scores at a small-to-medium effect size (r_s = .24). This finding suggests

that participant-reported comfort when interacting with real-world providers may be an important consideration in addition to assessing decision-making capacity scores as moderators. Critically, in the current study, no proposed constructs considered to be related to decision-making capacity (i.e., executive functions, global neurocognitive function, general health literacy, self-efficacy, see Figure 1) served as significant moderators of SDM on decisional conflict. Taken together, the consistency in pattern of findings (i.e., SDM benefiting those in the lower range of performance and specificity for decision-making capacity as opposed to related constructs) highlight the need for future studies to use robust assessments of decision-making capacity in SDM.

An example of an ideal future study guided by the current findings would involve administering the DMCAT and a battery of related medical decision-making capacity measures (e.g., UBACC-T; Capacity to Consent to Treatment Instrument; Marson, Ingram, Cody, & Harrell, 1995), to a large sample of older adults with mild cognitive impairment (MCI) and early Alzheimer's disease who are all undergoing an important medical decision of whether or not to take a medication for delaying memory declines. This is particularly relevant given that the DMCAT was developed and validated for use with older adults (Finucane & Guillione, 2010). Patients could be placed in an SDM group or treatment-as-usual group and followed-up long-term to assess both decisional conflict as well as health status (e.g., time to memory decline) and health-related quality of life. Similar to current findings, it would be predicted that individuals low in health-related decision-making measures would benefit from SDM more than those with high decisional conflict, and it would be predicted that SDM also would have heightened long-term quality of life (and possibly long-term health status) outcomes over time. As such, notwithstanding limitations,

the current study may provide important evidence for a global construct of health-related decision-making capacity, or at least measures that assess this construct, that could be particularly important for future clinical studies examining moderators of SDM interventions.

In addition to informing future studies of SDM, the current practical and clinical significance of the DMCAT may also serve to inform construction of SDM interventions. For example, the DMCAT is comprised of components assessing: (1) enacting decisions using data tables, (2) identification of information to support a particular a decision, and (3) consistency of medical decisions. Given the possible moderating role of performance on this measure for SDM affecting decisional conflict, it may be important to consider patient capacities to perform these sub-functions when designing SDM interventions. For example, previous studies have highlighted the importance of using decision aids and interventions that meet the needs of individuals with low literacy or educational backgrounds (Smith, Nutbeam, & McCaffery, 2013). Thus, SDM paradigms may wish to pay particular attention at limiting data tables (as tested by the DMCAT) in decisional aids, which also has been supported in previous studies citing basic numeracy as an important limitation for participating in SDM (Smith, Nutbeam, & McCaffery, 2013).

In addition to future directions guided by the possible interaction observed between the DMCAT and SDM group, future studies will need to consider mechanisms of action for SDM interventions on improving decisional conflict directly. For example, the current study showed significant *main effects* of two decision-making capacity measures, as well as a practically significant *main effect* (in the unexpected direction) of global neurocognitive function, predicting decisional conflict. Specifically, decision-making measures that showed significant *main effects* on predicting lower decisional conflict were the DMCAT

(performance-based understanding, dimension weighting, and consistency in choices) as well as self-reported thoroughness and control when making real-world decisions. In fact, *post hoc* analyses examining subscales of these measures and their association with decisional conflict across the entire sample revealed that better dimension weighting (i.e., correctly identifying *why* a decision was made) and self-reported *control* when making real-life medical decisions were the strongest predictors of lower decisional conflict. With these findings in mind, future studies and trials of SDM interventions may benefit from adding components aimed at improving these specific aspects of decision-making. For example, interventions could supplement SDM asking patients to "teach-back" to providers their rationale for choosing a decision (i.e., perform dimension weighting). In fact, similar interventions are commonly practiced in medicine by having patients teach back treatment regimen schedules and details (e.g., amount of a prescription taken at what time) to improve treatment adherence (Kornburger et al., 2013). Similarly, "teach-back" may expand upon currently observed associations between dimension weighting and decisional conflict by artificially strengthening for patients the connection between treatment choice and reasons for choosing that treatment. SDM interventions may also include components focused on improving organization and categorizing decisions as a way to improve patient control, since self-reported control was a significant predictor of decisional conflict. Although perceived control in decisions may be considered a relatively robust trait (Flynn & Smith, 2007), consistent with cognitive rehabilitation literature it is possible that improving perceived control through behavioral strategies (e.g., making lists, organizing treatment options) in SDM interventions may further benefit decisional conflict. Finally, the surprising trend-level finding indicating that higher global neurocognitive functioning was associated with higher

decisional conflict may indicate that individuals with high global neurocognitive function are at risk for having more conflict after decisions. While this finding could be spurious (NB. *post hoc* analysis revealed that no RBANS domain or individual raw score was a significant predictor of DCS [r_s range .01 to .12]), nor were any Table 1 variables related to both decisional conflict and global neurocognitive functioning), future studies should determine whether cognitive strategies embedded in SDM interventions might generally help improve decisional conflict across levels of neurocognitive functioning. For example, providers may discuss strategies with patients *during* SDM to address possible effects of global neurocognitive functioning on decisional conflict, such as providing not only information about treatment options but also methods for successfully enacting these treatments (e.g., using an alarm to take the medication, implementation intention or visualizing for attending required medical appointments).

Alternative Outcome Variables

While the primary outcome of the current study was decisional conflict, there are numerous other measures of SDM effectiveness that have been considered previously in studies of SDM, including patient satisfaction, knowledge, adherence, quality of life, and overall health (Shay & Lafata, 2015). Therefore, in addition to decisional conflict, the current study also considered recall of treatment information as well as perceived collaboration during SDM as exploratory outcomes.

In the current study, only a single measure of decision-making capacity (self-reported control and thoroughness) served as a trend-level moderator of the relationship between SDM and recall of treatment information. Specifically, there was *higher* recall of treatment information for the *control* group (versus the SDM group) only among individuals with high

reported levels of decision-making thoroughness, which was associated with a large effect size (estimated Cohen's *d* = -.71, versus *d* = .07 in the low reported decision-making thoroughness group). Moreover, this pattern of trend-level findings also was replicated for moderators of composite executive functions and global neurocognitive functions. Specifically, using effect sizes, individuals with *higher* neurocognitive functioning benefited from being in the *control* group by recalling more treatment information at a magnitude of a medium effect size (estimated *d* range -.28 to -.39), while those lower in neurocognitive function did not differ in recall across SDM and control groups, associated with minimal effect sizes (estimated *d* range .01 to .07). In other words, being in the control group appeared to boost recall for treatment information in individuals with already higher cognitive functioning and self-reported decision-making thoroughness. This finding was surprising and stood contrary to the proposed hypothesis that the *SDM* group would benefit individuals *low* in decision-making capacity (relative to individuals with high decision-making capacity) for recalling more treatment information. Critically, the control group and SDM groups interacted with treatment information and study aids differently during the decision-making task, and as such it is possible that the way these groups were manipulated afforded benefit for treatment information recall to individuals in the control group with higher cognitive functioning. Specifically, the control group was given time to "look over" (e.g., study) the decision aids while their provider stepped out of the room to prepare their medication prescription. During this time, it is possible that individuals with high cognitive functioning benefitted from having time to encode treatment information. In contrast, individuals with high cognitive functioning the SDM group may have been instead distracted by discussion of values and collaboration during SDM, and as such individuals high in

cognitive functioning would not have been able to allocate their relatively high cognitive resources towards encoding treatment information. Interestingly, a *post hoc* analysis examining possible demographic variables (i.e., Table 1) revealed that among individuals in the control group, select moderator variables of interest (i.e., executive functions, global neurocognitive functioning, self-reported decision-making control) were related to younger age, better perceived real-world interactions with medical providers, or having a family history of cancer. Therefore, it also is possible that the subgroup of individuals in the control group with higher cognitive functioning and self-reported decision-making control group also had generally higher functioning in other areas, including comfort in dealing with doctors and more experience with cancer and its effects on a family member. Thus, these individuals may have been able to draw from these experiences and use more elaborative encoding or retrieval strategies due to level of processing (e.g., Bradshaw & Anderson, 1982) based on their familiarity of working with doctors or in situations involving a cancer diagnosis. Taken together, these surprising findings indicating a *benefit* to being in the control group across levels of cognitive functioning and self-reported decision-making for recalling treatment information highlight the importance of collecting multiple outcomes when studying moderating patient variables on SDM interventions.

Regarding the outcome variable of perceived shared decision-making collaboration, data were most consistent with the hypothesis that there would be no interactions between SDM group and decision-making capacity measures. However, trend-level interactions were found between SDM group and two different health literacy measures—a performance-based test of identifying and using nutrition information and self-reported health literacy. Specifically, data indicated that the SDM group had higher perceived collaboration among

individuals with higher health literacy across both measures, with effect sizes in the extremely large range (estimated *d* range 1.21 – 1.46). In contrast, among individuals with low health literacy SDM and control groups showed a large (but a smaller relative to individuals with high health literacy) effect of SDM on perceived collaboration (*d* range .77 - .92). One potential reason for this specificity of health literacy is that individuals with more health literacy resources from which they could draw when participating in SDM, and therefore could allocate these resources towards being a more active participant with higher perceived collaboration. Moreover, given strong associations between health literacy measures and neurocognitive variables (see Table 3), it is possible that similar to the patterns of findings for treatment information recall as an outcome, individuals high in health literacy (but this time within the SDM group) may have been able to draw on more cognitive resources while participating in SDM and thus perceive more collaboration. In contrast, it is possible that individuals low in health literacy were relatively more focused on understanding treatment details and symptom information as opposed to full participation in their interaction with the provider. Thus, these individuals could have had diminished benefit from being in the SDM group when reporting perceived collaboration.

Taken together, these preliminary exploratory findings indicate that there are no statistically significant moderators explaining SDM effects on recall of treatment information or perceived collaboration during SDM. However, careful consideration of practical significance indicated that other related cofactors, namely neurocognitive function and health literacy, will need to be considered as moderators in future studies of SDM. Moreover, future studies will benefit from including multiple study outcomes (e.g., recall of treatment information, perceived collaboration with providers) given preliminary findings indicating

that self-reported decision-making control, neurocognitive functions, and health literacy may moderate the effect of SDM on these outcomes. Critically, including multiple study outcomes is particularly important in light of observed moderators that confer benefit (e.g., more treatment information recall, more perceived collaboration) for being in either the SDM group *or* the control group depending on the outcome being considered.

Conclusions

The current study does not provide standalone evidence to support the hypothesis that SDM effectiveness for easing decisional conflict (or any currently measured outcome variable) depends on individual differences decision-making capacity. However, this study was limited by having a healthy sample of undergraduates instead of a clinical population higher variability in decision-making capacity, using a hypothetical simulated medical decision scenario, and utilizing a relatively small sample size. Together, these limitations likely reduced power for finding the proposed moderating effect of individual difference in decision-making capacity on SDM and decisional conflict. Interpreting these data through an attempt to balance Type I and Type II error, in addition to the consideration of practical and clinical significance of findings, highlights a possible preliminary finding on a single measure of decision-making capacity that needs to be further investigated in future studies using robust study designs, ideally in clinical populations with real-world medical decisions.

Given that decision-making capacity and neurocognitive functioning represent understudied patient factors in the SDM literature, the current study is an important initial step towards determining whether SDM effectiveness for health and well-being outcomes can change as a function of individual neurocognitive and decision-making capacities. While future studies will need to clarify whether decision-making capacity influences the

effectiveness on SDM interventions, at the very least future SDM studies should be sure to include sufficient variability for neurocognitive functioning and decision-making capacity within their samples. This endeavor is particularly important for clinical populations that are at-risk for specific decision-making or neurocognitive dysfunction, such as those that evidence executive dysfunction associated with fronto-striatal pathway or ventromedial prefrontal cortex involvement. Should future studies indeed determine that decision-making capacity is an important and reliable moderator of SDM effectiveness, it will be important for more studies to determine whether decision-making capacity also predicts downstream health and well-being outcomes among groups being assisted by SDM. In parallel, the present study provides preliminary evidence of important considerations for providers who work with patients experiencing neurocognitive dysfunction. For example, in line with calls for evidence-based clinical neuropsychological practice (Chelune, 2010), neuropsychologists may wish to consider patient values (e.g., addressing memory problems versus depression) when providing recommendations to patients, particularly to individuals for whom testing shows neurocognitive impairment. In turn, research using neuropsychological measures of both global functioning and decision-making capacity may yet play an important role of identifying groups that will benefit from SDM. Finally, SDM interventions themselves also will require continued consideration and assessment to ensure individuals low in decision-making capacity or neurocognitive function can meaningfully and effectively participate in these interventions, thus having SDM serve the role of maximizing autonomy for making medical decisions in these individuals.

REFERENCES

Aiken, L. S., & West, S. G. (1991). Multiple Regression: Testing and interpreting interactions. Thousand Oaks: Sage.

Amrhein, V., Greenland, S., & McShane, B. (2019). Scientists rise up against statistical significance. *Nature*, *567*(7748), 305. https://doi.org/10.1038/d41586-019-00857-9

Anderson, N. H. A Simple Model for Information Integration. (1968). In R.P. Abelson, E. Aronson, W.J. McGuire, T.M. Newcomb, M.J. Rosenberg, & P.H. Tannenbaum (Eds.), Theories of Cognitive Consistency: A Sourcebook. Chicago: Rand McNally.

APA Presidential Task Force on Evidence-Based Practice. (2006). Evidence-based practice in psychology. *The American Psychologist*, *61*(4), 271–285. doi:10.1037/0003-066X.61.4.271

Beauchamp, T. L. (1994). Principles and other emerging paradigms in bioethics. *Indiana Law Journal (Indianapolis, Ind.: 1926)*, *69*(4), 955–971.

Bechara, A., Damasio, A. R., Damasio, H., & Anderson, S. W. (1994). Insensitivity to future consequences following damage to human prefrontal cortex. *Cognition*, *50*(1-3), 7–15.

Benjamini, Y., & Hochberg, Y. (1995). Controlling the False Discovery Rate: A Practical and Powerful Approach to Multiple Testing. *Journal of the Royal Statistical Society. Series B (Methodological)*, *57*(1), 289–300.

Boyle, P. A., Wilson, R. S., Yu, L., Buchman, A. S., & Bennett, D. A. (2013). Poor decision making is associated with an increased risk of mortality among community-dwelling older persons without dementia. *Neuroepidemiology*, *40*(4), 247–252. doi:10.1159/000342781

Bradshaw, G.L., & Anderson, J.R. (1982). Elaborative encoding as an explanation of levels of processing. *Journal of Verbal Learning and Verbal Behavior, 21*(2), 165-174.

Brand, M., Fujiwara, E., Borsutzky, S., Kalbe, E., Kessler, J., & Markowitsch, H. J. (2005). Decision-making deficits of korsakoff patients in a new gambling task with explicit rules: associations with executive functions. *Neuropsychology*, *19*(3), 267–277. doi:10.1037/0894-4105.19.3.267

Brand, M., Labudda, K., & Markowitsch, H. J. (2006). Neuropsychological correlates of decision-making in ambiguous and risky situations. *Neural Networks: The Official Journal of the International Neural Network Society*, *19*(8), 1266–1276. doi:10.1016/j.neunet.2006.03.001

Burton, C. Z., Twamley, E. W., Lee, L. C., Palmer, B. W., Jeste, D. V., Dunn, L. B., & Irwin, S. A. (2012). Undetected cognitive impairment and decision-making capacity in patients receiving hospice care. *The American Journal of Geriatric Psychiatry: Official Journal of the American Association for Geriatric Psychiatry*, *20*(4), 306–316. doi:10.1097/JGP.0b013e3182436987

Cantor, N. L. (2005). The bane of surrogate decision-making: defining the best interests of never-competent persons. *The Journal of Legal Medicine*, *26*(2), 155–205. doi:10.1080/01947640590949922

Charles, C., Gafni, A., and Whelan, T. (1999). Decision-making in the physician-patient encounter: Revisiting the shared treatment decision-making model. *Social Science and Medicine*, 49, 651–661.

Charles, C., Gafni, A. and Whelan, T. (1997). Shared decision-making in the medical encounter: What does it mean? (or it takes at least two to tango). *Social Science and Medicine*, 44, 681–692.

Chelune, G. J. (2010). Evidence-based research and practice in clinical neuropsychology. *The Clinical Neuropsychologist*, *24*(3), 454–467. doi:10.1080/13854040802360574

Chen, X., Zhu, C., Li, J., Qiu, L., Zhang, L., Yu, F., … Wang, K. (2013). Dissociation of decision making under ambiguity and decision making under risk in breast cancer patients receiving adjuvant chemotherapy: a neuropsychological study. *Brain Research*, *1533*, 63–72. doi:10.1016/j.brainres.2013.08.015

Chew, L. D., Bradley, K. A., & Boyko, E. J. (2004). Brief questions to identify patients with inadequate health literacy. *Family Medicine*, *36*(8), 588–594.

Davis, T. C., Long, S. W., Jackson, R. H., Mayeaux, E. J., George, R. B., Murphy, P. W., & Crouch, M. A. (1993). Rapid estimate of adult literacy in medicine: a shortened screening instrument. *Family Medicine*, *25*(6), 391–395.

Degner, L. F., Sloan, J. A., & Venkatesh, P. (1997). The Control Preferences Scale. *The Canadian Journal of Nursing Research = Revue Canadienne De Recherche En Sciences Infirmieres*, *29*(3), 21–43.

Delis, D. C., Kaplan, E., & Kramer, J. H. (2001). Delis-Kaplan executive function system. San Antonio, TX: The Psychological Corporation.

Denburg, N. L., Cole, C. A., Hernandez, M., Yamada, T. H., Tranel, D., Bechara, A., & Wallace, R. B. (2007). The orbitofrontal cortex, real-world decision making, and normal aging. *Annals of the New York Academy of Sciences*, *1121*, 480–498. doi:10.1196/annals.1401.031

DiMatteo, M. R. (2004). Variations in patients' adherence to medical recommendations: a quantitative review of 50 years of research. *Medical Care*, *42*(3), 200–209.

Doyle, K. L., Woods, S. P., Morgan, E. E., Iudicello, J. E., Cameron, M. V., Gilbert, P. E., … HIV Neurobehavioral Research Program (HNRP) Group. (2016). Health-Related Decision-Making in HIV Disease. *Journal of Clinical Psychology in Medical Settings*, *23*(2), 135–146. doi:10.1007/s10880-016-9455-x

Dunn, B. D., Dalgleish, T., & Lawrence, A. D. (2006). The somatic marker hypothesis: a critical evaluation. *Neuroscience and Biobehavioral Reviews*, *30*(2), 239–271. doi:10.1016/j.neubiorev.2005.07.001

Dunn, L. B., Nowrangi, M. A., Palmer, B. W., Jeste, D. V., & Saks, E. R. (2006). Assessing decisional capacity for clinical research or treatment: a review of instruments. *The American Journal of Psychiatry*, *163*(8), 1323–1334. doi:10.1176/ajp.2006.163.8.1323

Durand, M.-A., Carpenter, L., Dolan, H., Bravo, P., Mann, M., Bunn, F., & Elwyn, G. (2014). Do interventions designed to support shared decision-making reduce health inequalities? A systematic review and meta-analysis. *PloS One*, *9*(4), e94670. doi:10.1371/journal.pone.0094670

Dwamena, F., Holmes-Rovner, M., Gaulden, C. M., Jorgenson, S., Sadigh, G., Sikorskii, A., … Olomu, A. (2012). Interventions for providers to promote a patient-centred approach in clinical consultations. *The Cochrane Database of Systematic Reviews*, *12*, CD003267. doi:10.1002/14651858.CD003267.pub2

Ellis, R. J., Badiee, J., Vaida, F., Letendre, S., Heaton, R. K., Clifford, D., … CHARTER Group. (2011). CD4 nadir is a predictor of HIV neurocognitive impairment in the era of combination antiretroviral therapy. *AIDS (London, England)*, *25*(14), 1747–1751. doi:10.1097/QAD.0b013e32834a40cd

Evans, S. C., Roberts, M. C., Keeley, J. W., Blossom, J. B., Amaro, C. M., Garcia, A. M., … Reed, G. M. (2015). Vignette methodologies for studying clinicians' decision-making: Validity, utility, and application in ICD-11 field studies. *International Journal of Clinical and Health Psychology: IJCHP*, *15*(2), 160–170. https://doi.org/10.1016/j.ijchp.2014.12.001

Evens, R., Hoefler, M., Biber, K., & Lueken, U. (2016). The Iowa Gambling Task in Parkinson's disease: A meta-analysis on effects of disease and medication. *Neuropsychologia*, *91*, 163–172. doi:10.1016/j.neuropsychologia.2016.07.032

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods*, 41, 1149-1160.

Finucane, M. L., & Gullion, C. M. (2010). Developing a tool for measuring the decision-making competence of older adults. *Psychology and Aging*, *25*(2), 271–288. doi:10.1037/a0019106

Flynn, K. E., & Smith, M. A. (2007). Personality and health care decision-making style. *The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences*, *62*(5), P261-267.

French, D. J., West, R. J., Elander, J., & Wilding, J. M. (1993). Decision-making style, driving style, and self-reported involvement in road traffic accidents. *Ergonomics*, *36*(6), 627–644. doi:10.1080/00140139308967925

Galesic, M., & Garcia-Retamero, R. (2011). Do low-numeracy people avoid shared decision making? *Health Psychology: Official Journal of the Division of Health Psychology, American Psychological Association*, *30*(3), 336–341. doi:10.1037/a0022723

Ganzini, L., Lee, M. A., Heintz, R. T., Bloom, J. D., & Fenn, D. S. (1994). The effect of depression treatment on elderly patients' preferences for life-sustaining medical therapy. *The American Journal of Psychiatry*, *151*(11), 1631–1636. doi:10.1176/ajp.151.11.1631

Gardner, E. M., McLees, M. P., Steiner, J. F., Del Rio, C., & Burman, W. J. (2011). The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, *52*(6), 793–800. doi:10.1093/cid/ciq243

Gliner, J. A., Leech, N. L., & Morgan, G. A. (2002). Problems with null hypothesis significance testing (NHST): What do the textbooks say? *Journal of Experimental Education*, *71*(1), 83–92. https://doi.org/10.1080/00220970209602058

Goggins, K. M., Wallston, K. A., Nwosu, S., Schildcrout, J. S., Castel, L., Kripalani, S., & Vanderbilt Inpatient Cohort Study (VICS). (2014). Health literacy, numeracy, and other characteristics associated with hospitalized patients' preferences for involvement in decision making. *Journal of Health Communication*, *19 Suppl 2*, 29–43. doi:10.1080/10810730.2014.938841

Gondi, V., Pugh, S. L., Tome, W. A., Caine, C., Corn, B., Kanner, A., … Mehta, M. P. (2014). Preservation of memory with conformal avoidance of the hippocampal neural stem-cell compartment during whole-brain radiotherapy for brain metastases (RTOG 0933): a phase II multi-institutional trial. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*, *32*(34), 3810–3816. doi:10.1200/JCO.2014.57.2909

Gronwall, D. (1977). Paced Auditory Serial-Addition Task: A measure of recovery from concussion. *Perceptual and Motor Skills, 44*, 367–373.

Greenland, S., Senn, S. J., Rothman, K. J., Carlin, J. B., Poole, C., Goodman, S. N., & Altman, D. G. (2016). Statistical tests, P values, confidence intervals, and power: a guide to misinterpretations. *European Journal of Epidemiology*, *31*, 337–350. https://doi.org/10.1007/s10654-016-0149-3

Halverson, J. L., Martinez-Donate, A. P., Palta, M., Leal, T., Lubner, S., Walsh, M. C., … Trentham-Dietz, A. (2015). Health Literacy and Health-Related Quality of Life Among a Population-Based Sample of Cancer Patients. *Journal of Health Communication*, *20*(11), 1320–1329. doi:10.1080/10810730.2015.1018638

Hanoch, Y., Miron-Shatz, T., Rolison, J. J., Omer, Z., & Ozanne, E. (2015). Shared decision making in patients at risk of cancer: the role of domain and numeracy. *Health Expectations: An International Journal of Public Participation in Health Care and Health Policy*, *18*(6), 2799–2810. doi:10.1111/hex.12257

Hardy, D. J., Hinkin, C. H., Levine, A. J., Castellon, S. A., & Lam, M. N. (2006). Risky decision making assessed with the gambling task in adults with HIV. *Neuropsychology*, *20*(3), 355–360. doi:10.1037/0894-4105.20.3.355

Heckman, B. D., Catz, S. L., Heckman, T. G., Miller, J. G., & Kalichman, S. C. (2004). Adherence to antiretroviral therapy in rural persons living with HIV disease in the United States. *AIDS care*, *16*(2), 219–230. doi:10.1080/09540120410001641066

Huckans, M., Seelye, A., Woodhouse, J., Parcel, T., Mull, L., Schwartz, D., … Hoffman, W. (2011). Discounting of delayed rewards and executive dysfunction in individuals infected with hepatitis C. *Journal of Clinical and Experimental Neuropsychology*, *33*(2), 176–186. doi:10.1080/13803395.2010.499355

Hunink, M., Weinstein, M., Wittenberg, E., Drummond, M., Pliskin, J., Wong, J., & Glasziou, P. (2014). Decision Making in Health and Medicine: Integrating Evidence and Values. Cambridge: Cambridge University Press. doi:10.1017/CBO9781139506779

Institute of Medicine (US) Committee on Quality of Health Care in America. (2001). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington (DC): National Academies Press (US). Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK222274/

Ironson, G., Lucette, A., & McIntosh, R. (2015). Doctor-patient relationship: active patient involvement (DPR: API) is related to long survival status and predicts adherence change in HIV. Journal of AIDS Clinical Research, 6(2): 1–5.

Iudicello, J. E., Woods, S. P., Cattie, J. E., Doyle, K., Grant, I., & HIV Neurobehavioral Research Program Group. (2013). Risky decision-making in HIV-associated

neurocognitive disorders (HAND). *The Clinical Neuropsychologist*, *27*(2), 256–275. doi:10.1080/13854046.2012.740077

Jacks, A., Wainwright, D. A., Salazar, L., Grimes, R., York, M., Strutt, A. M., … Hasbun, R. (2015). Neurocognitive deficits increase risk of poor retention in care among older adults with newly diagnosed HIV infection. *AIDS (London, England)*, *29*(13), 1711–1714. doi:10.1097/QAD.0000000000000700

Janis, I. L., & Mann, L. (1977). Emergency decision making: a theoretical analysis of responses to disaster warnings. *Journal of Human Stress*, *3*(2), 35–45. https://doi.org/10.1080/0097840X.1977.9936085

Jeste, D. V., Palmer, B. W., Appelbaum, P. S., Golshan, S., Glorioso, D., Dunn, L. B., … Kraemer, H. C. (2007). A new brief instrument for assessing decisional capacity for clinical research. *Archives of General Psychiatry*, *64*(8), 966–974. doi:10.1001/archpsyc.64.8.966

Joosten, E. a. G., DeFuentes-Merillas, L., De Weert, G. H., Sensky, T., Van der Staak, C. P. F., & De Jong, C. a. J. (2008). Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. *Psychotherapy and Psychosomatics*, *77*(4), 219–226. doi:10.1159/000126073

Kaplan, R. M. (1991). Health-related quality of life in patient decision making. *The Journal of Social Issues*, *47*(4), 69–90.

Kaplan, B.A., Lemley, S.M., Reed, D.D., & Jarmolowicz, D.P. (2014). "21- and 27-Item Monetary Choice Questionnaire Automated Scorers" [software]. Center for Applied Neuroeconomics, University of Kansas.

Karlawish, J. (2008). Measuring decision-making capacity in cognitively impaired individuals. *Neuro-Signals*, *16*(1), 91–98. doi:10.1159/000109763

Kazdin, A. E. (1999). The meanings and measurement of clinical significance. *Journal of Consulting and Clinical Psychology*, *67*(3), 332–339. https://doi.org/10.1037/0022-006X.67.3.332

Kirby, K. N., Petry, N. M., & Bickel, W. K. (1999). Heroin addicts have higher discount rates for delayed rewards than non-drug-using controls. *Journal of Experimental Psychology. General*, *128*(1), 78–87.

Kornburger, C., Gibson, C., Sadowski, S., Maletta, K., & Klingbeil, C. (2013). Using “teach-back” to promote a safe transition from hospital to home: an evidence-based approach to improving the discharge process. *Journal of Pediatric Nursing*, *28*(3), 282–291. https://doi.org/10.1016/j.pedn.2012.10.007

Korteland, N. M., Ahmed, Y., Koolbergen, D. R., Brouwer, M., de Heer, F., Kluin, J., … Takkenberg, J. J. M. (2017). Does the Use of a Decision Aid Improve Decision Making in Prosthetic Heart Valve Selection? A Multicenter Randomized Trial. *Circulation. Cardiovascular Quality and Outcomes*, *10*(2). https://doi.org/10.1161/CIRCOUTCOMES.116.003178

Kriston, L., Scholl, I., Hölzel, L., Simon, D., Loh, A., & Härter, M. (2010). The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Education and Counseling*, *80*(1), 94–99. https://doi.org/10.1016/j.pec.2009.09.034

Krull, K. R., Annett, R. D., Pan, Z., Ness, K. K., Nathan, P. C., Srivastava, D. K., … Hudson, M. M. (2011). Neurocognitive functioning and health-related behaviours in adult survivors of childhood cancer: a report from the Childhood Cancer Survivor Study. *European Journal of Cancer (Oxford, England: 1990)*, *47*(9), 1380–1388. doi:10.1016/j.ejca.2011.03.001

Lee, E., & Emanuel, E. J. (2013). Shared decision making to improve care and reduce costs. *The New England Journal of Medicine*, *368*(1), 6–8. doi:10.1056/NEJMp1209500

Légaré, F., Stacey, D., Turcotte, S., Cossi, M.-J., Kryworuchko, J., Graham, I. D., … Donner-Banzhoff, N. (2014). Interventions for improving the adoption of shared decision making by healthcare professionals. *The Cochrane Database of Systematic Reviews*, (9), CD006732. doi:10.1002/14651858.CD006732.pub3

Lescure, F.-X., Omland, L. H., Engsig, F. N., Roed, C., Gerstoft, J., Pialoux, G., … Obel, N. (2011). Incidence and impact on mortality of severe neurocognitive disorders in persons with and without HIV infection: a Danish nationwide cohort study. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, *52*(2), 235–243. doi:10.1093/cid/ciq041

Levine, B., Robertson, I. H., Clare, L., Carter, G., Hong, J., Wilson, B. A., … Stuss, D. T. (2000). Rehabilitation of executive functioning: an experimental-clinical validation of goal management training. *Journal of the International Neuropsychological Society: JINS*, *6*(3), 299–312.

Lipkus, I. M., Samsa, G., & Rimer, B. K. (2001). General performance on a numeracy scale among highly educated samples. *Medical Decision Making: An International Journal of the Society for Medical Decision Making*, *21*(1), 37–44. doi:10.1177/0272989X0102100105

Ma, H., Lv, X., Han, Y., Zhang, F., Ye, R., Yu, F., … Wang, K. (2013). Decision-making impairments in patients with Wilson's disease. *Journal of Clinical and Experimental Neuropsychology*, *35*(5), 472–479. doi:10.1080/13803395.2013.789486

Makoul, G., & Clayman, M. L. (2006). An integrative model of shared decision making in medical encounters. *Patient Education and Counseling*, *60*(3), 301–312. doi:10.1016/j.pec.2005.06.010

Marson, D. C., Earnst, K. S., Jamil, F., Bartolucci, A., & Harrell, L. E. (2000). Consistency of physicians' legal standard and personal judgments of competency in patients with Alzheimer's disease. *Journal of the American Geriatrics Society*, *48*(8), 911–918.

Marson, D. C., Ingram, K. K., Cody, H. A., & Harrell, L. E. (1995). Assessing the competency of patients with Alzheimer's disease under different legal standards. A prototype instrument. *Archives of Neurology*, *52*(10), 949–954.

Mattavelli, G., Casarotti, A., Forgiarini, M., Riva, M., Bello, L., & Papagno, C. (2012). Decision-making abilities in patients with frontal low-grade glioma. *Journal of Neuro-Oncology*, *110*(1), 59–67. doi:10.1007/s11060-012-0934-0

McDonald-Miszczak, L., Maris, P., Fitzgibbon, T., Ritchie, G. (2004). A pilot study examining older adults' beliefs related to medication adherence: The BERMA Survey. *Journal of Aging and Health,* 16: 591– 614.

McGrady, M. E., Brown, G. A., & Pai, A. L. H. (2016). Medication adherence decision-making among adolescents and young adults with cancer. *European Journal of Oncology Nursing: The Official Journal of European Oncology Nursing Society*, *20*, 207–214. doi:10.1016/j.ejon.2015.08.007

McNair, D.M., Lorr, M., & Droppleman, L.F. (1981). *Manual for the Profile of Mood States*. San Diego, CA: Educational and Industrial Testing Service.

Medicine, I. of. (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Retrieved from https://www.nap.edu/catalog/10027/crossing-the-quality-chasm-a-new-health-system-for-the

Muhlert, N., Sethi, V., Cipolotti, L., Haroon, H., Parker, G. J. M., Yousry, T., … Chard, D. (2015). The grey matter correlates of impaired decision-making in multiple sclerosis. *Journal of Neurology, Neurosurgery, and Psychiatry*, *86*(5), 530–536. doi:10.1136/jnnp-2014-308169

National Cancer Institute. (2017). Types of Cancer Treatment. cgvTopicPage. Retrieved January 4, 2018, from https://www.cancer.gov/about-cancer/treatment/types

National Center for Health Statistics. Health, United States, 2016: With Chartbook on Long-term Trends in Health. Hyattsville, MD.

O'Connor, A. M. (1995). Validation of a decisional conflict scale. *Medical Decision Making: An International Journal of the Society for Medical Decision Making*, *15*(1), 25–30. doi:10.1177/0272989X9501500105

Odum, A. L. (2011). Delay discounting: I'm a k, you're a k. *Journal of the Experimental Analysis of Behavior*, *96*(3), 427–439. https://doi.org/10.1901/jeab.2011.96-423

Okonkwo, O. C., Griffith, H. R., Copeland, J. N., Belue, K., Lanza, S., Zamrini, E. Y., … Marson, D. C. (2008). Medical decision-making capacity in mild cognitive impairment: a 3-year longitudinal study. *Neurology*, *71*(19), 1474–1480. doi:10.1212/01.wnl.0000334301.32358.48

Pachet A, Newberry A, Erskine L. (2007). Assessing capacity in the complex patient: RCAT's Unique Evaluation and Consultation Model. *Canadian Psychology*. 48(3): 174-186.

Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010).

Randolph, C., Tierney, M.C., Mohr, E., Chase, T.N. The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS): preliminary clinical validity. Journal of Clinical Experimental Neuropsychology. 1998; 20(3):310–319.

Reger, M., Welsh, R., Razani, J., Martin, D. J., & Boone, K. B. (2002). A meta-analysis of the neuropsychological sequelae of HIV infection. *Journal of the International Neuropsychological Society: JINS*, *8*(3), 410–424.

Reyna, V. F., Nelson, W. L., Han, P. K., & Pignone, M. P. (2015a). Decision making and cancer. *The American Psychologist*, *70*(2), 105–118. doi:10.1037/a0036834

Reyna, V. F., Nelson, W. L., Han, P. K., & Pignone, M. P. (2015b). Decision making and cancer. *The American Psychologist*, *70*(2), 105–118. doi:10.1037/a0036834

Riddick, F. A. (2003). The Code of Medical Ethics of the American Medical Association. *The Ochsner Journal*, *5*(2), 6–10.

Schneider, J., Kaplan, S. H., Greenfield, S., Li, W., & Wilson, I. B. (2004). Better physician-patient relationships are associated with higher reported adherence to antiretroviral therapy in patients with HIV infection. *Journal of General Internal Medicine*, *19*(11), 1096–1103. doi:10.1111/j.1525-1497.2004.30418.x

Schoenthaler, A. M., Schwartz, B. S., Wood, C., & Stewart, W. F. (2012). Patient and physician factors associated with adherence to diabetes medications. *The Diabetes Educator*, *38*(3), 397–408. https://doi.org/10.1177/0145721712440333

Schwarzer, R., & Jerusalem, M. (1995). Generalized Self-Efficacy scale. In J. Weinman, S. Wright, & M. Johnston, Measures in health psychology: A user's portfolio. Causal and control beliefs (pp. 35-37). Windsor, UK: NFER-NELSON.

Shaffer, J.P. (1995). Multiple Hypothesis Testing. *Annual Review of Psychology, 46,* 561-584.

Shay, L.A., & Lafata, J. E. (2015). Where is the evidence? A systematic review of shared decision making and patient outcomes. *Medical Decision Making: An International Journal of the Society for Medical Decision Making*, *35*(1), 114–131. doi:10.1177/0272989X14551638

Shin, D.-Y., Choi, Y. H., Lee, H.-R., Na, I. I., Yuh, Y. J., Kim, B.-S., … Kang, H. J. (2016). A phase II trial of modified FOLFOX6 as first-line therapy for adenocarcinoma of an unknown primary site. *Cancer Chemotherapy and Pharmacology*, *77*(1), 163–168. doi:10.1007/s00280-015-2904-7

Shrout, P. E., & Rodgers, J. L. (2018). Psychology, Science, and Knowledge Construction: Broadening Perspectives from the Replication Crisis. *Annual Review of Psychology*, *69*, 487–510. https://doi.org/10.1146/annurev-psych-122216-011845

Sigurdardottir, S., Jerstad, T., Andelic, N., Roe, C., & Schanke, A.-K. (2010). Olfactory dysfunction, gambling task performance and intracranial lesions after traumatic brain injury. *Neuropsychology*, *24*(4), 504–513. doi:10.1037/a0018934

Silverberg, N. D., Wertheimer, J. C., & Fichtenberg, N. L. (2007). An effort index for the Repeatable Battery For The Assessment Of Neuropsychological Status (RBANS). *The Clinical Neuropsychologist*, *21*(5), 841–854. https://doi.org/10.1080/13854040600850958

Smith, S. K., Nutbeam, D., & McCaffery, K. J. (2013). Insights into the concept and measurement of health literacy from a study of shared decision-making in a low literacy population. *Journal of Health Psychology*, *18*(8), 1011–1022. doi:10.1177/1359105312468192

Stuss, D. T. (2011). Functions of the frontal lobes: relation to executive functions. *Journal of the International Neuropsychological Society: JINS*, *17*(5), 759–765. doi:10.1017/S1355617711000695

Tabachnick, B.G., & Fidell, L.S. (2019). *Using Multivariate Statistics*. Boston: Pearson/Allyn & Bacon.

Tallberg, I.-M., Stormoen, S., Almkvist, O., Eriksdotter, M., & Sundström, E. (2013). Investigating medical decision-making capacity in patients with cognitive impairment using a protocol based on linguistic features. *Scandinavian Journal of Psychology*, *54*(5), 386–392. doi:10.1111/sjop.12068

Taylor, B. A., Hart, R. D., Rigby, M. H., Trites, J., Taylor, S. M., & Hong, P. (2016). Decisional conflict in patients considering diagnostic thyroidectomy with

indeterminate fine needle aspirate cytopathology. *Journal of Otolaryngology*, *45*, 16. https://doi.org/10.1186/s40463-016-0130-x

Taylor, K. L., Williams, R. M., Davis, K., Luta, G., Penek, S., Barry, S., … Miller, E. (2013). Decision making in prostate cancer screening using decision aids vs usual care: a randomized clinical trial. *JAMA internal medicine*, *173*(18), 1704–1712. doi:10.1001/jamainternmed.2013.9253

Thompson, B. (2002). "Statistical," "Practical," and "Clinical": How Many Kinds of Significance Do Counselors Need to Consider? *Journal of Counseling & Development*, *80*(1), 64–71. https://doi.org/10.1002/j.1556-6678.2002.tb00167.x

Types of Cancer Treatment. (n.d.). *National Cancer Institute*. cgvTopicPage. Retrieved January 21, 2018, from https://www.cancer.gov/about-cancer/treatment/types

Van Staden, C. W., & Krüger, C. (2003). Incapacity to give informed consent owing to mental disorder. *Journal of Medical Ethics*, *29*(1), 41–43.

Von Neumann, J, & Morgenstern, O. (1944). *Theory of Games and Economic Behavior, 2nd Edition.* Princeton, NJ: Princeton University Press.

Weiss, B. D., Mays, M. Z., Martz, W., Castro, K. M., DeWalt, D. A., Pignone, M. P., … Hale, F. A. (2005). Quick assessment of literacy in primary care: the newest vital sign. *Annals of Family Medicine*, *3*(6), 514–522. doi:10.1370/afm.405

Wileyto, E. P., Audrain-McGovern, J., Epstein, L. H., & Lerman, C. (2004). Using logistic regression to estimate delay-discounting functions. *Behavior Research Methods, Instruments, & Computers: A Journal of the Psychonomic Society, Inc*, *36*(1), 41–51.

Wright, E. J., Grund, B., Robertson, K., Brew, B. J., Roediger, M., Bain, M. P., … INSIGHT SMART Study Group. (2010). Cardiovascular risk factors associated with lower baseline cognitive performance in HIV-positive persons. *Neurology*, *75*(10), 864–873. doi:10.1212/WNL.0b013e3181f11bd8

Wyszynski, A. A., & Garfein, C. F. (2005). Assessing Decisional Capacity and Informed Consent in Medical Patients: A Short, Practical Guide. In A. A. Wyszynski & B. Wyszynski (Eds.), Manual of psychiatric care for the medically ill (pp. 221-232). Arlington, VA: American Psychiatric Publishing.

Yzerbyt, V.Y., Muller, D., & Judd, C.M. (2003). Adjusting researchers' approach to adjustment: On the use of covariates when testing interactions. *Journal of Experimental Social Psychology, 40*, 424-431.