20th Anniversary update of the Ottawa Decision Support Framework:

Evidence syntheses of needs assessments and trials of patient decision aids

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Preface

Contributions of Collaborators

Elements	Chapter One	Chapter Two	Chapter Three
Protocol conceptualization, design and review	N/A	DS, KL, AO	DS, KL, AO
Provided additional background information on the evolution of the ODSF	AO	N/A	N/A
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Thesis Abstract

Purpose

To synthesize evidence on decisional needs assessments and patient decision aid (PtDA) trials based on the Ottawa Decision Support Framework (ODSF) in order to validate the concepts and test the main assertion in the ODSF.

Decisional needs

The systematic review studies (n=45) validated all of the decisional needs identified in the ODSF. Nine new manifestations of ODSF decisional needs emerged (e.g. information overload, unreceptive to information/deliberation, relationship barriers with practitioner).

PtDAs

The sub-analysis identified 24 ODSF PtDA trials. Compared to usual care, ODSF PtDAs improved decision quality, addressed decisional needs and reduced decision delay. Further evaluation is needed on downstream impacts of these improvements on decision-making.

Conclusions

Using Walker and Avant's theory testing steps, the integrated findings from the systematic review and sub-analysis validated the ODSF decisional needs concepts and tested the main assertion in the ODSF (that PtDAs address decisional needs and improve decision quality).

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List of Abbreviations

CNA	Canadian Nurses Association
CI	Confidence Interval
DCS	Decisional Conflict Scale
HCIC	Health Care in Canada
IPDAS	International Patient Decision Aids Standards
IPFCC	Institute for Patient- and Family-Centered Care
MD	Mean Difference
MMIC	Multidimensional Measure of Informed Choice
N/A	Not Assessed
N/R	Not Reported
ODSF	Ottawa Decision Support Framework
p	Probability
PtDA	Patient Decision Aid
RCT	Randomized Controlled Trial
RNAO	Registered Nurses Association of Ontario
RR	Relative Risk
SD	Standard deviation

Chapter One

Introduction

Introduction

Most patients want the opportunity to meaningfully engage in their healthcare decisions and to incorporate their preferences into decision-making (Chewning et al., 2012). Yet, a recent Canadian survey across 10 provinces found that only 39% (392/1010) of patients were asked for their ideas or preferences during decision-making (Haesebaert, Adekpedjou, Croteau, Robitaille, & Légaré, 2019). This is particularly problematic given that there may not be an obvious best course of action, or each option may have features that involve risk or loss (Eddy, 1992; O'Connor et al., 1999; O'Connor, Jacobsen, & Stacey, 2002). Furthermore, the features of the options that matter most to a patient will vary among individuals given that patients have different illness experiences, social circumstances, attitudes to risk, values, and preferences (Coulter & Collins, 2011).

One approach to mitigate this conflict is through shared decision making. Shared decision making is a patient-centered method defined as a collaborative approach between practitioners and patients that incorporates the best available evidence on the options, and is informed by the patient's personal values, circumstances and concerns (Elwyn et al., 2017; Makoul & Clayman, 2006). Decision-making should be shared with patients, since they are the ones who live with the consequences of health decisions and practitioners are not experts in patients personal circumstances (Carpenter & Niedenthal, 2018). This approach was recommended more than 30 years ago by a United States Presidential Commission, which considered shared decision making as a way to promote collaboration in decision-making between practitioners and patients (Coulter, 2018; United States President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982). Although there continues to be challenges with implementing shared decision making within routine clinical practice, a recent

report shows that it is on the current agenda of developed and developing countries at various policy, infrastructure and practice levels (Coulter, 2018).

Incorporation of shared decision making into healthcare in Canada is slow, and recent health policies and organizations call for better engagement of patients in healthcare decisions at individual and collective levels (Légaré et al., 2017). For example, British Columbia, Saskatchewan, and Ontario have "patient first" initiatives, while on a national level the Canadian Primary Preventive Task Force is incorporating shared decision making into their clinical practice guidelines (Coulter, 2018; Canadian Task Force on Preventative Health Care, 2018; Government of Saskatchewan, 2015; Ministry of Health and Long-Term Care, 2015; Ministry of Health British Columbia, 2018). In addition, the Canadian public increasingly supports the engagement of patients in healthcare decisions as indicated by the Health Care in Canada (HCIC) national surveys of Canadian public and practitioners' opinions about healthcare issues (Health Care in Canada Knowledge Translation Committee, 2018). The mean support scores for implementation of care decisions made in partnership between informed patients and their practitioners to enhance patient-centred care in 2013, 2016 and 2018 were 8.1, 8.4 and 8.5 out of 10, respectively; this indicates strong support for implementation of this shared decision making attribute.

A key strategy for supporting patient involvement in shared decision making is to design decision support interventions tailored to patients' decision-making needs (Coulter, 2018; O'Connor et al., 1998). When these interventions are tailored to patients' needs (e.g. low literacy, education, socioeconomic status), they can be more effective compared to those that are not (Coulter, 2018). A review of 15 shared decision making conceptual models and theories found that the Ottawa Decision Support Framework (ODSF) was the only theoretical framework

that considered decisional needs for all health and social decisions (Stacey, Légaré, Pouliot, Kryworuchko, & Dunn, 2010). The main premise of the ODSF is that unresolved decisional needs can adversely affect the quality of a decision (informed and based on the features that matter most to a patient) (O'Connor, 2018). Decision support interventions tailored to these needs can improve decision quality. Decision support can be provided using clinical counseling, patient decision aids (PtDAs), and/or decision coaching. According to the ODSF, the main decisional need categories are decisional conflict, inadequate knowledge and unrealistic expectations, unclear values, inadequate support and resources, and needs influenced by decision characteristics and personal and clinical characteristics (O'Connor, 2018).

Practitioners tend to focus more on providing factual information when patients may experience other decisional needs that require different supportive interventions (O'Connor, Stacey & Boland, 2015; Stacey, Chambers, Jacobsen, & Dunn, 2008; Stacey, Graham, O' Connor, & Pomey, 2005). If patients' decisional needs remain unresolved, there may be downstream effects on decision delay, feelings of regret, and blaming the practitioner for poor outcomes (Gattellari & Ward, 2005; Sun, 2005). The ODSF is known internationally and has been in use for 20 years to help guide practitioners in assessing patients' decisional needs and tailoring support to help patients with decision-making (O'Connor et al., 1998; O'Connor, 2006). However, it is not clear the extent to which it has been used and whether new decisional needs have been identified. Hence, the overall aims of this thesis were to synthesize evidence on decisional needs assessments and PtDA trials that were based on the ODSF in order to validate the concepts and test the main assertion in the ODSF (that PtDAs address decisional needs and improve decision quality).

The Ottawa Decision Support Framework

The following provides a description of the ODSF and a review of the literature focusing on the key elements of decisional needs, decision support interventions, and decision outcomes.

Evolution

The motivation for developing the ODSF stemmed from a practice question: how do you support patients making difficult health or social decisions, where the choice among competing actions involves risk, loss, regret, or challenge to personal life values? (O'Connor, 2018; O'Connor & O'Brien-Pallas, 1989). The ODSF was published in 1998 as a theoretical framework to guide researchers and practitioners in assessing patients' decisional needs, providing decision support interventions, and evaluating the effects on the quality of the decision and decision-making process, as well as outcomes of decisions (O'Connor et al., 1998). It was based on concepts and theories from prospect theory (Tversky & Kahneman, 1981), social psychology (Ajzen, 1980), decision analysis (Keeney, 1976), decisional conflict (Janis, 1977; O'Connor, 1995; O'Connor & O'Brien-Pallas, 1989), social support (Norbeck & Tilden, 1988) and other models using expectations and values (Feather, 1982; Fischhoff & Lichtenstein, 1980). These theories underlying the framework suggest that patients will make a decision depending on their perceptions of the decision, perceptions of important others involved in the decision, support in decision making, and personal and external resources to make and implement a choice (O'Connor et al., 2002; O'Connor et al., 1998). The patient's and practitioner's personal and clinical characteristics will also affect the decision and decision-making process (O'Connor et al., 2002; O'Connor et al., 1998). The ODSF applies to participants in the decision including the patient, family and the practitioner.

Since the original publication in 1998, the ODSF was updated using evidence on the effects of decision support interventions and the emerging consensus on the primary outcome (decision quality) for evaluation of decision aids (O'Connor, 2018; O'Connor & Légaré, 2009; O'Connor, 2006). The model depicting the concepts in the ODSF was also simplified for training purposes (Stacey et al., 2009). The current 2018 ODSF model and detailed description of concepts are found in Appendix A and Appendix B, respectively.

ODSF Concepts

The main premise of the ODSF is that the quality of a decision is influenced by decisional needs; where a quality decision is defined as being informed by the best available evidence and grounded in the patient's values and preferences (O'Connor et al., 2002; O'Connor et al., 1998; Stacey et al., 2009). Decision support interventions are then selected and tailored to meet the specific decisional needs of the patient with the aim of improving decision quality (O'Connor et al., 1998; Stacey, DeGrasse, & Johnston, 2002).

The ODSF is useful for difficult decisions that have multiple options, unknown outcomes, or known benefits and harms that patients' value differently (O'Connor et al., 1998; O'Connor, 2018). It is applicable in situations where a patient is facing a new circumstance, diagnosis, or developmental transition, but less so if the situation requires implementation or maintenance of action, or if deliberation is not required (Stacey et al., 2002). The three pillar concepts identified in the ODSF are now described in detail: decisional needs, decision support interventions, and decision outcomes.

Pillar 1: decisional needs.

A comprehensive list of ODSF decisional needs was first described in a Canadian study evaluating a decision aid for women considering hormone therapy after menopause (O'Connor et

al., 1998). The ODSF proposes that common modifiable decisional needs of patients (and families) can include personal uncertainty about the best choice (decisional conflict), lack of knowledge (about the condition, options, benefits, risks, probabilities), unrealistic expectations, and unclear values or priorities (personal desirability or importance of benefits vs. harms) (O'Connor & Légaré, 2009; O'Connor, Stacey, & Boland, 2015; O'Connor, 2006; O'Connor et al., 1998). There may be inadequate support and resources such as unclear or biased views of others, social pressure, mismatch in preferred or actual decision making roles, inadequate experience, confidence and skills in decision making, inadequate access to information, advice, emotional support, instrumental help, financial assistance, and health and social services (O'Connor & Légaré, 2009; O'Connor et al., 2015).

There may also be influences of complex decision characteristics as well as personal and clinical characteristics on decisional needs. (O'Connor et al., 2015; O'Connor et al., 1998). Most are non-modifiable, but they nevertheless need to be considered when tailoring decision support (Coulter, 2018; O'Connor et al., 1998). Influences related to complex decision characteristics include type, timing, and stage of decision-making, as well as if a patient is leaning towards an option (O'Connor, 2018; O'Connor et al., 2015; O'Connor et al., 1998). Regarding type of decision, common decisions include developmental transitions or clinical decisions such as, to screen, test, treat or palliate (O'Connor et al., 2015). Over 3000 healthcare treatments have been classified as: 11% beneficial, 24% probably beneficial, 7% need to weigh known benefits versus risks, 5% probably not beneficial, 3% likely to be ineffective or harmful, and 50% insufficient evidence of usefulness (BMJ Clinical Evidence, 2016). Even among beneficial treatments, there may be multiple options with different features that patients' value differently. The seriousness of outcomes and whether the outcomes are reversible are also factors in a decision that may

influence decisional needs (O'Connor et al., 2015). For example, a national survey of the decision-making needs of Canadians found that less decisional conflict was associated with people deciding about birth control compared to other decisions (e.g. medical, surgical, or placing a relative in a nursing home) (O' Connor et al., 2003).

The timing of the decision refers to the time-frame of when a decision needs to be made. A difficult decision that is urgent and made within a short time-frame may increase decisional conflict and a decision that does not have to be made for some time may increase decision delay (O'Connor et al., 2015). The stage of decision making and leaning towards a specific option can also influence the magnitude of decisional conflict (O'Connor et al., 2015). For example, if a patient is actively thinking about his/her options, decisional conflict may be higher, whereas if the patient is close to making a choice, decisional conflict may be lower (O'Connor et al., 2015; O'Connor, 2006).

Patient's personal and clinical characteristics that may influence their decisional needs include: age, developmental stage, gender, socioeconomic status, ethnicity, education, diagnosis and duration, and limitations in physical, emotional, cognitive or social abilities. For example, the Canadian survey found that more women and separated individuals reported making complex decisions (O' Connor et al., 2003). This survey also found that younger patients had higher decisional conflict and had a more independent role in decision making. Women also reported higher decisional conflict than men. A more recent Canadian survey, of more than 1000 Canadians across 10 provinces, found that patients who were older, living in rural areas, living in Quebec, and non-white were less likely to participate in shared decision making (Haesebaert et al., 2019).

These modifiable and non-modifiable decisional needs were supported by several decisional needs studies and surveys that were conducted at the population and clinical levels using the ODSF. In general, they endorse the categories of needs of the ODSF. In two large surveys, one Canadian and one Chilean, over 50% of participants reported feeling unsure about which option to choose when facing a decision (Bunn et al., 2006; O' Connor et al., 2003). In the Canadian national survey, those who felt uncertain were more likely to report feeling uninformed, unclear about personal values, unsupported in decision making, pressure from others to choose an option, or inadequate skills or motivation to participate in decision making (O' Connor et al., 2003). In another study, when practitioners were asked about their perceptions of difficult decisions, the most frequently mentioned ones were: cancer therapy, antidepressant drug therapy, level of care, lifestyle issues, screening tests, and hormone therapy (Légaré et al., 2006). Practitioners identified the following factors that made the decision difficult for the patient: feelings of uncertainty, fear of adverse outcomes, presence of symptoms, lack of support or undue pressure (e.g. perceptions of others and lack of advice from the physician), having to balance conflicting information, lack of understanding of the information, lacking information on alternatives, receiving too much information, and judging the source of information to be unreliable (Légaré et al., 2006).

Several smaller needs assessment studies for ten different decisions, nine Canadian and one American, have endorsed the needs identified in the ODSF for a variety of decisions (Baldé, Légaré, & Labrecque, 2006; Johnston et al., 2008; Jolicoeur, O'Connor, Hopkins, & Graham, 2009; Kavanaugh, Savage, Kilpatrick, Kimura, & Hershberger, 2005; Légaré et al., 2007; Mitra, Jacobsen, O'Connor, Pottie, & Tugwell, 2006; Murray, O'Connor, Fiset, & Viola, 2003; Stacey et al., 2002; Stacey et al., 2008; Taylor-Clapp, 2001). However, most studies were conducted in

Canada and it is not clear the extent to which the ODSF has been used over the last 20 years for other decisional needs assessments.

A review of the literature revealed three systematic reviews of decisional needs that focused on parental decision support needs regarding child health decisions (Jackson, Cheater, & Reid, 2008), down syndrome prenatal testing (St-Jacques et al., 2008), and decision-making needs among people with mental health diagnoses (Tlach et al., 2015). St-Jacques et al., (2008) used the ODSF as a taxonomy in their study, but there were no primary studies that used the ODSF to guide their decisional needs assessment methods. Findings from these systematic reviews revealed that patients' six main decision-making needs were: for information (Jackson et al., 2008; St-Jacques et al., 2008; Tlach et al., 2015), to talk to others in similar situations to hear or share personal experiences (Jackson et al., 2008; Tlach et al., 2015), to be in control over the preferred level of involvement in decision-making (Jackson et al., 2008), for assistance in handling pressure from others, for emotional guidance (e.g. anxiety, worry and/or fear generated by procedures or potential consequences) (St-Jacques et al., 2008), and for adequate access to services and practitioners (Tlach et al., 2015). The authors concluded that their reviews highlight the complexity in decision-making and how it is vital to consider multiple factors that influence decisional needs, since providing factual information alone is not adequate to support decision-making (Jackson et al., 2008; St-Jacques et al., 2008; Tlach et al., 2015). While these systematic reviews provide constructive considerations on decisional needs, they focused specifically on needs of one specific decision context.

Given that the ODSF was originally published 20 years ago, it is not clear if studies informed by the ODSF have identified new decisional needs. For example, a recent study, guided by the ODSF, revealed new influences of decision characteristics on decisional needs for patients

with chronic kidney disease that were not included in the ODSF (Loiselle, Michaud, & O'Connor, 2016). These new influences on decisional needs were specific to the complexity of the decision contexts and patients' stage of decision-making. Patients were unreceptive to deliberation and receiving information due to lack of acceptance of the severity of their kidney disease requiring treatment (dialysis) and strong emotional responses to their disease severity and treatment options (Loiselle, Michaud, & O'Connor, 2016).

Pillar 2: decision support interventions.

The second pillar of the ODSF addresses the concept of decision support. Decision support provides structured guidance to help patients deliberate on options and communicate with others (O'Connor et al., 2015). In this context, decision support is tailored to the patient depending on their decisional needs (O'Connor et al., 2015). To achieve this, the following steps are suggested: clarifying the decision, assessing patients' decisional needs, providing information and probabilities of outcomes, clarifying personal values, enhancing support from others and resources, and monitoring/facilitating progress in decision-making. Decision support also helps patients to determine their preferred role in decision-making (e.g. share, delegate, or make the decision on their own) (O'Connor et al., 2015).

Decision support is provided by way of interventions such as clinical counselling, coaching, and decision tools such as PtDAs (O'Connor, 2006). Clinical counseling is provided by practitioners who have the expertise, accountability and scope of practice to identify health or social problems and offer options to the patients (e.g. audiologists, nurses, nurse practitioners, occupational therapists, pharmacists, physicians, physiotherapists, psychologists, social workers and speech language therapists) (O'Connor et al., 2015). Within their scope of practice, they: (a) identify/diagnose a health or social problem; (b) identify options, benefits, harms, side effects,

probabilities, and scientific uncertainties; and (c) facilitate implementation of the final decision (e.g. refer, prescribe, order tests, perform procedures and provide therapy) (O'Connor et al., 2015). For those experiencing difficulties with a decision, patients can be referred to decision coaching and decision tools.

Decision coaching is defined as support to patients by a trained practitioner that is individualized and non-directive to assess and meet patients' decision-making needs (Jull et al., 2019; Stacey et al., 2012). Used alone or in combination with decision tools, coaching aims to develop the patient's skills in thinking about the options, preparing for discussing the decision in a consultation with his or her practitioner, and implementing the chosen option (O'Connor, Stacey, & Légaré, 2008; Stacey et al., 2012). The ODSF also guided the development of a generic decision tool, the Ottawa Personal Decision Guide, which is used internationally as a coaching tool (Coulter, 2018).

Decision tools include PtDAs and generic decision guides (O'Connor et al., 2015; Stacey et al., 2017). The ODSF is a commonly used theoretical framework to develop condition-specific PtDAs (Durand, Stiel, Boivin, & Elwyn, 2008; O'Connor et al., 1999). According to the International Patient Decision Aids Standard Collaboration (IPDAS), PtDAs: (1) make explicit the decision; (2) provide information on the disease/condition, options, benefits, harms, scientific uncertainties; and (3) clarify values by describing outcomes and/or asking the patient to rate the importance of benefits and harms (Elwyn et al., 2006; Joseph-Williams et al., 2014). Optional elements include presenting probabilities of outcomes tailored to the patient's health risk factors, providing patient stories, providing guidance in the steps of decision-making and communicating with others, and summarizing findings to share with practitioners. Of these decision support

interventions, PtDAs have the highest level of evidence indicating their effectiveness (Stacey et al., 2017).

Pillar 3: decision outcomes.

The third pillar of the ODSF refers to the concept of decision outcomes. The primary outcome is the quality of the decision. High quality decisions are defined in the ODSF as being informed by the best available evidence and grounded in the patient's values (Elwyn et al., 2006; O'Connor & O'Brien-Pallas, 1989; O'Connor et al., 2002; O'Connor et al., 1998). The premise is that quality decisions may then have a favourable effect on patients' actions such as decision delay and continuance of the chosen option (O'Connor, 2018; O'Connor et al., 1998). Moreover, there may be positive downstream impacts on achieving values-based health outcomes and minimizing emotions such as regret or blame (O'Connor et al., 1998; Sun, 2005). High quality decisions may also affect the use of health services and related costs by reducing over-use of options that informed patients do not value and increasing the under-use of options that they do value (O'Connor, 2018; O'Connor et al., 1998).

There are validated instruments based on the ODSF for measuring some of these outcomes (Ottawa Hospital Research Institute, 2017). For example, the Decisional Conflict Scale (DCS), measures decisional needs such as perceptions of feeling uncertain, uninformed, unclear about personal values, unsupported in decision-making, and ineffective decision-making (feeling the choice is not informed or grounded in personal values) (O'Connor, 1995). The clinical practice version, the SURE test, can be used to screen for decisional conflict using the first four of the five elements in the DCS (Légaré et al., 2010). These instruments have been validated, have demonstrated reliability and have measured needs before and after decision support interventions (Légaré et al., 2010; O'Connor, 1995). A review and appraisal of instruments used

in 35 randomized controlled trials (RCTs) measuring the effectiveness of decision support interventions as primary outcomes, found that the DCS was the most commonly used instrument in the evaluation of PtDAs (Kryworuchko, Stacey, Bennett, & Graham, 2008). A more recent scoping review identified 394 studies using the DCS over the last 20 years and reported lower decisional conflict after exposure to decision support interventions (Garvelink et al., 2019). Furthermore, if no decision support interventions were used, decisional conflict was higher in the longer term. The decisional need most consistently improved in this scoping review was the decisional conflict subscale of feeling uninformed. Some studies have demonstrated a correlation between higher decisional needs, as measured by the DCS, and lower knowledge scores (O'Connor 1995; Sun 2005), remaining undecided (O'Connor 1995; Sun 2005), feeling more regret (Brehaut et al. 2003; Sun 2005), and blaming others for bad outcomes (Gattellari & Ward, 2005; Sun, 2005). However, correlation does not imply causation.

The evidence for measuring effectiveness of PtDAs developed based on the ODSF was informally reviewed shortly after the publication of the ODSF (O'Connor et al., 1999). In 2010, at an ODSF international workshop (Stacey, O'Connor, et al., 2010), the results of 24 ODSF-based PtDAs evaluated in RCTs were compared to 66 PtDAs that did not use the ODSF evaluated in RCTs (Brinkman & Lawson, 2010). Both types of PtDAs had positive effects on measures of decisional needs using the DCS, improved knowledge and realistic expectations, informed values-based choices, reduced the proportion who remain undecided and had no effect on continuance of the chosen option. The ODSF-based PtDAs were not evaluated using measures of regret or blame, or values-based health outcomes (Stacey, O'Connor, et al., 2010). Since this review, more trials of PtDAs have been published and a more formal sub-analysis of trials of the ODSF-based PtDAs is required (Stacey et al. 2017). An analysis would confirm that

PtDAs informed by the ODSF helped to resolve decisional needs and improve decision quality, which is the primary outcome of the ODSF.

The most recent systematic review of RCTs compared usual care to PtDAs (Stacey et al. 2017). PtDAs evaluated in 105 RCTs significantly reduced the proportion of patients who were undecided, improved patients' knowledge and made them feel more informed and clearer about their values. The effect of PtDAs on increased or decreased use of treatments varied with the decision. In addition, patients probably have a more active role in decision-making and more accurate risk perceptions without adverse effects on health outcomes or satisfaction. Only one of seven trials showed an effect on reducing regret and no trials reported blame as an outcome measure. Further research is needed on the effects on adherence with the chosen option, cost-effectiveness, and use with lower literacy populations (Stacey et al. 2017).

A systematic review of 10 trials using decision coaching showed improved knowledge when compared to usual care (Stacey et al., 2012). When paired with a PtDA, there was also improved knowledge and participation in decision-making. Decision coaching with a PtDA compared to a PtDA alone revealed that although there was no difference in knowledge or participation, there was improved satisfaction with decision-making and increased values-choice agreement without any negative outcomes. There is a Cochrane review of decision coaching underway as indicated by the registration of the title (Jull, et al., 2019).

Summary

In summary, people will face difficult health or social decisions throughout their lifetime when facing a new circumstance, diagnosis, or developmental transition. Involving patients in shared decision making is on the current policy agenda in some Canadian provinces and in many other countries. However, many patients have various decision-making needs and require

support to participate in decision-making. For 20 years researchers and practitioners have used the ODSF to assess decisional needs, provide decision support, and evaluate effects on decision outcomes. However, the decisional needs component of the ODSF needs updating with a more rigorous synthesis of evidence from all of the decisional needs assessment studies. Furthermore, a more formal analysis is required to determine the effectiveness of ODSF-based PtDAs on resolving decisional needs and improving decision quality, which are the primary outcomes of the ODSF.

Research Aim and Objectives

The overall aims of this thesis were to synthesize evidence on decisional needs assessments and PtDA trials that were based on the ODSF in order to validate the concepts and test the main assertion in the ODSF (that PtDAs address decisional needs and improve decision quality). This article-based thesis consists of two papers.

The first paper presented in Chapter Two is titled, "A Systematic Review of the Decisional Needs of Patients and Families Making Health or Social Decisions". The specific objectives in Chapter Two were to: (a) synthesize the evidence from ODSF-based decisional needs studies; (b) identify new decisional needs; and (c) validate decisional needs already identified in the ODSF.

The second paper presented in Chapter Three is titled, "What is the Effectiveness of Patient Decision Aids Developed Using the Ottawa Decision Support Framework? Sub-analysis of a Systematic Review". The specific objective in Chapter Three was to compare the effectiveness of PtDAs developed using the ODSF to usual care.

Chapter Four provides an integrated discussion of the findings across these two papers, discusses how these findings contribute to validating and testing the ODSF, and provides

implications for nursing practice, education, leadership, collaboration and areas for further research.

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Chapter Two

20th Anniversary update of the Ottawa Decision Support Framework: A systematic review of the decisional needs of patients and families making health or social decisions

Abstract

Background

The Ottawa Decision Support Framework (ODSF) guides practitioners' support for patients making difficult health or social decisions. The premise is that decision support improves quality decision-making by addressing decisional needs.

Objectives

The aims were to: (a) synthesize the evidence from ODSF-based decisional needs assessment studies; (b) identify new decisional needs; and (c) validate decisional needs already identified in the ODSF.

Methods

A mixed studies systematic review using Cochrane methods. Electronic databases were searched: Medline, CINAHL, PsycINFO, Cochrane Library, Embase, AMED, Scopus, Web of Science and Social Services Abstracts. Inclusion criteria: assessments of patients' or families' decisional needs when making health or social decisions for themselves, a child, or a mentally incapable person; or practitioners or families reporting on patients' decisional needs. Data were analyzed using narrative synthesis.

Results

Of 4532 citations, 45 studies from seven countries were identified as decisional needs assessments based on the ODSF. All ODSF decisional needs categories were reported in 11 to 41 studies. Nine new manifestations of decisional needs were: difficulty believing the chances of outcomes applied to them, information overload, lacking access to information about other's experiences with options, being unreceptive to information/deliberation (due to lack of acceptance of the condition/need for treatment, powerful emotions limiting information

processing, and being unmotivated to consider delayed/unpredictable decisions), difficult sharing deliberations with family, difficulty involving family in decision-making, and relationship barriers with practitioners.

Conclusion

In this first synthesis of decisional needs for patients and families making health and social decisions based on the ODSF, all ODSF needs were validated and new manifestations were identified.

Background

Patients and families often have decisional needs when faced with decisions that have more than one option, unknown outcomes, or known benefits and harms that patients' value differently (O'Connor, 2018). They require assistance in making a decision that is informed with the best available evidence and considerate of a patient's personal values and circumstances (Anderson et al., 2016; Légaré et al., 2011; O'Connor, Jacobsen, & Stacey, 2002).

The Ottawa Decision Support Framework (ODSF) was developed to guide practitioners' support for patients making difficult health decisions (O'Connor et al., 1998) (Appendix A). The main premise of the framework is that the quality of a decision can be adversely affected by unresolved decisional needs; where a quality decision is defined as being informed by the best available evidence and grounded in the patient's values (O'Connor et al., 1998; O'Connor, 2018; Stacey et al., 2009). Decision support interventions that address patients' specific decisional needs may improve decision quality, have positive effects on actions (decision delay and continuance of one's chosen option), and downstream impacts (values-based health outcomes, regret, blame, and appropriate use of health services) (O'Connor, 2018).

The ODSF proposes that common modifiable decisional needs of patients and families include personal uncertainty about the best choice (decisional conflict), lack of essential knowledge (about the condition, options, benefits, harms, scientific uncertainties), unrealistic expectations (perceived likelihood of benefits/harms), and unclear values (personal desirability or importance of benefits vs. harms) (Figure 2.1) (O'Connor et al., 1998; O'Connor, 2018; O'Connor & Légaré, 2009; O'Connor, Stacey, & Boland, 2015). There may be inadequate support and resources such as unclear or biased views of others, social pressure, mismatches in preferred and actual decision-making roles, inadequate internal resources (decisional experience,

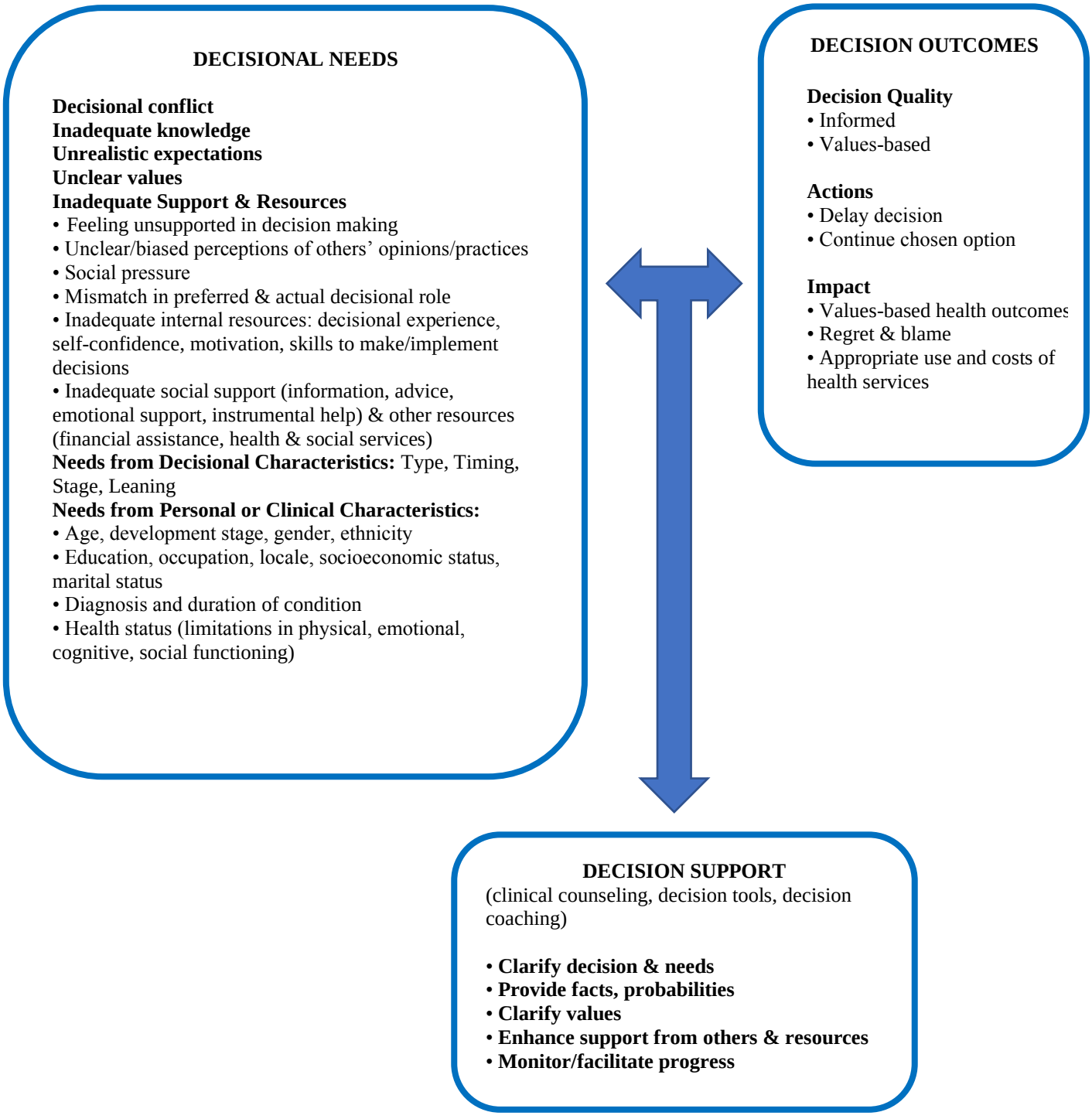

Figure 2.1. The Ottawa Decision Support Framework (with expanded decisional need categories and sub-categories)**.** Based on O'Connor, A.M. (2006). *Ottawa decision support framework* and the Ottawa Decision Support Tutorial, Ottawa Hospital Research Institute. Retrieved from https://decisionaid.ohri.ca

confidence, motivation and skills); and inadequate social support (information, advice, emotional support, instrumental help) and other resources (financial assistance, health and social services) (O'Connor, 2018; O'Connor & Légaré, 2009; O'Connor et al., 2015).

The ODSF also asserts that decisional needs can be influenced by the characteristics of the patient and of the decision itself (O'Connor et al., 1998; O'Connor, 2018). For example, decisional needs may be amplified if support and resources are not tailored appropriately to age, developmental stage, gender, education, marital status, ethnicity, socioeconomic status, occupation, locale, diagnosis and duration of condition, and health status (physical, emotional, cognitive, social) (O'Connor et al., 1998; O'Connor, 2018). Decision characteristics that often amplify needs include: (a) type (e.g. multiple options, scientifically uncertain outcomes, known outcomes that people value differently, and serious or permanent effects); (b) timing (e.g. delayed/urgent time-frame when a decision needs to be made); and (c) stage of decision-making (e.g. unreceptive to information and deliberation due to denial, hasty decision-making, premature closure, or polarized leaning) (O'Connor et al., 2015).

Since the ODSF was initially published in 1998, there have been reviews synthesizing the evidence on decision support interventions and the findings from the Decisional Conflict Scale (DCS), which assesses the effects of decision support interventions on resolving decisional needs (Garvelink et al., 2015; O'Connor et al., 2009; Stacey et al., 2012, Stacey et al., 2017). The only known syntheses of decisional needs focused on condition-specific needs including parental needs for decisions about a child (Jackson, Cheater, & Reid, 2008), down syndrome prenatal screening (St-Jacques et al., 2008) and decision-making needs among people with mental health diagnoses (Tlach et al., 2015). These reviews reported that main decision-making needs were: for information (Jackson et al., 2008; St-Jacques et al., 2008; Tlach et al., 2015), to talk to others in

similar situations to hear or share personal experiences (Jackson et al., 2008; Tlach et al., 2015), to be in control over the preferred level of involvement in decision-making (Jackson et al., 2008), for assistance in handling pressure from others, for emotional guidance (e.g. anxiety, worry, and/or fear generated by procedures or potential consequences) (St-Jacques et al., 2008), and for adequate access to services and practitioners (Tlach et al., 2015). Only one of these systematic reviews used the ODSF, but the primary studies did not have to be based on the ODSF (St-Jacques et al., 2008). Additionally, PROSPERO was searched for existing systematic review protocols on the topic of decisional needs. None were found. One systematic review protocol focuses on complex care decision needs in primary care and their study eligibility criteria are more limited (Bujold et al., 2017).

Objectives

The aim of this mixed studies systematic review was to describe the decisional needs of patients and families facing health decisions. Specific objectives were to: (a) synthesize the evidence from ODSF-based decisional needs studies; (b) identify new decisional needs; and (c) validate decisional needs already identified in the ODSF.

Methods

Study Design

We conducted a mixed studies systematic review guided by the "Cochrane Handbook for Systematic Review of Interventions" (Higgins & Green, 2011). The ODSF was chosen as the theoretical framework to guide the systematic review given it is the only framework that explicitly identifies patients' decisional needs and discusses use of interventions to address identified needs (O'Connor et al., 1998). This study is reported according to the PRISMA criteria

(Moher, 2010) and the protocol was registered in PROSPERO a priori (registration #CRD42018116736) (Appendix C).

Information Sources

Nine electronic databases were searched from database inception to October 6, 2018: Medline (via OVID), CINAHL (via EBSCOHost), PsycINFO (via OVID), Cochrane Library (via OVID), Embase (via OVID), AMED (via OVID), Scopus, Web of Science and Social Services Abstracts (via Proquest). A supplemental hand-search of the reference lists of three systematic reviews was done to identify any primary studies that may have used the ODSF (Jackson et al., 2008; St-Jacques et al., 2008; Tlach et al., 2015).

Search Strategy

The search strategy was developed with an academic librarian (LS). The Medline search strategy is included below and was adapted for the other listed databases. LH performed the search.

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to October 6, 2018>

Search Strategy:

1 Ottawa Decision* Framework.mp.

2 Ottawa Decision* Support*.mp.

3 Ottawa framework*.mp.

4 ODSF.mp.

5 decision* support* framework.mp.

6 DSF.mp.

7 1 or 2 or 3 or 4 or 5 or 6

The ODSF and related terms (as listed in lines 1 through 6 above) were used as the keyword search term and all fields were searched (e.g., titles, abstracts, text). This preliminary search located 1011 potentially relevant articles in Medline. Since this search did not include a large number of articles, we decided not to apply further limitations to the search strategy (e.g., date range).

In Scopus, citation searches included: the original published article describing the framework (O'Connor et al., 1998); a paper by Stacey et al., (2009) which includes a visual depiction of the ODSF; the chapter on "Decisional Conflict" in the "Encyclopedia of Medical Decision Making" as it contains an evolved and clear definition of the concepts in the ODSF since the original publication (O'Connor & Légaré, 2009); and the Jacobsen, O'Connor, and Stacey (2013) workbook, "Decisional Needs in Populations: A Workbook for Assessing Patients' and Practitioners' Decision Making Needs" that was developed based on the ODSF concepts and has been used to guide decisional needs assessment studies. A citation search for this workbook was also conducted in PubMed. We contacted experts in the field who are known developers and evaluators of patient decision aids (PtDAs) using the Shared@Shared Decision Making Network closed group on Facebook to further inquire about decisional needs assessment studies.

Eligibility Criteria

The eligibility criteria were informed by PIPOH, defined by population, phenomena of interest, practitioners and patients, outcomes and health setting (Table 2.1):

(P) Population: children, youth and adults making health or social decisions for themselves, a child or a mentally incapable other;

(I) Phenomena of Interest: decisional needs of people making health or social decisions in primary studies with a specific objective to examine these needs, and whose methods were guided by the ODSF or the decisional needs assessment workbook of Jacobsen et al., (2013);
(P) Practitioners/Patients: no restrictions; practitioner and family perspectives on patients' decisional needs and patient perspectives on their decisional needs when making a health or social decision for themselves, a child, or mentally incapable person;
(O) Outcomes: any reported decisional needs whether or not they map onto the ODSF;
(H) Health-Related Setting: no restrictions were placed on setting.

Studies were excluded if the decisional needs were related to hypothetical scenarios, advance care planning, or if the primary study was not guided by the ODSF. Studies that may have referenced the Jacobsen et al., (2013) workbook, "Decisional Needs in Populations", had to explicitly state how the workbook was used to guide their methods. No exclusion criteria were specific to the populations, practitioners, patients, outcomes or health-related settings.

Only primary studies published in peer-reviewed journals that list decisional needs assessment as a study objective were included. Studies could be quantitative, qualitative or mixed methods studies. Abstract-only publications and non-peer reviewed studies were also excluded from this study (e.g. dissertations, commentaries, letters, editorials). Given the ODSF was first published in 1998, studies from 1998 onwards were considered. There were no restrictions on geographical location or language in our search.

Table 2.1 *Eligibility Criteria*

Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
Population	-children, youth and adults making health or social decisions for themselves, a child or a mentally incapable other	-no restrictions
Phenomena of Interest	-decisional needs of people making health or social decisions -primary studies with an objective to examine decisional needs -needs assessment methods guided by the ODSF or the workbook by Jacobsen et al., (2013)	-decisional needs related to hypothetical scenarios (e.g. advance care planning); studies that do not use the ODSF; or studies referencing the Jacobsen et al., (2013) workbook do not explicitly state in their methods how this workbook was used
Practitioners/Patients	- practitioner and family perspectives on patients' decisional needs and patient perspectives on their decisional needs when making a health or social decision for themselves, a child, or mentally incapable person	-no restrictions
Outcomes	-any decisional needs	-no restrictions
Health-Related Setting	-no restrictions will be placed on settings (e.g. hospital, primary care, out-patient clinics, community, health centers, home care, community hospitals, telephone, outreach)	-no restrictions
Study Designs	-primary peer-reviewed studies (quantitative, qualitative and mixed methods studies);	-non-peer reviewed studies (e.g. dissertations, commentaries, letters, editorials); abstract-only papers; study reviews (e.g. systematic reviews, literature reviews, scoping reviews, etc.)
Framework	Ottawa Decision Support Framework	-all other theories, frameworks and conceptual models
Geographical Location	-no restrictions	-no restrictions
Language	-all languages were included in the search -if the title and abstract met the inclusion criteria, the full paper will be included if translation is within resource means	-no restrictions

Study Records

Data management.

Search results were uploaded to Covidence to assist with screening (https://community.cochrane.org/help/tools-and-software/covidence). Prior to the formal screening of articles, a pilot test was conducted with two eligible articles to test and refine the screening criteria.

Selection process.

Two authors independently screened articles in Covidence using two screening steps (LH, KL, LB, DS). The first step involved screening titles and abstracts to determine if an article met the PIPOH eligibility criteria. Articles were only excluded if both reviewers agreed. Otherwise, they continued to be included. In the second step, full-texts of remaining citations were screened using the PIPOH criteria by two authors independently (LH, KL, LB, DS). Articles at this step were only excluded if both reviewers agreed and disagreements between reviewers were resolved through discussion. If a consensus was not reached, a third reviewer acted as an arbitrator. During screening, reviewers were not blinded to the study authors or institutions that sponsored or funded the studies.

Data collection process.

A standardized extraction grid was developed and used in Microsoft Excel to extract relevant data from included articles. Two data extractors (LH, GH) used this grid independently and their extracted data were compared. A pilot test of three articles with both extractors was done as a calibration exercise to test the grid before starting the formal review. Disagreements regarding the extracted data were resolved by discussion.

Data Items

As recommended in the Cochrane Handbook, we extracted data on the characteristics of the article, the decision, and the patient participants and practitioners (Higgins & Green, 2011). The main results extracted were the decisional needs identified within the studies (Table 2.2).

Table 2.2 *Data Extracted*

Category	Description of Data Extracted
General Study Information	First author, publication year, country/location
Method Characteristics	Study aim(s), setting, population focus, sample size, methodology, study design type
Characteristics of the decisions in the studies	• the health or social decision to be made • number of decisions considered • participants making decisions for themselves or on behalf of another • time frame or urgency of the decision • stage of decision-making
Characteristics of the study participants	Patient/family (personal and clinical characteristics): sex, gender, age, socioeconomic status, education, occupation, ethnicity, marital status, health status (physical, emotional, cognitive, social) and duration of condition; Practitioner: discipline, work setting, years of experience, age, sex and gender
ODSF Decisional Needs (O'Connor & Légaré, 2009; O'Connor et al., 1998; O'Connor et al., 2006; O'Connor et al., 2015; O'Connor, 2018).	Decisional Needs • Decisional conflict (personal uncertainty about the best choice) • Inadequate knowledge (about the condition, options, benefits, risks, probabilities) • Unrealistic expectations • Unclear values or priorities (personal desirability or importance of benefits vs. harms) • Inadequate support and resources • Decisional characteristics influencing needs • Personal and clinical characteristics influencing needs • Other needs not yet identified
Conclusions	As described by the author(s)
Limitations	As described by the author(s)

Outcomes

The outcomes of interest for this systematic review are the decisional needs of patients or families facing health or social decisions as identified in the ODSF or newly identified. Family is defined by the patient and can include biological, legal, or emotional relations (Clayman, Gulbrandsen, & Morris, 2017; Institute for Patient- and Family-Centered Care [IPFCC], 2019). For the purpose of this review, caregivers will also be referred to as family. According to the ODSF, decisional needs are decisional conflict, inadequate knowledge, unrealistic expectations, unclear values, inadequate support and resources, and needs that are influenced by decision characteristics (type, timing, stage, leaning) and personal and clinical characteristics (O'Connor, 2006). We also anticipated identifying some new decisional needs such as complex decision contexts, unreceptive stage of decision-making from powerful emotions (e.g. fear, anxiety), and lack of acceptance of the condition or the need for treatment (e.g. emotional effects of information) (Loiselle, Michaud, & O'Connor, 2016).

Quality Appraisal

We used the Mixed Method Appraisal Tool (MMAT) 2018 version to appraise and describe the methodological quality of included quantitative, qualitative and mixed method studies (Hong, Fàbregues, et al., 2018; Hong, Pluye, et al., 2018). The MMAT has moderately reproducible to perfect agreement for inter-rater reliability scores (kappa score of 0.72 pre- and .94 post-discussion) (Pace et al., 2011). In our review, we pilot tested the MMAT with three articles to ensure homogenous interpretation between the two appraisers. Discrepancies were resolved through discussion.

Data Analysis and Synthesis

Narrative synthesis.

According to Popay et al., (2006), there are four elements of narrative synthesis: (1) developing a theory of how the intervention works, (2) developing a preliminary synthesis of findings of included studies, (3) exploring relationships in the data, and (4) assessing the robustness of the synthesis. Since our review was not focused on an intervention being evaluated, we did not focus on this first element of theory development. The ODSF was used as a theoretical framework to interpret our findings and to identify additional outcomes that may inform and result in the update of the framework by working through elements two through four.

Element 2: developing a preliminary synthesis of findings of included studies.

This step guided the preliminary description of the studies included in the synthesis and helped to map our findings (Popay et al., 2006). The tools and techniques that were used included directed content analysis, groupings and clustering, and tabulation (Popay et al., 2006). We used Hsieh and Shannon's (2005) directed content analysis steps: (1) we identified key concepts (decisional needs categories) from the ODSF and refined their conceptual definitions of decisional needs in a coding manual; (2) we developed operational definitions for each decisional need by listing their behavioural manifestations using structured items from ODSF-based needs assessment interview guides, surveys, and instruments (Appendix D); (3) we began coding data with these predetermined codes in an excel spreadsheet; data that could not be coded were identified as "other" and analyzed later to determine if they represent a new category or if they were a new manifestation or contributing factor to an existing code; (4) we identified decisional need subcategories in the coding manual during a subsequent analysis by returning to the text and reanalyzing after the initial coding process; and (5) we reported the evidence using

rank order comparisons of the frequencies of codes (e.g. tabulation) in table format. The studies were also reported within the group whom is offering their perspective on decisional needs (e.g. patients, practitioners, families). When the proportion of patients experiencing a need were provided in the quantitative, qualitative and mixed methods studies, these numbers were synthesized and reported.

Element 3: exploring relationships in the data.

Any patterns that emerged from the preliminary synthesis were evaluated in this step by exploring the relationships within and across studies (Popay et al., 2006). This step specifically went beyond a preliminary synthesis and paid attention to the relationship(s) between decisional needs reported within and across studies (Popay et al., 2006).

Element 4: assessing the robustness of the synthesis.

To ensure the robustness of our synthesis, Popay et al., (2006) recommends including a summary discussion of the synthesis that includes a critical reflection on the synthesis process. This was added to the strengths, limitations and conclusion section in our study. We included a reflection that looked at the evidence used to support the synthesis, assumptions that were made, and where future research is required.

Results

Study Selection

The database search yielded 7135 citations including duplicates and the supplemental searches added 399 citations (Figure 2.2). In the reference lists of three reviews that were hand searched (Jackson et al., 2008; St-Jacques et al., 2008; Tlach et al., 2015), only one primary study used the ODSF and this study was also identified in the database search (Stacey et al., 2008). After screening titles and abstracts, 125 studies were retrieved for full-text screening.

There were 45 studies included. Reasons for exclusion of studies at full-text screening are included in Figure 2.2.

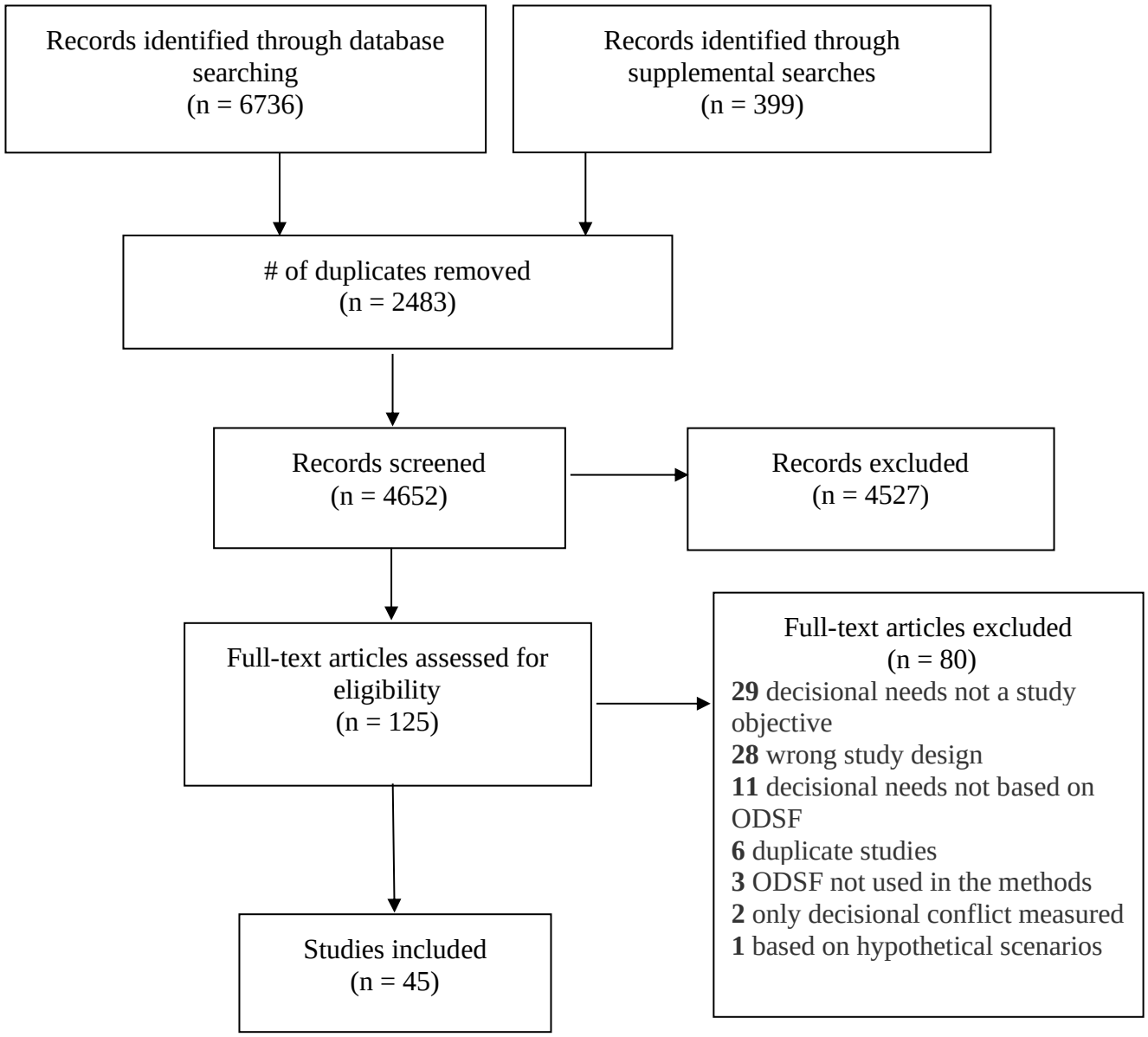

Figure 2.2. PRISMA flow diagram. Adapted from the PRISMA Flow Diagram (2009) retrieved from http://prisma-statement.org/PRISMAStatement/FlowDiagram.aspx

Characteristics of studies

Of 45 decisional needs assessments studies based on the ODSF, 36 studies offered perspectives from patients (2857 participants), 21 from practitioners (523 participants), and 11 from family members (173 participants). Of the 11 studies, six were families making decisions on behalf of a child (Grobman et al., 2010; Johnston et al., 2008; Kavanaugh et al., 2005; Kavanaugh et al., 2009; Li et al., 2016; Moro et al., 2011) and five studies were families supporting patients with decisions (Blumenthal-Barby et al., 2015; Burke et al., 2018; Fischer et al., 2018b; Nijhuis et al., 2016; Wilhelms et al., 2017). Studies were conducted in seven countries: Canada (n=22), United States (n=14), Australia (n=4), Netherlands (n=2), Chile (n=1), United Kingdom (n=1), and Malaysia (n=1). Two studies were population surveys that elicited a range of difficult decisions and 43 studies focused on 29 specific decisions (Table 2.3). These decisions were related to medical treatment (n=15; 33%), surgical (n=8; 18%), mental health treatment (n=5; 11%), decisions for infants or children (n=5; 11%), screening (n=3; 7%), preventative care (n=2; 4%), location of care (n=2; 4%), weight management (n=2; 4%) and obstetrics (n=1; 2%). Participants were recruited from secondary care (n=20; 44%), tertiary care (n=9; 20%), the community (n=8; 18%), primary care (n=3; 7%), and both secondary and tertiary care (n=3; 7%).

Patients and families were interviewed at various stages of decision-making including those who were: (a) in the process of making a decision (e.g. decided or undecided about the decision, or prospectively thinking about the decision) (n=18; 40%); (b) retrospectively reporting on a past decision (n=10; 22%); or (c) in the process of making a decision or retrospectively reporting on a past decision (n=14; 31%). The remaining three studies interviewed practitioners only.

Table 2.3 *Characteristics of Included Studies*

Author, Year, Country	Decision	Data Collection	How ODSF was used in study	Setting	Participants
Qualitative Studies (n=27)					
Abdullah[1] 2013, Malaysia	Breast cancer (early)	Interviews	Informed the interview guide	2 breast surgical clinics	8 women with early breast cancer (stage 1 or 2)
Balneaves[2], 2016, Canada	Menopausal symptoms after breast cancer	Focus groups and interviews	Informed the interview guide	2 Canadian urban cancer centers	22 women with stages I to IIIb breast cancer considering complementary therapies
Burke[3], 2018, United States	Location for post-acute care	Interviews	Informed the analysis	3 hospitals and 3 SNFs	32 previously community-dwelling older adults ≥ 65 years old; 22 Caregivers
Culver[4], 2011, United States	Reducing risk of breast cancer	Interviews and focus groups	Guided decision aid development	Not reported	11 women BRCA+, history of stage 0-IIIa breast cancer, 6 months past initial genetic counseling
Fisher[5,6,7] 2017, 2018, Australia	Bipolar II condition	Interviews	Informed the interview guide	Outpatient settings (general or specialist clinics)	20 practitioners for adult with BPII[6]; 20 practitioners for adult with BPII[7]; 28 patients with BPII-diagnosis[8]; 13 family members of adult with BPII[8]
Grobman[8], 2010, United States	Premature infants	Case study interviews and chart review	Informed the interview guide	3 tertiary care hospitals	40 women at high risk of preterm delivery and 14 fathers; 52 physicians and nurses
Jolicoeur[9], 2009, Canada	Recurrent ovarian cancer	Interviews and chart review	Informed the interview guide, chart audit and analysis	1 center	13 women with advance stage ovarian cancer
Jull[10], 2016, Canada	Type 1 diabetes	Interviews	Informed the interview guide	community	8 adults with type 1 diabetes for durations of 1 to 20+ years
Kavanaugh[11, 12], 2005, 2009, United States	Extremely premature infants	Case study	Informed the interview guide and analysis	1 inpatient unit at hospital with high-risk perinatal care	6 mothers and 2 fathers; 8 practitioners[12] 1 mother and 1 father; 3 practitioners[13]

Khatri[13], 2011, Canada	Knee osteoarthritis OA	Interviews	Informed the interview guide and analysis	1 orthopaedic clinic	20 patients with grade III or grade IV medial compartment OA of the knee; 14 arthroplasty surgeons
Légaré[14], 2007, Canada	Menopause	Interviews and focus groups	Informed the interview guide and analysis	2 cities	40 peri- or postmenopausal women; 15 physicians, nurses, women's advocacy group, NHP store owners, pharmacists, policy makers
Li[15], 2016, Canada	Genome-wide sequencing (GWS) for child	Interviews and focus groups	Informed the interview guide	1 children's hospital	15 parents who consented to GWS or had children with undiagnosed conditions that were suspected to be genetic in origin
Loiselle[16], 2016, Canada	Renal replacement therapies	Interviews and focus groups	Informed the interview guide and analysis	1 nephrology center	17 patients with CKD; 2 peer helpers, 7 nephrologists and 1 social worker
Marshall[17], 2018, United States	Contraception methods	Interviews	Informed the interview guide	OB/GYN clinic	21 women
Matlock[18], 2011, United States	ICD implantation	Interviews	Used population needs assessment workbook for interview guide	2 hospital clinics	14 patients with ICDs and 6 patients who declined ICDs; 11 cardiologists
Mitra[19], 2006, Canada	HIV testing	Interviews	Informed the interview guide and analysis	1 outpatient clinic for immigrant health and support	8 immigrant and refugee women from HIV endemic countries; 12 practitioners
Moro[20], 2011, United States	Life support for extremely premature infants	Collective case study interviews and chart review	Informed the interview guide	3 hospitals	5 mothers; 8 practitioners
Nijhuis[21], 2016, Netherlands	Advanced Parkinson's disease	Interviews and focus groups	Focus group and interview guides were designed using several decision-making frameworks, e.g., the Cabana model and the ODSF	11 hospital clinics	20 patients who received advanced treatments; 10 practitioners; 16 caregivers

Poirier[22], 2016, Canada	Nutritional approaches for weight loss	Focus groups	Informed the interview guide and analysis	urban community	17 postmenopausal women with abdominal obesity and intention of weight loss
Raynes-Greenow[23], 2007, Australia	Labour pain	Focus groups	Informed the interview guide	Antenatal clinic	25 primiparous women weeks or more gestation planning a vaginal birth
Scheer[24], 2012, Canada	Rectal cancer	Interviews and chart review	Informed the survey	Cancer Assessment Center	30 patients with rectal cancer treated with low anterior resection or abdominoperineal resection
Vandemheen[25] 2006, Canada	Referral for lung transplant for cystic fibrosis (CF)	Interviews	Guided decision aid development	1 cystic fibrosis clinic	3 CF patients who lived within a 2-hour drive from the transplant center
Wilhelms[26], 2017, United States	LVAD placement	Grounded theory interviews	Informed the interview guide	1 Methodist Hospital	15 LVAD patients; 15 LVAD candidates; 15 LVAD decliners; 15 LVAD caregivers (N=60)
Wood[27], 2018, Canada	Cervical cancer	Interviews	Informed the interview guide	Clinics serving vulnerable populations	7 women from minority populations eligible for cervical cancer screening program; 5 practitioners
Quantitative surveys (n=11)					
Bunn[28], 2006, Chile	Multiple health and social decisions	Interview guided survey with DCS	Informed the survey	Primary care centers in an impoverished community	554 adult women registered at primary healthcare centers (57.7% RR)
Döring[#29], 2014, United States	Idiopathic trigger finger	Online survey	Informed the survey	Tertiary hospital	84 newly diagnosed patients (88.4% RR) 105 hand surgeons
duLong[30], 2016, Netherlands	Hip and knee osteoarthritis	Post-intervention survey	Informed the survey	Orthopedic outpatient clinic	172 patients with moderate or severe osteoarthritis in the knee or hip (77% RR) 33 orthopaedic surgeons (50% RR)
Hageman[31], 2014, United States	Carpal tunnel syndrome	Online survey	Informed the survey	Clinic in tertiary care hospital	79 patients with CTS (86.8% RR) 103 hand surgeons

Manne[32], 2016, United States	Breast reconstruction (BR) surgery	Baseline survey	Informed selection of predictors and used in analysis	4 outpatient surgical oncology clinics	55 women with early stage breast cancer (56.7% RR)
O'Connor[33], 2003, Canada	Multiple health and social decisions	Telephone survey	Informed the survey	National communities	635 adults over 18 years of age (42% RR)
Patel[34], 2011, United States	Depression during pregnancy	Online survey	Informed the survey	Online	100 women who were pregnant or had given birth within the past year diagnosed with MDD by a practitioner (44% RR)
Stacey[35], 2002, Canada	High risk for breast cancer	Survey completed in clinic	Informed the survey	High-Risk Breast Assessment Clinic	97 high-risk women
Stacey[36], 2008, Canada	Depression	Interview guided survey	Informed the interview guide	1 psychiatric outpatient clinic; 1 community hospital; 1 inpatient unit on discharge	94 patients diagnosed with either depression or bipolar condition (90.3% RR)
Tan[37,38], 2010, Canada	Psoriasis	Survey	Informed the survey	national online survey	248 patients diagnosed with psoriasis by a physician[37]; 70 dermatologists[38] (15% RR)
Mixed Methods Studies (n=7)					
Baldé[39], 2006, Canada	Sterilization	Interviews	Informed the interview guide and analysis	6 major vasectomy centres	42 men consulting a physician who performs vasectomy; 11 physicians
Blumenthal-Barby[40], 2015, United States	LVAD implantation	Grounded theory interviews and surveys	Informed the interview guide and survey	Hospital and LVAD clinic	15 patients with LVAD and 15 candidates for LVAD (N=30); 15 caregivers
Johnston[41], 2008, Canada	Hearing loss for children including cochlear implants	Interviews	Informed the interview guide and analysis	Canadian cochlear implant centre	8 parents; 8 implant team members (80% RR)
Murray[42], 2003, Canada	Place of care at end-of-life	Survey	Informed the survey	Inpatient & outpatient units	20 women with advanced cancer and life expectancy of <9 months
Ng[43] 2014, United Kingdom	Type 2 diabetes mellitus	Qualitative interviews and focus groups	Guided the presentation of the information and value clarification exercise	Not reported	patients with type 2 diabetes (sample size not reported); practitioners (sample size not reported)

Stacey[44], 2010, Canada	Cancer treatment	Interview-guided survey	Informed the survey	1 outpatient cancer clinic	192 patients on chemotherapy or radiotherapy or both
Stacey[45], 2015, Canada	Body weight management	Interview guided survey	Informed the interview guide and survey	Community neighbourhoods	60 professional women aged 40 to 65 years; 5 practitioners

Characteristics of Participants

Patients and families were typically female (73%; n=1972; 67%; n=106). Practitioners were typically male (62%; n=291). The majority of patients were Caucasian (83%; n=409) and completed post-secondary education (56%; n=568) or high school (22%; n=226). Families were typically Black/African American (42%; n=52) or Caucasian (27%; n=33) and completed post-secondary education (47%; n=29) or high school (18%; n=11). Practitioners were mostly specialists (74%; n=382) (Table 2.4).

Table 2.4 *Participant Characteristics*

	Patients	Family	Practitioners
No. of studies: (N=45)	36	11	21
Total No. of participants	2857	173	523
Gender	33 studies; n=2718	8 studies; n=158	18 studies; n=472
Men	27%	33%	62%
Women	73%	67%	38%
Race/ethnicity	15 studies n=491	7 studies; n=124	N/R
Caucasian	83%	27%	
Black/African American	4%	42%	
Hispanic	3%	18%	
Asian	2%	5%	
Other (e.g. non-white, South Asian, Malay, Chinese, Native American, mixed/biracial)	7%	3%	
Unknown	1%	5%	
Education:	22 studies n=1019	4 studies; n=62	N/R
Grade school	4%	2%	
High School	22%	18%	
Some college	8%	13%	
Post-secondary school	56%	47%	
Graduate/Post-graduate	6%	8%	
Other (e.g. certificate programs)	2%	13%	
Unknown	2%	0	
Marital Status:	20 studies/ n=1304	7 studies; n=114	N/R
Married/common-law/partnered	63%	69%	
Not married/Single	21%	21%	
Separated/Divorced/Widowed	14%	6%	
Partnered/ not living together	0	1%	
Unknown	2%	3%	
Work Status:	11 studies; n=1199	2 studies; n=28	N/R
Employed	36%	53%	
Not employed	52%	39%	
Studying,	5%	4%	
Unknown	7%	4%	
Age (years):	18 – 96 (38 studies)	20 – 79 (4 studies)	20 - >60 (9 studies)
Disciplines:	N/A	N/A	21 studies; n=523
Specialists			74%
Physicians			9%
Nurses/NPs			8%;
Psychologists			4%
Other			5%
Work Setting:	N/A	N/A	20 studies
Hospitals			62%
Community/Primary Care			8%
Outpatient Clinics			31%
Years of Experience:	N/A	N/A	0 - >30 (16 studies)

Quality Appraisal

Of the 27 qualitative studies, 20 (74%) met all of the MMAT quality criteria and seven met two to four of the five criteria (Table 2.5). All qualitative studies used an appropriate approach to answer the research question and adequate data collection methods, 23 described findings that were adequately derived from the data, 24 supported results with quotes, and 23 demonstrated coherence between data sources, collection, analysis and interpretation.

Of the 11 quantitative descriptive studies, two (18%) met all of the MMAT quality criteria and nine met two to four of the five criteria (Table 2.6). Ten quantitative studies had relevant sampling strategies, six had samples that represented the target population, ten used appropriate measurements, and two had low nonresponse bias.

Of the seven mixed methods studies, three (43%) met all of the quality MMAT criteria and four met five of the criteria (Table 2.7). All mixed methods studies had adequate rationale to use a mixed methods research design, and three studies adhered to the quality criteria of each tradition of the method involved. None reported differences between quantitative and qualitative results. No studies were excluded due to quality appraisal findings.

Table 2.5 *MMAT Qualitative Results*

MMAT Qualitative Items	Clear research questions	Data addresses research questions	Qualitative appropriate for research questions	Qualitative methods can address questions	Are findings derived from data	Interpretation of results substantiated by data	Coherence between data sources, collection, analysis, interpretation
Qualitative Studies							
Abdullah, 2013	● □	● □	● □	● □	● □	● □	● □
Balneaves 2016	● □	● □	● □	● □	● □	● □	● □
Culver 2011	● □	● □	● □	● □	● □	◐	◐
Fisher 2017	● □	● □	● □	● □	● □	● □	● □
Vandemheem 2006	● □	● □	● □	● □	▲	● □	◆
Burke 2018	● □	● □	● □	● □	● □	● □	● □
Fisher 2018 (a)	● □	● □	● □	● □	● □	● □	● □
Fisher 2018 (b)	● □	● □	● □	● □	● □	● □	● □
Grobman 2010	● □	● □	● □	● □	◆	● □	● □
Jolicoeur 2009	● □	● □	● □	● □	● □	● □	● □
Jull 2016	● □	● □	● □	● □	● □	● □	● □
Kavanaugh 2005	● □	● □	● □	● □	◆	● □	● □
Kavanaugh 2009	● □	● □	● □	● □	◆	● □	● □
Khatri 2011	● □	● □	● □	● □	◐	◐	◐
Légaré 2007	● □	● □	● □	● □	● □	● □	● □
Li 2016	● □	● □	● □	● □	● □	● □	● □
Loiselle 2016	● □	● □	● □	● □	● □	● □	● □
Marshall 2018	● □	● □	● □	● □	● □	● □	● □
Matlock 2011	● □	● □	● □	● □	● □	● □	● □
Mitra 2006	● □	● □	● □	● □	● □	● □	● □
Moro 2011	● □	● □	● □	● □	● □	● □	● □
Nijhuis 2016	● □	● □	● □	● □	● □	● □	● □
Poirier 2016	● □	● □	● □	● □	● □	● □	● □
Raynes-Greenow 2007	● □	● □	● □	● □	● □	● □	● □
Scheer 2012	● □	● □	● □	● □	● □	◐	◐
Wilhelms 2017	● □	● □	● □	● □	◐	● □	● □
Wood 2018	● □	● □	● □	● □	● □	● □	● □

Note. ● = yes; ◐ = partial yes; ◆ = unclear; ▲ = no

Table 2.6 *MMAT Quantitate Results*

MMAT Quantitative Items	Clear research questions	Data addresses research questions	Sampling strategy relevant to questions	Sample representative of target population	Measurements appropriate	Low risk of nonresponse bias	Statistical analysis appropriate to questions
Quantitative Studies							
Bunn, 2006	● □	● □	● □	● □	● □	● □	● □
Döring 2014	● □	● □	● □	● □	● □	◎	● □
duLong 2016	● □	● □	● □	● □	● □	◎	● □
Hageman 2014	● □	● □	◆	◎	● □	◎	● □
Manne 2016	● □	● □	● □	● □	● □	◎	● □
O'Connor 2003	● □	● □	● □	◎	● □	◎	● □
Patel 2011	● □	● □	● □	◆	● □	▲	● □
Stacey 2002	● □	● □	● □	◎	◎	◆	● □
Stacey 2008	● □	● □	● □	● □	● □	● □	● □
Tan 2010	● □	● □	● □	● □	● □	◎	● □
Tan 2011	● □	● □	● □	◎	● □	▲	● □

Note. ● = yes; ◎ = partial yes; ◆ = unclear; ▲ = no

Table 2.7 *MMAT Mixed Methods Results*

MMAT Mixed Methods Items	Clear research questions	Data addresses research questions	Rationale for mixed methods	Different components integrated to answer questions	Outputs of integration of qualitative and quantitative adequately interpreted	Divergences/inconsistencies between quantitative & qualitative results addressed	Study adheres to quality criteria of each tradition methods
Mixed Methods Studies							
Balde, 2006	●	●	●	●	●	●	●
Johnston 2008	●	●	●	●	●	●	◐
Blumenthal-Barby 2015	●	●	●	●	●	●	◐
Murray 2003	●	●	●	●	●	●	◐
Stacey 2010	●	●	●	●	●	●	●
Ng 2014	●	●	●	●	●	●	◐
Stacey 2015	●	●	●	●	●	●	●

Note. ● = yes; ◐ = partial yes; ◆ = unclear; ▲ = no

Decisional Needs

All of the ODSF decisional needs *categories* were reported in at least 11 of 45 studies: inadequate support and resources (41 studies), inadequate knowledge (40 studies), unclear values (20 studies), decisional conflict (20 studies), needs from personal and clinical characteristics (22 studies) and the characteristics of the decision (19 studies), and unrealistic expectations (11 studies) (Appendix E). All *individual* decisional needs identified within the broader categories were validated in at least two studies.

The five most common manifestations of decisional needs were: (1) having inadequate knowledge of benefits, risks and outcomes (n=29); (2) having inadequate access to information about the health condition, options, benefits, risks, or scientific uncertainties (n=29); (3) feeling unclear about what is important (n=20); (4) feeling unsure about what to choose (n=17); and (5) feeling unsupported in decision-making (n=15).

Modifiable Decisional Needs

Decisional conflict and manifestations.

Of 45 studies, 20 reported behavioural manifestations of decisional conflict in the ODSF from all perspectives (e.g. patients, families and practitioners) (Table 2.8). All behavioural manifestations in the ODSF were reported in at least four studies: feeling unsure about what to choose, worrying what could go wrong if they make a choice, wanting to delay the decision, questioning what is important to them, feeling distressed or upset, wavering between the choices they face, feeling like they cannot get the decision off their minds, and feeling physically stressed (e.g. tense muscles, a racing heartbeat, or difficulty sleeping). The hallmark manifestation, feeling unsure about what to choose, was the most commonly cited manifestation of decisional conflict (17/45 studies). Nearly half of patients reported feeling unsure (1113/2262

patients; 9 studies), worrying about what could go wrong (593/1254 patients; 6 studies), and questioning what was important to them (393/691; 5 studies).

Inadequate knowledge.

Of 45 studies, 40 reported inadequate knowledge (89%) as a decisional need of patients or families (Table 2.8). Inadequate knowledge of benefits, risks & outcomes was the most cited manifestation of this need (29 studies) with 51% of patients (n=356; 9 studies) and 55% of practitioners (n=153; 6 studies) reporting this need. Inadequate knowledge of options was reported in 14 studies followed by inadequate understanding of the condition or situation (11 studies).

Unrealistic expectations.

Eleven of 45 studies (24%) reported unrealistic expectations as a decisional need of patients (Table 2.8). This was reported in five studies as patients' perceptions of the likelihood of outcomes not being aligned with current evidence on the chances of these outcomes. Five studies reported patients did not know the chances of the benefits and risks; 21% of patients (n=129/603; 3 studies) and 8% of practitioners described this need (n=14/186; 2 studies). A new manifestation of unrealistic expectations was patients having difficulty believing that the chances of outcomes applied to them (Matlock et al., 2011).

Table 2.8 *Decisional Needs: Decisional Conflict, Inadequate Knowledge, Unrealistic Expectations and Unclear Values*

Decisional Need Manifestations (and contributing factors)	Total # of Studies (N=45)	Patient Perspective (reported manifestation)	Family Perspective	Practitioner Perspective (reported patients' manifestation)
Decisional Conflict (20 studies)				
2.8.1 Felt *unsure* about what to choose	17	n = 9 studies 49% (1113/2262 patients)*[9,11,13,15,28,30,33,34,36]	n = 1 study 75% (6/8)*[41]	n = 4 studies 28% (51/185)*[5,13,38,39]
2.8.2 *Worried* what could go wrong if they made a choice	8	n = 6 studies 48% (593/1254)*[13,19,28,30,33,36]	n = 1 study 100% (8/8)*[41]	n = 2 studies 76% (29/38)*[13,19]
2.8.3 Wanted to *delay* the decision	8	n = 6 studies 18% (234/1270)* [13,28,30,33,34,36]	N/R	n = 2 studies 27% (7/26)*[13,19]
2.8.4 *Questioned* what was important to them	7	n = 5 studies 57% (393/691)*[13,19,30,33,36]	n = 1 study 13% (1/8)*[41]	n = 2 studies 46% (12/26)*[13,19]
2.8.5 Felt *distressed* or *upset*	6	n = 5 studies 25% (193/776)*[13,19,28,30,36]	n = 1 study 38% (3/8)*[41]	n = 2 studies 42% (11/26)*[13,19]
2.8.6 Wavered between the choices they faced	6	n = 4 studies 19% (230/1237)*[13,28,30,33,36]	n = 1 study 13% (1/8)*[41]	n = 1 study 14% (2/14)*[13]
2.8.7 Felt like they couldn't get the decision *off their minds*	4	n = 3 studies 21% (60/281)*[13,30,36]	n = 1 study 13% (1/8)*[41]	n = 1 study 7% (1/14)*[13]
2.8.8 Felt *physically stressed* (tense muscles, a racing heartbeat, or difficulty sleeping)	4	n = 3 studies 25% (69/281)*[13,30,36]	n = 1 study 38% (3/8)* [41]	N/R
Inadequate Knowledge (40 studies)				
2.8.9 Inadequate knowledge of benefits, risks & outcomes	29	n = 27 studies[3,8,9,10,14,15,17,18,19,21,22,24,25,26,27,28,29,30,31,32,36,37,39,42,43,44,45] 51% (356/693; 9 studies*)	n = 1 study 25% (2/8; 1 study*)[41]	n = 11 studies[6,7,14,19,20,27,29,38,41,43,45] 55% (153/279; 6 studies*)
2.8.10 Inadequate knowledge of options	14	n = 10 studies[2,13,17,19,21,23,27, 28,30,33] 31% (318/1031; 5 studies*)	n = 3 studies[3,7,41] 13% (1/8; 1 study*)	n = 4 studies[13,18,19,30] 41% (32/78; 4 studies*)
2.8.11 Inadequate understanding of condition/situation	11	n = 8 studies[1,2,8,10,12,15,22,27] 50% (11/22; 2 studies*)	N/R	n = 3 studies[6,19,38] 49% (40/82; 2 studies*)

2.8.12 Unaware that a decision needs to be made	4	n = 4 studies[21,24,27,40] 35% (21/60; 2 studies*)	n = 1 study[40] 47% (7/15; 1 study*)	N/R
Unrealistic Expectations (11 studies)				
2.8.13 Perceptions of likelihood of outcomes is not aligned with current evidence of the chances of these outcomes	5	n = 5 studies[14,16,20,23,40] 78% (7/9; 1 study*)	N/R	N/R
2.8.14 Don't know the chances of the benefits, risk	5	n = 5 studies[13,24,30,33,36] 21% (129/603; 3 studies*)	N/R	n = 2 studies[13,30] 8% (14/186; 2 studies*)
NEW:2.8.15 Difficulty believing the chances of outcomes applied to them	*1*	*n = 1 study[18]*	*N/R*	*N/R*
Unclear Values (20 studies)				
2.8.16 Unclear about what is important to them	20	n = 18 studies[4,7,10,13,16,17, 18,27,28,29,30,31,33,36,37,39,40,42] 21% (258/1220; 7 studies*)	N/R	n = 7 studies[5,13,27,29, 31,38,39] 24% (71/292; 4 studies*)

Note. N/R = not reported; Superscript numbers indicate references from Table 2.3
*# of studies reporting proportion of patients who reported needs

Unclear values.

Of 45 studies, 20 (44%) described patients feeling unclear about what is important to them (Table 2.8). In seven studies, 21% (n=258) of patients reported feeling unclear and 24% (n=71; 4 studies) of practitioners reported patients experiencing this need.

Inadequate support and resources.

Of 45 studies, 41 (91%) reported inadequate support and resources as a decisional need (Table 2.9). Twenty-eight studies (62%) reported in the sub-category of inadequate support. The three most common needs were feeling unsupported in decision-making (15 studies), feeling pressure from others (14 studies) and having misperceptions of others' opinions who were involved in the decision (10 studies). Feeling unsupported in decision-making was experienced

by 36% of patients who reported this need (n=435; 9 studies), and 31% of practitioners (n=24; 5 studies) reported patients experienced social pressure during decision-making.

Twenty of 45 studies (44%) reported on the sub-category of inadequate internal resources (decisional experience, self-confidence, motivation, skills) (Table 2.9). The three most reported needs in this subcategory were inadequate skills in decision-making (9 studies), inadequate experience with the situation, options, outcomes, or decision-making process (8 studies), and inadequate motivation to make a decision (7 studies). Having inadequate skills in decision-making was experienced by 25% of patients (n=194; 4 studies). Inadequate experience with decision-making was described as either patients not having had to make a previous decision for themselves (Loiselle et al., 2016) or as being influenced by previous experiences with the situation or outcomes (Burke et al., 2018; Fisher, Manicavasagar, Sharpe, Laidsaar-Powell, & Juraskova, 2018b; Li et al., 2016; Moro et al., 2011). Positive experiences seemed to ease the decision-making processes (Jolicoeur, O'Connor, Hopkins, & Graham, 2009), whereas patients with negative experiences were uncertain in decision-making (Fisher, Manicavasagar, Sharpe, Laidsaar-Powell, & Juraskova, 2017; Marshall, Kandahari, & Raine-Bennett, 2018; Wood et al., 2018). Inadequate motivation was described by patients and practitioners as lacking motivation or not feeling ready to make a decision. Two studies found a correlation between patients who felt uncertain and lacking motivation or readiness to make a decision ($p<0.05$) (O' Connor et al., 2003; Stacey et al., 2008).

As shown in Table 2.9, 39 of 45 studies (87%) reported on the subcategory of inadequate social support (information, advice, emotional support, instrumental help) and other resources (financial assistance, health and social services). The largest number of studies (37/45; 82%) focused on inadequate information (lacking information, information overload, poor quality).

Table 2.9 *Decisional Needs: Inadequate Support and Resources (41/45 Studies)*

Decisional Need	Total # of Studies (N=45)	Patient Perspective (reported manifestation)	Family Perspective	Practitioner Perspective (reported patients' manifestation)
Inadequate Support (28 studies)				
2.9.1 Feeling unsupported in decision-making	15	n = 12 studies[2,13,14,16,19,21,28,29,30,31,33,36] 36% (435/1220; 9 studies*)	n = 2 studies[3,41] 25% (2/8; 1 study*)	n = 6 studies[14,19,30,31,41,45] 9% (15/168; 5 studies*)
2.9.2 Social Pressure	14	n = 12 studies[10,13,14,16,18,19,22,28,30,33,36,37] 16% (115/705; 6 studies*)	N/R	n = 5 studies[13,19,30,39,41] 31% (24/78; 5 studies*)
2.9.3 Unclear/ biased views of others' opinions/ practices - *misperceptions of others' opinions/practices involved in the decision*	10	n = 8 studies[1,13,14,16,17,20,21,23]	n = 1 study[21]	n = 3 studies[5,13,18]
2.9.4 Unclear/ biased views of others' opinions/ practices - *conflicting recommendations from others*	6	n = 5 studies[2,11,13,14,36] 15% (3/20; 1 study*)	N/R	n = 3 studies[2,5,13] 9% (3/34; 2 studies*)
2.9.5 Unclear/ biased views of others' opinions/ practices - *don't know the opinions/practices of others involved in the decision*	1	n = 1 study[17]	N/R	N/R
Inadequate Internal Resources (20 studies): decisional experience, self-confidence, motivation, skills				
2.9.6 Inadequate decision making skills - *to make a decision*	9	n = 8 studies[16,28,30,33,35,36,37] 25% (194/777; 4 studies*)	N/R	n = 3 studies[13,30,38] 7% (3/44; 2 studies*)
2.9.7 Inadequate experience - *Previous experience with situation, options, outcomes, decision-making process, other*	8	n = 7 studies[3,7,9,15,17,20,27] 100% (5/5; 1 study*)[20]	N/R	n = 2 studies[5,20] 10% (2/20; 1 study*)
2.9.8 Inadequate motivation	7	n = 6 studies[13,22,30,33,36,45] 13% (78/603; 3 studies*)	N/R	n = 4 studies[13,30,41,45] 12% (6/52; 3 studies*)
2.9.9 Inadequate experience – *lack of experience*	2	n = 1 study[16]	n = 1 study[41]	N/R

2.9.10 Inadequate self-confidence in decision-making	2	n = 2 studies[16,27]	N/R	N/R
2.9.11 Inadequate decision-making skills - *to implement a decision*	1	n = 1 study[22]	N/R	N/R
Inadequate Social Support and Other Resources (39 studies): information, advice, instrumental help, emotional support, financial assistance, health and social services				
2.9.12 Inadequate access to information about health condition, options, benefits, risks, scientific uncertainties	29	n = 24 studies[1,2,3,7,8,9,10,11,12,13,14,16,21,25,28,29,30,31,35,36,37,43,44,45] 57% (954/1686; 16 studies*)	n = 1 study[7]	n = 12 studies[6,7,11,13,19,21,27,29,31,38,41,43] 39% (42/108; 8 studies*)
2.9.13 Inadequate access to health & social services	15	n = 12 studies[1,7,10,14,15,16,19,22,25,27,37,44] 87% (227/262; 3 studies*)	N/R	n = 6 studies[6,14,19,21,27,38] 33% (9/27; 2 studies*)
2.9.14 Lacking information about what others decide or recommend	14	n = 13 studies[2,4,7,21,25,29,30,31,33,35,39,42,45] 27% (257/965; 8 studies*)	n = 1 study[41] 50% (4/8; 1 study*)	n = 4 studies[29,31,41,45] 5% (11/221; 4 studies*)
2.9.15 Poor quality information	6	n = 5 studies[2,11,14,16,21] 67% (8/12; 2 studies*)	N/R	n = 2 studies[14,41] 13% (1/8; 2 studies*)
2.9.16 Inadequate access to advice - *lacking advice from important others involved in the decision*	6	n = 5 studies[1,2,3,40,42] 33% (10/30; 1 study*)	n = 1 study[40] 40% (6/15; 1 study*)	n = 1 study[31] 23% (24/103; 1 study*)
2.9.17 Inadequate access to financial assistance	6	n = 3 studies[14,22,28] 48% (265/554; 1 study*)	N/R	n = 3 studies[6,38,45] 79% (55/70; 1 study*)
NEW:2.9.18 Too much information "information overload"	*6*	*n = 6 studies[2,13,14,15,16,30]* *8% (16/205; 3 studies*)*	*N/R*	*n = 2 studies[13,30]* *30% (13/44; 2 studies*)*
NEW:2.9.19 Lacking access to (did not receive) information about other's experiences with options (procedures, side effects, outcomes)	*6*	*n = 6 studies[1,3,16,17,18,40]* *87% (26/30; 1 study*)*	*n = 1 study[40]* *33% (5/15; 1 study*)*	*n = 1 study[18]*
2.9.20 Inadequate access to emotional support	3	n = 3 studies[10,16,42] 80% (16/20; 1 study*)	N/R	N/R
2.9.21 Inadequate access to advice - *poor quality advice*	2	n = 2 studies[2,14]	N/R	N/R

from important others involved in the decision				
2.9.22 Inadequate access to instrumental help *(e.g. transportation, housekeeping, daycare, access to caregiver)*	2	n = 2 studies[3,40] 70% (21/30; 1 study*)	n = 1 study[40] 47% (7/15; 1 study*)	N/R
2.9.23 Lacking access to (did not receive) information about the health condition	1	n = 1 study[10] 100% (8/8; 1 study*)	N/R	N/R
2.9.24 Lacking access to (did not receive) information about the chances of benefits and harms/how likely each pro/con	1	n = 1 study[13]	N/R	n = 1 study[13]

Note. N/R = not reported; Superscript numbers indicate references from Table 2.3
*# of studies reporting proportion of patients who reported needs

Of these, the most common manifestation (29 studies) was lacking information about the options (e.g. features of the options, benefits and risks, scientific uncertainties, or navigating the healthcare system). It was experienced by 57% of patients (n=954; 16 studies) and 39% of practitioners reported it (n=42; 8 studies). Fourteen studies reported lacking information about what others decided or recommended, and six studies reported poor quality information (e.g., unreliable, unbalanced, contradictory, too technical) as a manifestation of inadequate social support. Two new manifestations of inadequate information were identified. In six studies, patients and practitioners reported receiving too much information (e.g. "information overload"), and six studies described lacking information about others' experiences with the options (e.g. procedures, side effects, outcomes).

The next most commonly reported need was inadequate access to health and social services (15 studies), which was identified by 87% patients (227/262; 3 studies). Studies also reported inadequate access to advice from important others involved in the decision (6 studies) and inadequate access to financial assistance (6 studies).

Difficult decisional roles and needs.

Of 45 studies, 18 (40%) reported patients' preferred role in decision-making (Table 2.10). Half (10/20; 1 study) of practitioners considered involving patients in decision-making as critically important and 55% (58/106; 2 studies) of patients reported preferring an active role or wanting to be involved in decision-making. Practitioners preferred to share the decision with the patient (68%; 80/117; 2 studies) and patients preferred to make the decision, typically after considering the advice of a practitioner (49%; 127/261; 6 studies).

Family role in decision-making.

Of 45 studies, 20 (44%) reported patients involving or considering important others during decision-making (Table 2.10). Families were involved in the decision as reported by patients (39%; 1115/2864; 10 studies) and practitioners (38%; 110/290; 5 studies).

New manifestations of difficult decisional roles were apparent in 13 studies from the patient, family and practitioners perspective (Table 2.10). Although the ODSF applies to all participants (e.g. patients, families, practitioners), the decisional role needs of families are not explicitly described. Therefore, two new operational definitions were developed to identify decisional role needs of families. The first one was coded as difficulty involving family members in decision-making. Contributing factors were patients not wanting to worry their family and inadequate family knowledge of the condition and treatment options (Fisher et al., 2018b). The second operational definition was difficult sharing family deliberation on options. Contributing factors were that families experienced communication barriers (Burke et al., 2018; Fisher et al., 2018b; Nijhuis, Van Heek, Bloem, Post, & Faber, 2016), had different information needs (Blumenthal-Barby et al., 2015; Fisher et al., 2018b; Nijhuis et al., 2016), and valued outcomes of options differently (Baldé, Légaré, & Labrecque, 2006).

Relationship barriers with practitioners.

Ten studies identified the need to have a relationship with one's practitioner when engaged in decision-making (Table 2.10). Therefore, a new operational definition was created. Contributing factors were a need for trust and established relationships with practitioners during decision-making (Blumenthal-Barby et al., 2015; Kavanaugh, Moro, Savage, Reyes, & Wydra, 2009; Li et al., 2016; Loiselle et al., 2016; Mitra, Jacobsen, O'Connor, Pottie, & Tugwell, 2006; Moro et al., 2011; Wood et al., 2018). One study found the only variable that significantly correlated with less decisional conflict was a stronger patient-practitioner relationship (Pearson rho = -0.49; $P<0.01$) (du Long, Hageman, Vuijk, Rakic, & Haverkamp, 2016). This decisional need was further elaborated as needing clear communication (Kavanaugh et al., 2009; Moro et al., 2011; Nijhuis et al., 2016), mutual respect (Kavanaugh et al., 2009; Nijhuis et al., 2016), empathy and compassionate care (Grobman, Kavanaugh, Moro, Deregnier, & Savage, 2010; Kavanaugh et al., 2009), and honesty (Grobman et al., 2010; Jolicoeur et al., 2009; Kavanaugh et al., 2009; Kavanaugh, Savage, Kilpatrick, Kimura, & Hershberger, 2005).

Table 2.10 *Inadequate Support and Resources: Decisional Role and Needs (33/45 studies)*

Roles in Decision-Making	Total # Studies (N=45)	Patient Perspective (patients reported need)	Family Perspective	Practitioner Perspective (reported patients need)
Preferred Role in Decision-Making (18 studies)				
2.10.1 Patient-led	9	n = 9 studies[1,7,13,14,19,29,31,36,42] 49% (127/261; 6 studies*)	N/R	n = 2 studies[13,31] 29% (34/117; 2 studies*)
2.10.2 Other, Active or involved	8	n = 6 studies[2,3,11,21,23,34] 55% (58/106; 2 studies*)	n = 1 study[40]	n = 1 study[6] 50% (10/20)
2.10.3 Shared	7	n = 7 studies[1,13,14,31,34,36,42] 36% (129/361; 7 studies*)	N/R	n = 2 studies[13,31] 68% (80/117; 2 studies*)
2.10.4 Delegated (led by practitioner or family)	7	n = 7 studies[1,9,13,14,31,34,36] 16% (55/354; 7 studies*)	N/R	n = 2 studies[13,31] 3% (3/117; 2 studies*)
Needs related to preferred and actual role in decision-making (4 studies)				
2.10.5 Mismatch of informed person's preferred and actual role in decision-making	4	n = 4 studies[3,7,9,10] 23% (3/13; 1 study*)	N/R	N/R
Important Others Involved in the Decision (20 studies)				
2.10.6 Family involved in decision	19	n = 17 studies [2,4,7,9,11,14,19,20,28,30,31,33,36,37,42,44,45] 39% (1115/2864; 10 studies*)	n = 1 study[8]	n = 7 studies[14,20,27,29,30,31,45] 38% (110/290; 5 studies*)
2.10.7 Practitioner involved in decision	13	n = 13 studies[4,9,11,14,19,23,29,30,31,33,36,44,45] 39% (483/1248; 9 studies*)	N/R	n = 5 studies[14,19,30,31,45] 41% (60/148; 3 studies*)
2.10.8 Friends involved in decision	10	n = 10 studies[2,4,11,19,28,30,31,36,44,45] 19% (97/503; 5 studies*)	N/R	n = 3 studies[30,31,45] 11% (14/133; 2 studies*)
Needs Related to Difficult Decisional Roles and needs in Decision-Making (13 studies)				
NEW:2.10.9 Needs related to relationship barriers with practitioners	*10*	*n = 2 studies[7,15,16,19,20,21,27,30]*	*N/R*	*n = 2 studies[8,12]*
NEW:2.10.10 Family role in decision-making – difficult shared family deliberation on options	*5*	*n = 2 studies[7,39]*	*n = 4 studies [3,7,21,40]*	*N/R*
NEW:2.10.11 Family role in decision-making – difficulty involving family member in decision-making	*1*	*n = 1 study[7]*	*n = 1 study[7]*	*N/R*

Note. N/R = not reported; Superscript numbers indicate references from Table 2.3
*# of studies reporting proportion of patients who reported needs

Decision Characteristics Influencing Decisional Needs

Decision type influences.

Of 45 studies, 7 (16%) reported characteristics of types of decisions that influenced needs (Table 2.11). The most common decision type characteristics that influenced decisional needs were: outcomes that were valued differently by the affected population (n=3); unknown outcomes (n=2); permanent effects (n=1); and multiple options (n=1). Patients and families valued outcomes differently for decisions regarding life prolongation, lifestyle, and responsibility changes (Matlock et al., 2011; Wilhelms, Blumenthal-Barby, Kostick, Estep, & Bruce, 2017). Parents making decisions for infants valued outcomes, such as pain and suffering, differently which affected their decision-making (Moro et al., 2011). Permanent effects was a concern for 48% (n=20) of men and 45% (n=5) of practitioners in deciding about men's sterilization (Baldé et al., 2006).

Two population surveys found that those making decisions about institutionalization and family issues reported more behavioural manifestations of decisional conflict (Bunn et al., 2006; O' Connor et al., 2003). Decisions about institutionalization were associated with more physical stress (54%; 95% CI 33-74) compared to birth control decisions (23%; 95% CI 15-33) and more decision delay (50%; 95% CI 7-20) compared to surgical decisions (20%; 95% CI 16-34) (O' Connor et al., 2003). Decisions about family issues, such as care for family members, were associated with higher rates of distress compared to other decisions about treatment, screening or reproduction (p=0.028) (Bunn et al., 2006).

Decision timing influences.

Eight studies (18%) reported decision timing influences (Table 2.11). Three studies reported that patients delayed decision-making for decisions where clinical symptoms were absent (Loiselle et al., 2016), not deemed as a high priority compared to other life priorities (Mitra et al., 2006), and when the decision was too far in the future or the active experience was unpredictable (Raynes-Greenow, Roberts, McCaffery, & Clarke, 2007). Patients also had more decisional conflict when there was a longer length in time since diagnosis and the decision being made ($r=.32$, $p < .05$) (Manne et al., 2016).

Decisional stage influences.

Six studies (13%) reported that patients were unreceptive to information or deliberation (Table 2.11). Three new factors contributing to lack of receptivity were identified. First, powerful emotions affected patients' ability to process information (Kavanaugh et al., 2009; Loiselle et al., 2016). Second, patients were unmotivated because the decision was too far off in the future or unpredictable (Raynes-Greenow et al., 2007). Third, patients had difficulty accepting their condition or the need for treatment (Fisher et al., 2017; Fisher, Manicavasagar, Sharpe, Laidsaar-Powell, & Juraskova, 2018a; Loiselle et al., 2016; Mitra et al., 2006). Factors contributing to lack of acceptance included: (1) having no clinical symptoms at the time of decision-making (Loiselle et al., 2016); (2) strong emotional responses (e.g. fear or anxiety) when learning about one's condition or options presented (Loiselle et al., 2016; Mitra et al., 2006; Raynes-Greenow et al., 2007); and (3) having a bipolar condition (Fisher et al., 2017, 2018a).

Personal and Clinical Characteristics Influencing Needs

Of 45 studies, 22 (49%) cited the need for considering clinical and personal characteristics of the patient and the need for tailoring decision support according to these characteristics (Table 2.11). In 16 studies, patients, families, and practitioners reported the need to consider health status (e.g. physical, cognitive, and emotional functioning) when providing decision support. Physical limitations included active or unresolved medical problems impairing decision-making (e.g. sedating medications, unresolved pain or weakness, or disrupted sleep/wake cycle) (Burke et al., 2018; Fisher et al., 2017; Jolicoeur et al., 2009; Légaré et al., 2007; Loiselle et al., 2016; Stacey et al., 2008). Cognitive limitations included cognitive impairment or memory problems (Légaré et al., 2007; Loiselle et al., 2016) and emotional limitations were distress, fear, anxiety, worry, uncertainty, frustration, and feeling out of control (Li et al., 2016; Loiselle et al., 2016; Matlock et al., 2011; Stacey et al., 2008). Emotions were related to a new or progressing condition (Abdullah et al., 2013; Jull, Witteman, Ferne, Yoganathan, & Stacey, 2016; Li et al., 2016; Wilhelms et al., 2017) or *fear of the unknown* regarding outcomes of the options (Baldé et al., 2006; Balneaves et al., 2016; Fisher et al., 2017; Marshall et al., 2018). Four studies reported the need to tailor decision support according to patients' health status (Fisher et al., 2017, 2018a; Loiselle et al., 2016; Matlock et al., 2011).

Eight studies mentioned the need to consider sociodemographic characteristics and five studies described tailoring information accordingly. For example, being female in a large population-based study was associated with more decisional conflict (O' Connor et al., 2003). Decisional conflict was lower in older patients in one larger population-based study in primary care (O' Connor et al., 2003) and higher in another (Bunn et al., 2006). Information needs also varied across different age ranges (Bunn et al., 2006; Nijhuis et al., 2016; Stacey, DeGrasse, &

Johnston, 2002) and was influenced by health literacy (Fisher et al., 2018a; Légaré et al., 2007; Stacey, Paquet, & Samant, 2010). Patients who had a more dependent role in decision-making were typically older or had lower education (O' Connor et al., 2003).

Table 2.11 *Decisional, Personal and Clinical Characteristics Influencing Needs*

Characteristic	Total # of Studies (N=45)	Patient Perspective (patients reported need)	Family Perspective	Practitioner Perspective (reported patients need)
Decisional Characteristics (19 studies)				
Decision Type (7 studies)				
2.11.1 Outcomes are *valued differently by affected population*	3	n = 2 studies[18,26]	n = 2 studies[20, 26]	N/R
2.11.2 Outcomes have *permanent effects*	1	n = 1 study[39] 48% (20/42; 1 study*)	N/R	n = 1 study[39] 45% (5/11; 1 study*)
2.11.3 Unknown outcomes	2	n = 2 studies[5,7]	N/R	n = 1 study[5]
2.11.4 Multiple options	1	n = 1 study[17]	N/R	N/R
Decision Timing (8 studies)				
2.11.5 Delayed	4	n = 4 studies[16,19,23,32]	N/R	N/R
2.11.6 Decision needs to be made soon	3	n = 2 studies[1,3]	N/R	n = 1 study[11]
2.11.7 Urgent	2	n = 2 studies[9,16] 8% (1/13; 1 study*)	N/R	N/R
Decisional Stage (6 studies)				
NEW:2.11.8 Unreceptive to information/deliberation due to powerful emotions that limit information processing	*2*	*n = 2 studies[11,16]*	*N/R*	*N/R*
NEW:2.11.9 Unreceptive to information/deliberation due to being unmotivated because the decision is too far off into the future or unpredictable	*1*	*n = 1 study[23]*	*N/R*	*N/R*
NEW:2.11.10 Unreceptive to information/deliberation due to lack of acceptance of condition or treatment	*4*	*n=2 studies[16,19]*	*N/R*	*n = 2 studies[5,6]*

Contributing factors to unreceptive to information/deliberation from lack of acceptance of condition/need for treatment:				
NEW:2.11.10a Acceptance of condition/treatment impaired by strong emotional responses to their condition or options	3	n = 3 studies[16,19,23]	N/R	N/R
NEW:2.11.10b Acceptance of condition/treatment impaired by lack of clinical symptoms	1	n = 1 study[16]	N/R	N/R
NEW:2.11.10c Acceptance condition/treatment impaired by clinical condition (bipolar condition)	2	N/R	N/R	*n = 2 studies[5,6]*
Personal & Clinical Characteristic Needs (22 studies)				
2.11.11 Clinical - *special needs considering diagnosis & duration of condition, & health status (physical, emotional, cognitive, social)*	16	n = 14 studies[1,2,3,9,10, 14,15,16,17,26,33,36,37,39]	n = 2 studies[3,15]	n = 3 studies[5,14,18,39]
2.11.12 Personal - *special needs considering age, gender, education, marital status, ethnicity, occupation, locale, socioeconomic status*	8	n = 6 studies[11,16,28,33, 34,35]	N/R	n = 2 studies[5,21]
2.11.13 Personal - *need for tailored information to meet age, developmental stage, gender, ethnicity, or education*	5	n = 3 studies[14,18,21]	N/R	n = 2 studies[5,6]
2.11.14 Clinical - *need for tailored information to meet diagnosis or its duration*	4	n = 2 studies[16,18]	N/R	n = 2 studies[5,6]

Note. N/R = not reported; Superscript numbers indicate references from Table 2.3
* # of studies reporting proportion of patients who reported influencing characteristics on needs

Practitioners also described tailoring decision support to patients' social background or life circumstances (Fisher et al., 2017; Nijhuis et al., 2016). A new personal characteristic identified was considering religious faith as an important factor in decision-making (Kavanaugh et al., 2005).

Discussion

The objectives of this systematic review were to synthesize evidence on decisional needs to validate existing concepts of decisional needs in the ODSF and to identify any new decisional needs. All of the ODSF decisional needs categories were validated in at least 11 of 45 studies: inadequate support and resources (n=41 studies), inadequate knowledge (n=40), unclear values (n=20), decisional conflict (n=20), needs from personal and clinical characteristics (n=22) and the characteristics of the decision (n=19), and unrealistic expectations (n=11). All individual decisional needs identified within the broader categories were validated in at least two studies. The five most common manifestations of decisional needs were: (1) having inadequate knowledge of benefits, risks and outcomes (n=29); (2) having inadequate access to information about the health condition, options, benefits, risks, or scientific uncertainties (n=29); (3) feeling unclear about what is important (n=20); (4) feeling unsure about what to choose (n=17); and (5) feeling unsupported in decision-making (n=15). Additionally, the ODSF operational definitions of decisional needs were updated and nine new manifestations of decisional needs were identified. These results led to three observations.

First, the ODSF decisional needs were present in 29 health decisions and seven countries. This is a broader context since the ODSF was first published in 1998, which was applied to one health decision (menopause) in one country (Canada) (O'Connor et al., 1998). Yet, the five most frequent decisional needs remain the same. Patients' most frequent decisional need manifestation is inadequate information and knowledge, but there are significant decisional needs beyond what providing factual information will address. Our finding of patients having more than just informational needs is consistent with other systematic reviews assessing decisional needs (Jackson et al., 2008; St-Jacques et al., 2008).

Given the identification of consistent decisional needs across a wide range of decisions, practitioners should screen for modifiable decisional needs and influential factors that can make the decision even more difficult. This is also consistent with the findings of another systematic review of decisional needs that focused on parental decision support needs regarding child health decisions (Jackson et al., 2008). One way to screen for modifiable decisional needs is by using the SURE test which asks patients four questions: (1) do you feel SURE about the best choice for you; (2) do you know the benefits and risks of each option; (3) are you clear about which benefits and risks matter most to you; and (4) do you have enough support and advice to make a choice (Légaré et al., 2010). These screening questions correspond with the five most frequent decisional need manifestations identified in our review.

Second, we identified nine new manifestations of decisional needs and contributing factors, which required us to update the operational definitions of inadequate support and resources (information and decisional role and needs), decisional stage needs, and unrealistic expectations. The new manifestations of inadequate information were information overload (6 studies) and lacking information about other's experiences with options (6 studies). Information overload was identified in decisions related to menopause (Balneaves et al., 2016; Légaré et al., 2007), osteoarthritis (du Long et al., 2016; Khatri, O'Connor, & Dervin, 2011), renal replacement therapies (Loiselle et al., 2016) and genome-wide sequencing for a child (Li et al., 2016). Information overload has been identified as a factor in another study for influencing decisions for patients with chronic kidney disease (Registered Nurses Association of Ontario [RNAO], 2009). However, this factor has not been extensively studied in healthcare and a systematic review on information overload in consumer health-related information is underway (Lee, Roehrer, & Cummings, 2017). In management sciences, potential outcomes of information overload are

linked to ignoring information, misinterpretation, more stress, potential paralysis, and delaying decisions (Eppler & Mengis, 2004). Feeling confused from information overload is an assessment component in the Jacobsen et al., (2013) workbook, "Decisional Needs in Populations", which is informed by the ODSF, but is not explicitly included in the ODSF itself. The ODSF requires updating to reflect this finding.

Regarding lacking access to information about other's experiences, patients described the need for vicariously imagining the experiences of options regarding breast cancer treatment (Abdullah et al., 2013), location for post-acute care (Burke et al., 2018), renal replacement therapies (Loiselle et al., 2016), contraception methods (Marshall et al., 2018), and implantable cardiac devices (Blumenthal-Barby et al., 2015; Matlock et al., 2011). Vicarious experience helps people to judge how they value the features of an option (O'Connor et al., 1998). Moreover, the opportunity to hear first-hand personal experiences of others in similar situations can help to reassure patients and ease their decision-making (Jackson et al., 2008; St-Jacques et al., 2008). Note that this need differs from the need for information on how other patients deliberate on decisions, which is already captured in the ODSF (O'Connor, 2006).

Regarding the decisional stage need of being unreceptive to information and/or deliberation, three new contributing factors were identified. The first was powerful emotions that impaired information processing (Kavanaugh et al., 2005; Loiselle et al., 2016). Patients experiencing powerful emotional responses required additional support prior to providing information, as well as, throughout decision-making stages (Loiselle et al., 2016). The second contributing factor was lack of acceptance of the condition or need for treatment, which was reported for decisions associated with chronic illness. Patients' difficulty accepting their condition or need for treatment occurred in patients who did not have clinical symptoms to cue

them to their worsening kidney disease (Loiselle et al., 2016), had strong emotional responses (e.g. fear or anxiety) to their condition or information about options (Loiselle et al., 2016; Mitra et al., 2006; Raynes-Greenow et al., 2007), or, in the case of having a bipolar condition, had fluctuating attitudes to the diagnosis and medications (Fisher et al., 2017, 2018a). This has implications for decision support steps outlined in the ODSF. For example, when patients have strong emotional responses to the condition or options, such as fear or anxiety, they need to have their emotions acknowledged and if possible, managed (Jackson et al., 2008; Loiselle et al., 2016; St-Jacques et al., 2008). An assessment for lack of acceptance of the condition or need for treatment could be integrated into the ODSF as the first step in providing decision support.

The third contributing factor to lack of receptivity to information and/or deliberation was being unmotivated because the condition is unpredictable. For example, women were reluctant to make decisions about labour analgesic methods because they did not know what to expect and felt the need to remain flexible in their labour plans (Raynes-Greenow et al., 2007). This finding is similar to O'Brien, Butler and Casey (2017) and Kingdon et al., (2009) who also argued decision-making in child birth can be unpredictable and is dependent on labour circumstances and actual experiences of childbirth. In this context, women described needing to have a sense of trusting and established relationships with practitioners who are involved in labour and delivery decisions (O'Brien et al., 2017).

Regarding inadequate support and resources, three new manifestations of difficult decisional roles and needs emerged. The first new manifestation focused on relationship barriers with practitioners describing a need for a trusting and established relationship with the practitioner during decision-making (Blumenthal-Barby et al., 2015; Kavanaugh et al., 2009; Li et al., 2016; Loiselle et al., 2016; Mitra et al., 2006; Moro et al., 2011; Wood et al., 2018) and is

a recognized facilitator of shared decision-making (Boland et al., 2019; Gulbrandsen et al., 2016; Lown, Hanson, & Clark, 2009). Therapeutic relationships aim to advance the best interest and outcomes for the patient or family, which is fundamental to nursing practice and quality decisions (O'Connor et al., 1998; Registered Nurses Association of Ontario [RNAO], 2002). Conveying trust, respect, empathy, and validation can help establish therapeutic relationships with patients and families (RNAO, 2002). These qualities could be incorporated more explicitly into the ODSF decision support strategies in helping patients and families progress in decision-making.

The other two new manifestations of difficult decisional roles and needs were difficultly involving family in decision-making and difficulty sharing deliberations with family. The majority of included studies reported patients involving or considering important others during decision-making. Family role needs were emphasized when patients had greater needs or when the decision relied on families to take on a caregiver role (e.g. chronic or debilitating conditions) (Baldé et al., 2006; Blumenthal-Barby et al., 2015; Burke et al., 2018; Fisher et al., 2018b; Nijhuis et al., 2016). Similarly, a systematic review of patient-family-practitioner decision-making found that patients with higher needs were more likely to involve family (Laidsaar-Powell et al., 2013). The features of options can impact family members and patients often rely on others to help support them during the decision-making process and to successfully implement a chosen option (de Rosenroll, Higuchi, Dutton, Murray, & Stacey, 2013; Murray et al., 2009). Our results highlight that families often have their own decisional needs specific to unclear values and being uninformed that also need to be assessed and considered in decision-making, which is consistent with the literature (de Rosenroll et al., 2013). Assessing needs related to family role in decision-making could be made more explicit in the ODSF so that

tailored decision support interventions can be provided. One example of a decision support intervention to enhance deliberation discussions between a patient and his/her family is the Ottawa Personal Decision Guide for Two (https://decisionaid.ohri.ca/docs/das/OPDGx2.pdf) which is designed to help people involved in the decision to identify their decision-making needs, so they can be shared, compared and discussed (Feenstra, Lawson, Harrison, Boland, & Stacey, 2015). This decision guide and the ODSF could be updated to include a more explicit assessment of needs related to family role in decision-making.

Strengths and Limitations

Our study protocol was developed a-priori and was registered in PROSPERO (Appendix C). The data included in this review were independently screened and extracted by two authors. Our research team also included experts in the field of shared decision-making, creators of the ODSF and an academic librarian and researchers with experience in the conduct of systematic reviews.

There are a few limitations to this systematic review. First, only studies that used the ODSF were included, therefore decisional needs found in studies using other frameworks or methodologies were not eligible. Second, our study may also be subject to publication bias as only peer-reviewed journals are included; however, we had an exhaustive search, identified 45 studies from across a range of health and social decisions, and did not exclude any studies based on the quality appraisal ratings. Third, we also may have missed needs assessments embedded in PtDA development papers if decisional needs were not listed as an objective of the study.

Conclusion

This is the first synthesis of decisional needs based on the ODSF for patients and families making health or social decisions. All of the decisional needs identified in the ODSF were

validated and we analyzed new manifestations of decisional needs to be added to the ODSF. The array of decisional needs that were identified can guide practitioners in tailoring their decision support and monitoring the effects. Furthermore, the new operational definitions in the coding manual may help future researchers conduct needs assessments. Operational definitions can also be used in training. Our findings will be used to update the ODSF, online tutorial, and needs assessment surveys and interview guides.

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Chapter Three

What is the effectiveness of patient decision aids developed using the Ottawa Decision Support Framework? Sub-analysis of a systematic review

Abstract

Background

An assertion of the Ottawa Decision Support Framework (ODSF) is that patient decision aids (PtDAs), as decision support interventions, improve quality decision-making by addressing decisional needs. The ODSF has been used for 20 years to develop PtDAs, but there is no formal analysis of the effectiveness of ODSF-based PtDAs.

Purpose

To determine the effectiveness of PtDAs developed using the ODSF for patients facing health decisions compared to usual care.

Methods

A sub-analysis of randomized controlled trials included in a 2017 Cochrane review of PtDAs. Trials were eligible if they evaluated a PtDA that was developed based on the ODSF compared to usual care in adults considering a treatment, screening or prevention decision. Primary outcomes were based on the ODSF. Meta-analysis was conducted for outcomes with similar measurements and others were reported descriptively.

Results

Of 105 trials, 24 evaluated PtDAs developed using the ODSF. Compared to usual care, ODSF-based PtDAs improved knowledge (MD 13.85; 95% CI 10.32-17.37; 14 trials), increased accurate risk perceptions (RR 2.41; 95% CI 1.66-3.48; 7 trials), increased the likelihood of choosing an option congruent with values (RR 1.32; 95% CI 1.09-1.59; 6 trials), reduced perceived decisional needs as measured using the Decisional Conflict Scale (MD -5.92; 95% CI -8.58 to -3.26; 15 trials), and lowered the proportion of patients who were undecided (RR 0.65; CI 0.50-0.83; 13 trials).

Conclusion

Twenty-four PtDAs developed based on the ODSF were evaluated and showed patients had improved decision quality and fewer decisional needs; thereby validating the assertion of the ODSF.

Background

Patient decision aids (PtDAs) are effective interventions for supporting patient involvement in decision-making when decisions have more than one option and when patients may value features of the options differently (Stacey, Légaré, et al., 2017; Stacey, 2016). At a minimum, they make explicit the decision, provide information on the disease/condition, options, benefits, harms, scientific uncertainties, and help patients clarify their values by describing outcomes and/or asking the patient to rate the importance of benefits and harms (Elwyn et al., 2006; Joseph-Williams et al., 2013).

A systematic review identified 105 randomized controlled trials (RCTs) of PtDAs compared to usual care (Stacey, Légaré, et al., 2017; Stacey, Légaré, & Lewis, 2017). Patients exposed to PtDAs have: (a) improved knowledge about options, benefits and harms (GRADE: high quality evidence); (b) reduced decisional conflict from feeling uninformed and unclear about personal values (high quality evidence); (c) increased participation in decision-making (moderate quality evidence); (d) more realistic expectations (moderate quality evidence); and (e) better congruence between their values and the option chosen (low quality evidence).

Beyond the minimal elements, the structure of PtDAs depends on the developer and is often influenced by the theoretical framework guiding the development of the PtDA. A review of theories used in the development of PtDAs included in a Cochrane review showed that 34% reported the use of theories (Durand, Stiel, Boivin, & Elwyn, 2008). Of these, the Ottawa Decision Support Framework (ODSF) was the most commonly utilized.

The ODSF is a theoretical framework that was first published in 1998 when PtDAs were emerging and was updated in 2006 and 2018 (O'Connor et al., 1998; O'Connor, 2018; O'Connor, 2006). Based on expectancy value, decisional conflict, and social support theories, it

guides practitioners in supporting patients making difficult decisions with multiple options, unknown outcomes, and known outcomes that patients value differently (O'Connor et al., 1998). The premise of the ODSF is that unresolved decisional needs adversely affects decision-making; decision support that addresses these needs improves the quality of decisions (informed by the best available evidence and congruent with a patient's personal values) (O'Connor et al., 1998; O'Connor, 2018; O'Connor, 2006). Better decision quality favourably affects actions (e.g. decision delay and continuance of chosen option), which has positive downstream impacts on values-based health outcomes, regret and blame, and the appropriate use and cost of health services (O'Connor, 2018; O'Connor, 2006).

Decisional needs include decisional conflict (personal uncertainty about the best course of action), inadequate knowledge, unrealistic expectations, unclear values, and inadequate support and resources (O'Connor, 2018). Decision support interventions are provided as clinical counseling, PtDAs, and decision coaching. PtDAs have the highest level of evidence indicating their effectiveness on decision quality (Stacey, Légaré, et al., 2017). PtDAs developed using the ODSF are designed to: (a) make explicit the decision and guide people to deliberate about options in a series of steps; (b) inform about the health condition, options and possible outcomes of options using the latest quality-rated scientific evidence; (c) create realistic expectations by using diagrams that show our best scientific estimate of what happens to 100-1000 people like them; (d) clarify personal value or importance of the benefits and risks or side effects of options using a rating scale; and (e) guide patients to communicate to their practitioner their knowledge of options, personal values, current leaning toward options, unresolved decisional needs; and next steps (O' Connor et al., 2015). Most ODSF-based PtDAs are designed to be used after patients are informed about their condition and the need to consider options, and also before they

have a follow-up consultation with their practitioner (O' Connor et al., 2015). Patients can provide a summary of their completed PtDA to their practitioner as a way to communicate their needs and preferences. Some of the older versions of the ODSF-based PtDAs also included balanced narratives of how other patients have made the decision (O'Connor et al., 1999; Ottawa Hospital Research Institute, 2015). Some of the newer ODSF-based PtDAs include the SURE test, which can help screen for unresolved decisional needs (Légaré et al., 2010; O' Connor et al., 2015).

Given that the ODSF has influenced PtDA development over the last 20 years, it is important to consider if ODSF-based PtDAs resolve patients' decisional needs and improve decision quality. However, no formal analysis focused on ODSF-based PtDAs has been done.

Purpose

The overall aim was to determine the effectiveness of PtDAs developed using the ODSF for patients facing health decisions compared to usual care.

Methods

Study design

This study is a sub-analysis of RCTs included in the 2017 Cochrane review, "Decision Aids for People Facing Health Treatment or Screening Decisions" (Stacey, Légaré, et al., 2017). Methods were guided by the "Cochrane Handbook for Systematic Review of Interventions" (Higgins, 2011). Full details about the methods are available in the 2017 Cochrane review (Stacey, Légaré, et al., 2017). In the 2017 Cochrane review, the following electronic databases were searched from inception to April 2015: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (Ovid), Embase (Ovid), PsycINFO (Ovid), and CINAHL (Ovid). Trial registries were searched as well as grey literature using the same timeline. Eligible trials

evaluated a PtDA about a health decision for a patient or family member compared to usual care (e.g. groups exposed to usual care, general information, clinical practice guideline, placebo intervention, or no intervention). Excluded studies evaluated decisions that were hypothetical, advance care planning, or lifestyle. Details about the search strategies and MeSH terms are available in the 2017 Cochrane review. A total of 46,054 citations were identified through database searching and 258 through additional sources; 105 RCTs of PtDAs were extracted and included in the 2017 Cochrane review.

For this sub-analysis study, eligible studies were RCTs included in the 2017 Cochrane review that included a PtDA developed based on the ODSF. All 105 trials included in the 2017 Cochrane review were reviewed by two independent reviewers (LH, AO) to determine if the ODSF was used to guide PtDA development. If the development of the PtDA was not well described, the original development papers or the PtDA itself were obtained and reviewed. Reviewers' disagreements and uncertainties were resolved through discussion and when necessary, involved a third reviewer (DS).

Data Extraction

In the 2017 Cochrane review, data extraction was conducted by two independent reviewers and disagreements were resolved by discussion or a third party. For this study, the only extra data that was extracted was information on the framework(s) used to develop the PtDA.

Primary Outcomes

The primary outcomes in this sub-analysis focused on the assertion of the ODSF, that the PtDAs would improve decision quality by addressing decisional needs. Decision quality indicators were defined as informed (knowledge and accurate risk perception) and values-based

choice (choice is congruent with patients' informed values). The extent to which decisional needs were resolved was defined as reductions in patients' perceptions of feeling uninformed, having unclear values, feeling unsupported, and having made an ineffective decision. An additional primary outcome focused on reduced decision delay. These were primary outcomes reported in the 2017 Cochrane review (Stacey, Légaré, et al., 2017).

Decision quality.

Knowledge.

The ODSF defines knowledge as the cognizance of the health condition or situation, the options available, and their consequences (e.g. benefits and risks) (O'Connor et al., 1998). In the trials, participants' knowledge was tested based on their answers to information in a PtDA (Stacey, Légaré, et al., 2017). The knowledge scores reported in the trials were transformed to percentage scales ranging from 0% (no correct responses) to 100% (all correct responses) (Stacey, Légaré, et al., 2017).

Accurate risk perceptions.

The ODSF defines expectations as a patient's perception of the likelihood of outcomes occurring (e.g. benefits and risks) (O'Connor et al., 1998). Accurate risk perceptions were measured as patients who accurately perceive the probabilities of outcomes of patients in similar contexts based on scientific evidence (Stacey, Légaré, et al., 2017).

Congruence between chosen option and values.

The ODSF defines values as the personal desirability of the outcomes and features of the options (O'Connor et al., 1998). We assessed the congruence between the chosen option and the informed patient's values (Stacey, Légaré, et al., 2017).

Reduction in decisional needs.

The five subscales in the Decisional Conflict Scale (DCS) were used to measure the extent to which PtDAs reduced patients' perceptions of feeling uncertain about the best choice for them, uninformed, unclear about personal values, unsupported in decision-making, and having made an ineffective decision. Each of these subscales obtain a rating from three to four scoring items that contributes to the total decisional conflict score (O' Connor, 1993). The total scores and subscale scores from trials that used the DCS were transformed to a percentage scale ranging from 0 (no decisional conflict) to 100 points (extreme decisional conflict) (Stacey, Légaré, et al., 2017).

Decision actions.

Delayed decision-making.

The ODSF hypothesizes that when decisional needs are addressed, patients are less likely to delay decisions (O'Connor et al., 1998). We assessed the proportion of participants who remained undecided in the trials to evaluate decision delay.

Secondary Outcomes

Secondary outcomes from the ODSF were hypothesized improvements on actions (continuance or adherence with chosen option) and downstream impacts (values-based health outcomes, regret, blame, and appropriate use and cost of health services (O'Connor, 2018; O'Connor, 2006; Stacey et al., 2009). Additional secondary outcomes were the remaining primary outcomes in the 2017 Cochrane review (patient-practitioner communication, participation in decision-making, and satisfaction with the choice, with the process of decision-making, and with the preparation for decision-making) (Stacey, Légaré, et al., 2017) that are not outcomes in the current ODSF (O'Connor, 2018).

ODSF outcomes.

Adherence with chosen option.

The ODSF hypothesizes that when decisional needs are addressed, patients are more likely to continue with, or adhere to, their chosen option (O'Connor et al., 1998). We assessed if included trials measured adherence to chosen option.

Values-based health outcomes.

Difficult decisions have no clear best answers in terms of overall health outcomes and therefore involve making value trade-offs between benefits versus harms (O'Connor et al., 1998). The ODSF proposes that improving quality decision-making will favourably impact patient's values-based health outcomes. For example, did patients achieve outcomes they valued most and avoid outcomes they valued least? We assessed if included trials measured values-based health outcomes.

Decisional regret and blame.

The ODSF proposes that improving quality decision-making will favourably impact patients' regret and blame (O'Connor, 2018; O'Connor, 2006). This hypothesis is based on the observed positive correlations between decisional needs (higher DCS scores) and regret (Brehaut et al., 2003) and blame (Gattellari & Ward, 2005). We assessed if included trials measured decisional regret and blame.

Appropriate use of resources.

According to the ODSF, when the quality of decision-making is improved, it may favourably impact on the use and costs of health services by reducing the over-use of services that informed patients don't value and increasing the under-use of services that they do value

(O'Connor, 2018; O'Connor, 2006). We assessed if included trials measured cost-effectiveness or resource use of interventions.

Other primary outcomes of the 2017 Cochrane review.

Remaining primary outcomes of the 2017 Cochrane review were other decision-making process variables including patient-practitioner communication, participation in decision-making, and satisfaction (with the choice, with the process of decision-making, and with the preparation for decision-making) (Stacey, Légaré, et al., 2017). While these variables are not outcomes in the current ODSF (O'Connor, 2018), we assessed them for information purposes to see how ODSF PtDAs perform regarding other primary decision-making process outcomes included in the larger review.

Data Analysis

Analysis was consistent with the methods used in the Cochrane review (Stacey et al., 2017). Briefly, dichotomous outcomes were analyzed based on the number of events and the number of people assessed in the intervention and comparison groups. This data was used to calculate the risk ratio (RR) with a 95% confidence interval. For continuous measures, data was analyzed based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% confidence intervals (CI). A random-effects model was used because of the diverse nature of the decision types being combined, and we anticipated variability in the populations, decision types and control comparisons of the included trials. Although this study focused on ODSF-based PtDAs, we also compared and discussed findings from this sub-analysis to an analysis of non-ODSF based PtDA trials.

Risk of Bias

In the 2017 Cochrane review, two reviewers independently assessed risk of bias using the "Cochrane Risk of Bias Tool" (Higgins, 2011; Stacey et al., 2017). Disagreements were resolved by consensus and/or third party, as needed. In this sub-analysis, all trials had domains with low risk of bias scores. Two studies were judged to have high risk of bias in two domains due to attrition bias (Chambers et al., 2012) and for having unclear blinding of participants (Man-Son-Hing et al., 2000).

Unit of analysis issues.

Four studies in this sub-analysis (Allen et al., 2010; Mathers et al., 2012; McAlister et al., 2005; Nagle et al., 2008) used cluster randomization methods and the adjusted data factoring in the ICC used in the 2017 Cochrane review was also used for this sub-analysis.

Results

Characteristics of studies

Of 105 trials in the 2017 Cochrane review, 24 trials evaluated a PtDA developed using the ODSF (7,278 participants). Inter-rater agreement between the two independent reviewers was 94.3% (99/105); six studies required discussion with the third reviewer. Of these 24 trials, four used the ODSF with other frameworks and theories including the International Patient Decision Aids Standards (IPDAS) (Chabrera et al., 2015), edutainment (Jibaja-Weiss et al., 2011), social cognitive theory, the precaution adoption model, elaboration likelihood model (McBride et al., 2002), and the Medical Research Council (United Kingdom) framework (Schwartz et al., 2009).

Characteristics of included trials are in Table 3.1. The 24 trials were conducted in five countries including Australia, Canada, Spain, United Kingdom and United States. ODSF PtDAs were based on health treatment decisions (n=11; 46%), screening decisions (n=7; 29%) and

prevention decisions (n=6; 25%). The decisions focused on clinical areas which included cancer (11/24; 46%), and obstetrics (3/24; 13%), with the remaining PtDAs focused in various clinical areas: menopausal treatments (2/24; 8%), stroke prevention (2/24; 8%), autologous pre-donation (Laupacis et al., 2006), type II diabetes (Mathers et al., 2012), coronary angiography (Schwalm, Stacey, Pericak, & Natarajan, 2012), cystic fibrosis (Vandemheen et al., 2009), immunization (Chambers et al., 2012) and osteoporosis (Oakley & Walley, 2006).

Participants' ages ranged from 16 to 87 (data in 13 trials; 4606 participants) (Table 3.2). Participants' sex was 56% (4087/7278) female and 44% (3186/7278) male. The majority of participants (44%) were Caucasian (data in 7 trials; 3018 participants) and were high school (33%) or college graduates (28%) (data in 20 trials; 6912 participants).

Table 3.1 *Characteristics of Included Trials*

Author, Year, Country	**Health Decision**	**# of Participants (PtDA+ Usual Care groups)**	**PtDA Format**	**Comparison**	**Outcomes** (*primary outcomes of study) **(Bold = ODSF outcomes)**
Health Screening (n=7)					
Allen, 2010, United States	Prostate cancer	398 + 414 aged 45–70 years	Computer-based	Usual care	**Decisional status*, knowledge*,** self-efficacy*, **consistency between values and decision*,** involvement in decision-making**, decisional conflict;** preferred options
Lepore, 2012, United States	Prostate cancer	244 + 246 African American men aged 45-70 years	Written material plus standard educational pamphlet and telephone education	Educational pamphlet and telephone education about fruit and vegetable consumption	**Knowledge*, decisional conflict*, benefit-to-risk ratio of testing,** physician visit to discuss testing*, **adherence to choice;** PSA screening, anxiety
Mathieu, 2007, Australia	Mammography for women aged ≥70	367 + 367 aged 70–71 years	Written material	Information brochure	**Informed choice***, **knowledge***, **decisional conflict***, **objective and perceived risk of breast cancer***; actual decision*, preference/intention, anxiety, breast cancer worry, attitudes about screening
Mathieu 2010, Australia	Mammography for women aged 40-49	117 + 204 aged 38-45 years	Computer-based	Delayed access to PtDA	**Knowledge***, **decisional conflict, undecided**; intent to start screening, anxiety
McCaffery, 2010, Australia	Cervical cancer	104 + 104 + 106 aged 16-70 years	(design material not indicated)	Direct referral to 2 controls: HPV DNA testing group and repeat smear testing group	**Knowledge,** emotional (distress), cognitive effects**;** quality of life*, behavioural
Nagle, 2008, Australia	Prenatal testing of fetal abnormalities	167 + 171 aged ≥ 18 years	Written material	Usual care (pamphlet)	**Informed choice*, decisional conflict***; anxiety, depression, attitudes to the pregnancy/fetus and acceptability of the resource
Schroy, 2011, U.S.	Colorectal cancer	212(a) + 223(b) + 231 aged 50-75 years	Computer-based 2 groups: a) PtDA and b) PtDA plus personalized	Directed to prevention website	**Knowledge*,** satisfaction with decision-making process*, **test concordance*;** preferred choice, screening intentions*

			risk assessment		
Health Treatment (n=12)					
Berry, 2011, U.S.	Prostate cancer	266 + 228 men	Computer-based	Usual care	**Decisional conflict***, **proportion undecided,** treatment preference
Chabrera, 2015, Spain	Prostate cancer	61 + 61 aged ≥45 years	Written material	Standard information	**Knowledge*, decisional conflict*;** satisfaction with decision-making*, coping*
Jibaja-Weiss 2011, U.S.	Breast-conserving cancer surgery	40 + 36 women	Computer-based	Usual care	**Proportion undecided, knowledge,** satisfaction with decision, satisfaction with decision-making process, **decisional conflict;** surgical treatment preference
Laupacis, 2006, Canada	Autologous pre-donation in cardiac surgery	60 + 60 men & women aged ≥ 18 years	Audiotape and written booklet	Usual care	**Knowledge, decisional conflict, risk perception,** satisfaction with decision & decision-making, **accurate risk perception**; uptake of option
Légaré, 2008, Canada	Natural health products for menopausal symptoms	44 + 41 women aged 45–64 years	Written material	General information brochure	**Decisional conflict*, knowledge, congruence between personal values, proportion undecided;** preferred choice
Leighl, 2011, Australia & Canada	Chemotherapy in advanced colorectal cancer	107 + 100 males & females aged ≥ 18 years	Consultation, audiotape and written material	Usual care	**Knowledge*,** satisfaction with decision*, **decisional conflict,** decision involvement preference & consultation; anxiety, treatment decisions made, quality of life
Mathers, 2012	Type II diabetes	95 + 80 males & females aged 39-87 years	Written material and consultation	Usual care	**Decision quality*, knowledge*, realistic expectations*, regret, proportion undecided**, participation in decision-making, **adherence with chosen option**; preference option, glycaemic control
McBride, 2002, U.S.	Hormone replacement therapy	289 + 292 aged 45-54 years	Computer-based and telephone survey	Telephone survey and delayed PtDA	**Perceived risk,** confidence, satisfaction with decision-making
Nassar, 2007, Australia	Management options for breech presentation	102 + 98 females	Audiotape and written material	Usual care with standard counselling	**Decisional conflict*, knowledge*, values and choice predisposition,** satisfaction with decision-making*; anxiety*, ECV uptake, maternal and perinatal outcomes, compliance and acceptability
Schwalm, 2012, Canada	Vascular access in coronary angiography	76 + 74 aged ≥18 years	Written material	Usual care	**Decisional conflict*, knowledge, risk perceptions, values**; impact of patients choosing their vascular access

Shorten, 2005, Australia	Birth options after a caesarean delivery	85 + 84 females	Written material	Usual care	**Knowledge*, decisional conflict*,** preference*; satisfaction with experience*****recorded mode of birth*
Vandemheen, 2009, Canada & Australia	Lung transplantation for advanced cystic fibrosis	70 + 79 aged ≥18 years	Written material and computer-based	Usual care	**Knowledge*, realistic expectations*, decisional conflict*, value congruence with choice made;** preparation for decision-making choice, durability of the decision, acceptability of decision aid
Health Prevention (n=5)					
Chambers, 2012, Canada	Influenza immunization	48 + 59 healthcare personnel	Computer-based Received PtDA + control group interventions	Usual education pamphlet	Confidence in decision*, **uncertainty**; intent
Man-Son-Hing, 1999, Canada & U.S.	Antithrombotic therapy for stroke prevention in atrial fibrillation	139 + 148 males & females	Audiotape and written booklet	Usual care	**Knowledge, expectations, decisional conflict, adherence,** satisfaction with decision-making process; patient choice (personal input into the choice vs their physicians)
McAlister, 2005, Canada	Antithrombotic therapy for stroke prevention in atrial fibrillation	219 + 215 males & females	Audiotape and written booklet	Usual care	**Knowledge, expectations, decisional conflict*;** change in antithrombotic therapy at 3 months*, persistence of effects at 12 months
Oakley, 2006, U.K.	Bisphosphonate medication to prevent osteoporotic fracture	16 + 17 women	Audiotape and written booklet	Usual care	**Decisional conflict, decision adherence***; acceptability*, consider changing therapy, information
Schwartz, 2009, U.S.	Risk reducing mastectomy for BRCA1/2 carriers	100 + 114 aged 25-75 years	Computer-based	Usual care	**Decisional conflict;** decision satisfaction, management decision

Table 3.2 *Participant Characteristics*

No. of studies: (N=24)	Participants
Total No. of participants	7278
Sex	
Males	44%
Females	56%
Race/ethnicity	7 studies n=3018
Caucasian	44%
Black/African American	19%
Unknown	35%
Multiple Race	2%
Education:	20 studies n=6912
Some High School	8%
High School graduate	33%
Some college	15%
Four-year college graduate	28%
Post-graduate	1%
Unknown	13%
Age (years)	16-87

Primary Outcomes

Table 3.3 provides a summary of primary outcomes for ODSF-based PtDAs compared with usual care for adults considering health decisions**.**

Decision quality.

Knowledge.

Out of 24 trials, 14 measured the effects of ODSF-based PtDAs on knowledge (Table 3.3). Patients receiving usual care had, on average, 60 out of 100 correct answers compared to patients in the decision aid group, who on average, scored 74 out of 100 correct answers (MD 13.85; 95% CI 10.32-17.37; 14 trials). All trials were statistically significant and had a consistent direction of effect favouring the decision aid compared to usual care (Figure 3.1).

Table 3.3 *Summary of Primary Outcomes for ODSF-based PtDAs Compared with Usual Care for Adults Considering Health Decisions*

Outcomes	Usual care	ODSF-based PtDA	*RR* (95% CI)	No of participants (studies)
Knowledge* **(mean %, mean difference)**	59.8% (40 - 79)	13.85 higher (10.32 – 17.37)	-	3422 (14)
Accurate risk perception*	237 per 1000	572 per 1000 (394 to 826 per 1000)	2.41 (1.66, 3.48)	1722 (7)
Congruence between chosen options and values	530 per 1000	700 per 1000 (578 to 843 per 1000)	1.32 (1.09, 1.59)	1277 (4)
Decisional Conflict total score (mean difference)	24.5% (13.5 – 51.7)	5.92 lower (-8.58 to -3.26)	-	3951 (15)
Decisional Conflict: uncertainty subscale (mean difference)	22.4% (12.83 – 43.8)	3.21 lower (-6.70 to 0.27)	-	2514 (11)
Decisional Conflict: uninformed subscale (mean difference)	24.7% (12.75 – 61.1)	7.27 lower (-10.80 to -3.73)	-	2513 (11)
Decisional Conflict: unclear about personal values subscale (mean difference)	25.5% (15.5 – 53.2)	7.41 lower (-12.46 to -2.36)	-	2514 (11)
Decisional Conflict: unsupported subscale (mean difference)	21.9% (14.5 – 51.7)	4.08 lower (-7.52 to -0.64)	-	2513 (11)
Decisional conflict: ineffective choice subscale (mean difference)	22.2% (15 – 49.5)	5.56 lower (-9.30 to -1.82)	-	2430 (10)
Delayed decision-making (proportion undecided)[a]	188 per 1000	121 per 1000 (94 to 156 per 1000)	0.65 (0.50, 0.83)	3362 (13)

Note. CI = confidence interval; *RR* = Risk Ratio

*all studies show statistically significant improvement

[a]lower proportion is favourable

Table 3.4 *Effects on Primary Outcomes for ODSF-based PtDAs Compared with non-ODSF PtDAs*

Outcomes	ODSF-based PtDAs				PtDAs not based on ODSF			
	No of trials	**No of participants**	***MD*[a] (95% CI)**	***RR* (95% CI)**	**No of trials**	**No of participants**	***MD* (95% CI)**	***RR* (95% CI)**
Knowledge	14	3422	13.85 (10.32, 17.37)	-	38	9894	13.11 (10.53, 15.69)	-
Accurate risk perception	7	1722	-	2.41 (1.66, 3.48)	10	3374	-	1.92 (1.41, 2.61)
Informed values-choice congruence	4	1277	-	1.32 (1.09, 1.59)	6	3349	-	3.14 (1.52, 6.48)
Decisional conflict total score	15	3951	-5.92 (-8.58, – 3.26)	-	23	4834	-8.24 (-11.00, -5.47)	-
Decisional conflict uncertainty subscale	11	2514	-3.21 (-6.70, 0.27)	-	17	3686	-4.69 (-7.73, -1.64	-
Decisional conflict: uninformed subscale	11	2513	-7.27 (-10.80, -3.73)	-	16	3194	-11.04 (-15.81, -6.28)	-
Decisional conflict: unclear about personal values subscale	11	2514	-7.41 (-12.46, -2.36)	-	12	2554	-10.29 (-15.03, -5.55)	-
Decisional Conflict: unsupported subscale (mean %; mean difference)	11	2513	-4.08 (-7.52, -0.64)	-	13	2701	-8.28 (-11.87, -4.69)	-
Decisional conflict: ineffective choice subscale	10	2430	-5.56 (-9.30, -1.82)	-	14	2811	-6.92 (-10.48, -3.36)	-
Delayed decision making (proportion undecided)	13	3362	-	0.65 (0.50, 0.83)	10	2069	-	0.66 (0.48, 0.91)

Note: MD = mean difference; *RR* = risk ratio; CI = confidence interval

[a]Random Effects

Four additional trials also measured knowledge but were not able to be pooled in the meta-analysis since only statistical values were reported (Légaré, Dodin, Stacey, Leblanc, & Tapp, 2008; Mathers et al., 2012; Mathieu et al., 2012; Mathieu et al., 2007; Nagle et al., 2008). Three of these trials showed statistical significance in PtDAs improving knowledge (Mathers et al., 2012; Mathieu et al., 2007; Nagle et al., 2008). One trial did not show a difference in knowledge between the PtDA group and the usual care group (Légaré, Dodin, Stacey, Leblanc, & Tapp, 2008).

Compared to usual care, non-ODSF PtDAs revealed higher knowledge scores after the intervention (MD 13.11; 95% CI 10.53-15.69; 38 trials). ODSF-based PtDAs also had higher knowledge scores (MD 13.85; 95% CI 10.32-17.37; 14 trials) (Table 3.4).

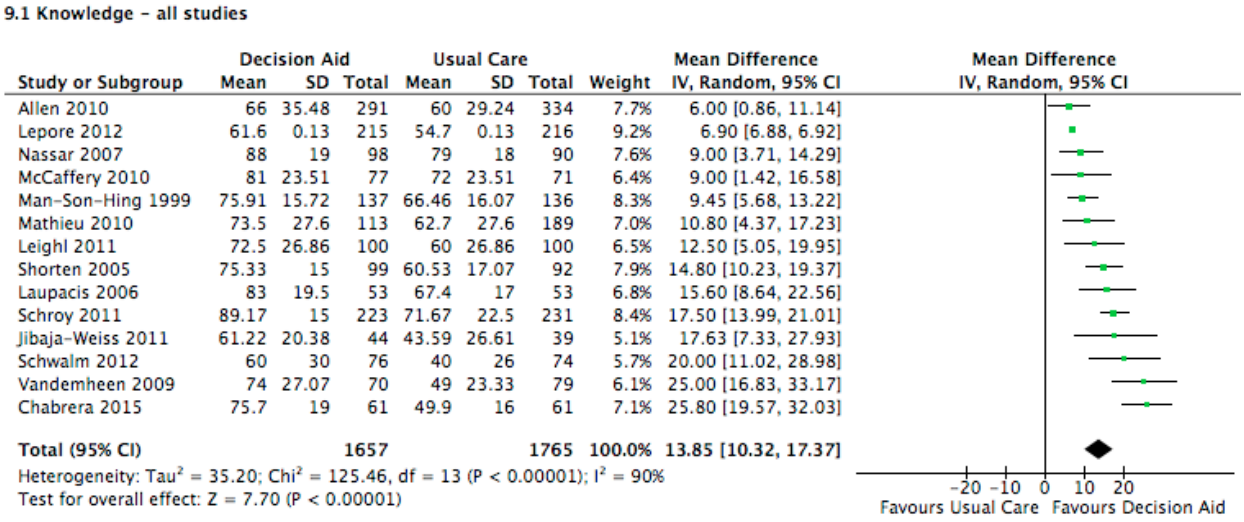

Figure 3.1. Forest plot of the effect of ODSF-based PtDAs on knowledge.

Accurate risk perceptions.

Of the 24 included trials, seven trials examined the effects of the PtDAs on the accuracy of patients' perceived chances of outcomes. Patients who received the ODSF-based PtDA were nearly two and a half times as likely (RR 2.41; 95% CI 1.66-3.48; 7 trials) to accurately interpret risks compared to patients who received usual care. All studies were statistically significant and showed an increase in accuracy of risk perception with the PtDA (Figure 3.2).

PtDAs that were not based on the ODSF also showed an increase in accurate risk perceptions compared to usual care (RR 1.92; 95% CI 1.41–2.61; 10 trials). ODSF-based PtDAs also showed an increase in accurate risk perceptions (RR 2.41; 95% CI 1.66-3.48; 7 trials) (Table 3.4).

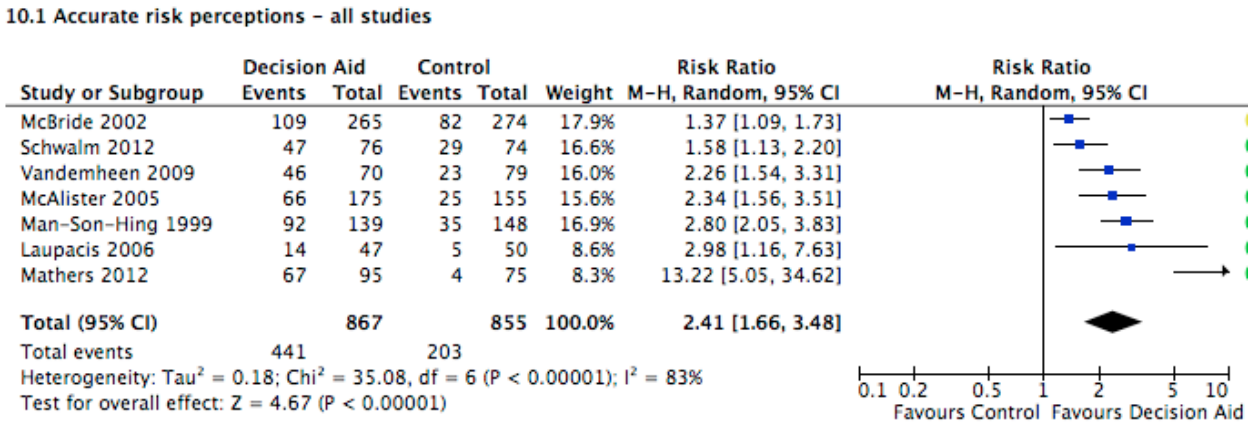

Figure 3.2. Forest plot of the effect of ODSF-based PtDAs on accurate risk perceptions.

Congruence between patients' chosen option and their informed values.

Four out of 24 trials measured the effectiveness of ODSF-based PtDAs on congruency of choice with patients' informed values, which considered knowledge in their measurements (Mathieu et al., 2007; Mathieu et al., 2010; Nagle et al., 2008; Schwalm et al., 2012). Three of these studies (Mathieu et al., 2007; Mathieu et al., 2010; Nagle et al., 2008) measured informed

choice using the Multidimensional Measure of Informed Choice (MMIC) which defines informed choice as the choice implemented is consistent with personal values and based on relevant knowledge (Michie, Dormandy, & Marteau, 2002; Stacey, Légaré, et al., 2017). Decisions are classified as informed when individuals score higher than the midpoint on knowledge and attitude dimensions, and uptake is congruent with attitude. Schwalm et al., (2012) evaluated the outcome of informed values-based decisions by comparing those with knowledge scores ≥ 60% with values scores that matched the treatment received. Two studies used preferred choice measuring intention of future screening (Mathieu et al., 2007; Mathieu et al., 2010) and two studies used actual choice implemented (Nagle et al., 2008; Schwalm et al., 2012). In the pooled meta-analysis, patients who received the ODSF-based PtDA compared to those who received usual care were more likely to select an option congruent with their informed values (RR 1.32; 95% CI 1.09-1.59; 4 trials) (Figure 3.3).

There were two other studies that measured value congruence with chosen option without considering knowledge (Légaré et al., 2008; Vandemheen et al., 2009). Vandemheen et al. (2009) found no differences between interventions. Légaré et al., (2008) reported that women's valuing of the non-chemical aspect of natural health products was positively associated with their choice of natural health products in managing menopausal symptoms (P = 0.006). There was no difference in achieving values-choice congruence between patients exposed to ODSF-based PtDAs and usual care for these studies.

Compared to usual care, non-ODSF PtDAs had higher effectiveness on informed values-choice congruence (RR 3.14; CI 1.52-6.48; 6 trials). ODSF-based PtDAs also had higher effectiveness on informed values-choice congruence (RR 1.32; 95% CI 1.09-1.59; 4 trials) (Table 3.4).

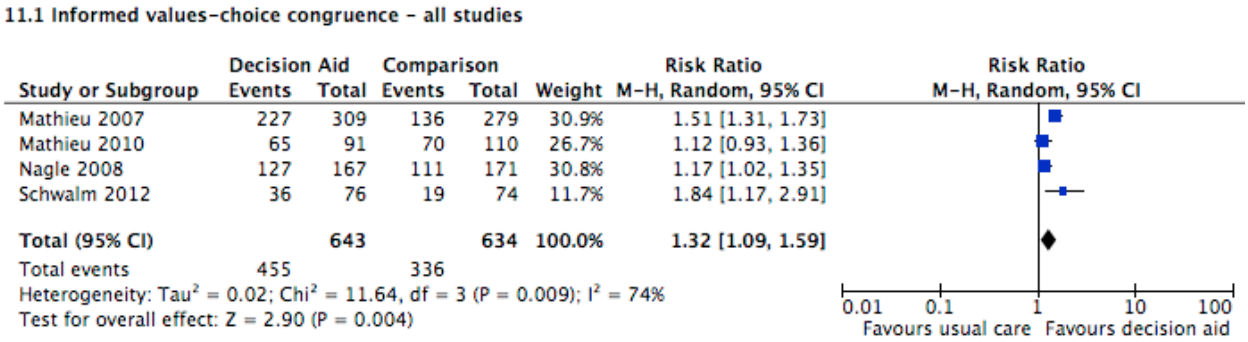

Figure 3.3. Forest plot of the effect of ODSF-based PtDAs on congruence between chosen option and values.

Reduction in decisional needs.

Fifteen out of 24 trials used the DCS to elicit participants' perceptions of decisional needs. Compared to usual care, ODSF-based PtDAs were more effective in lowering total DCS scores (MD -5.92; 95% CI -8.58 to -3.26) (Figure 3.4).

Five studies (Berry et al., 2013; Leighl et al., 2011; Mathieu et al., 2010; Oakley & Walley, 2006; Schwartz et al., 2009) could not be pooled in the meta-analysis because only statistical values were reported. Berry et al., (2013), found a slight reduction in total DCS Scores with the PtDA (-1.75 units; 95% CI, 3.60 to 0.011; p=0.07) and Schwartz et al., (2006) found a significant decrease in total DCS scores for those who were undecided compared to usual care (B = -.46, z = -3.1, p<.002). Oakley and Walley (2006) only used the DCS in the ODSF PtDA group and found that total scores were reduced from pre-intervention to post-intervention (pre-intervention, median (range), 2.5 (1.8–3.4) vs 2.0 (1.0–2.4) post-intervention, P<0.001). Leighl et al., (2011) and Mathieu et al., (2010) found no statistical difference in total DCS scores between ODSF-based PtDAs and usual care.

Compared to usual care, non-ODSF PtDAs lowered total DCS scores (MD -8.24; 95% CI -11.00 to -5.47; 23 trials). ODSF-based PtDAs also lowered total DCS scores (MD -5.92; 95% CI -8.58 to -3.26) (Table 3.4).

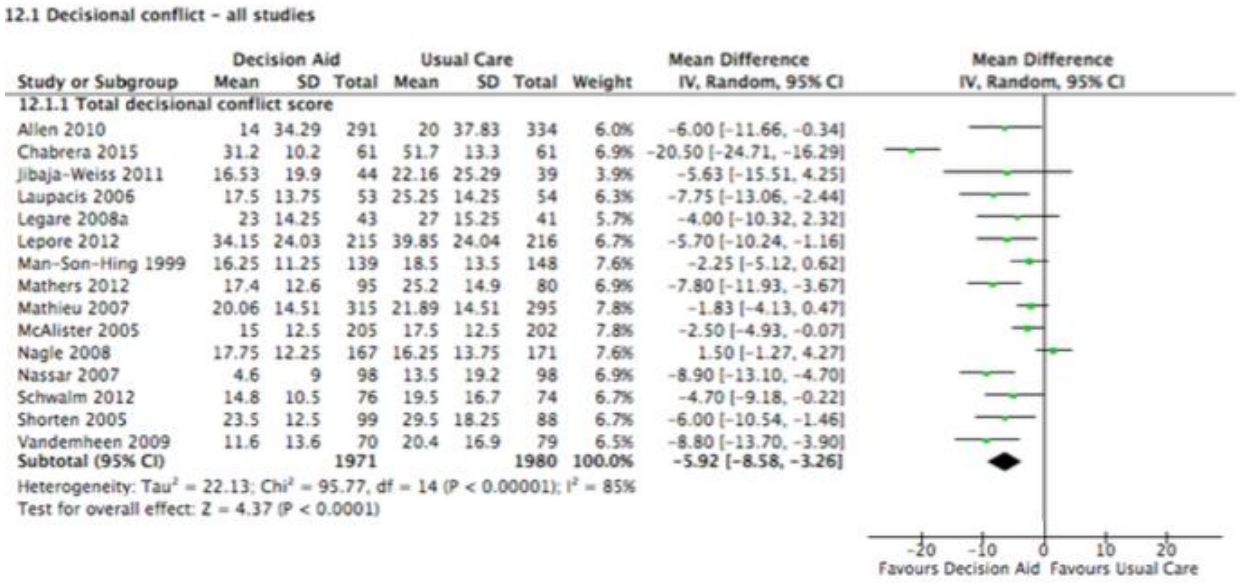

Figure 3.4. Forest plot of the effect of ODSF-based PtDAs on total decisional conflict.

DCS sub-scales.

Of 24 trials, 11 measured the effect of ODSF-based PtDAs on DCS subscales.

Uncertainty subscale.

There was no difference between usual care and patients who received the ODSF-based PtDA on uncertainty about choices (MD -3.21; 95% CI -6.70 to 0.27; 11 trials) (Figure 3.5). One trial not included in the meta-analysis found a statistically significant decrease in uncertainty compared to the control group (P=0.04) (Berry et al., 2013). Non-ODSF PtDAs reduced uncertainty about choices compared to usual care (MD -4.69; CI -7.73 to -1.64; 17 trials) (Table 3.4).

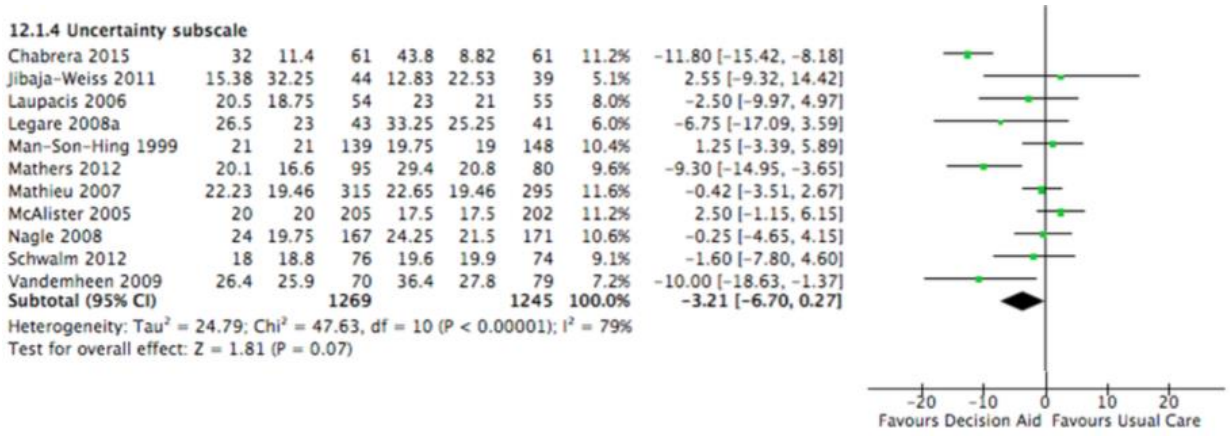

Figure 3.5. Forest plot of the effect of ODSF-based PtDAs on the decisional conflict uncertainty subscale.

Uninformed subscale.

Compared to usual care, ODSF-based PtDAs significantly reduced patients' perceptions of feeling uninformed (MD -7.27; 95% CI -10.80 to -3.73; 11 trials) (Figure 3.6). No significant difference was found in the Berry et al., (2013) trial not included in the meta-analysis. Compared to usual care, non-ODSF PtDAs also reduced patients' perceptions of feeling uninformed (MD -11.04; 95% CI -15.81 to -6.28; 16 trials) (Table 3.4).

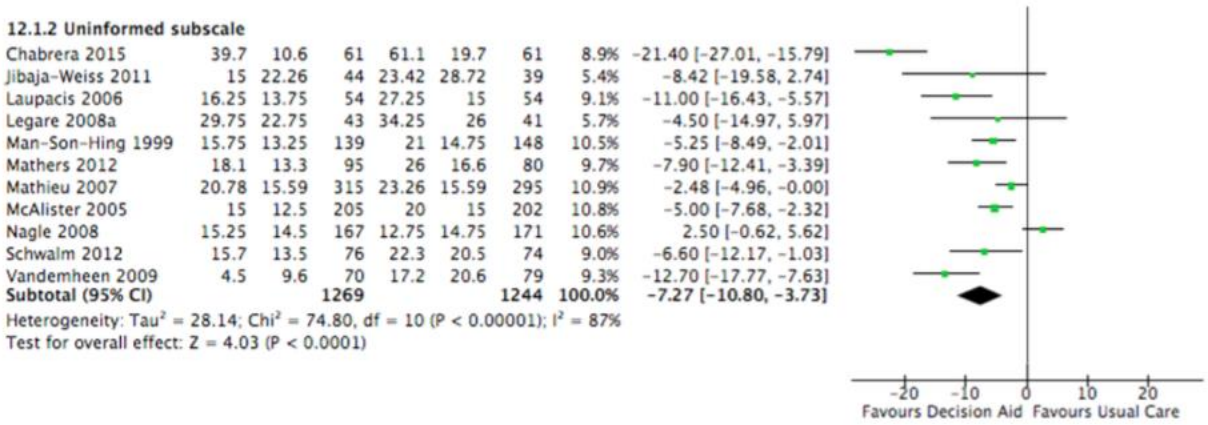

Figure 3.6. Forest plot of the effect of ODSF-based PtDAs on the decisional conflict uninformed subscale.

Unclear personal values subscale.

Compared to usual care, there was a significant reduction in unclear values when patients received the ODSF-based PtDAs (MD -7.41; 95% CI -12.46 to -2.36; 11 trials) (Figure 3.7). There was also a statistically significant improvement in patients who received the ODSF-based PtDA for the one trial not pooled in the analysis (p=0.002) (Berry et al., 2013). Compared to usual care, non-ODSF PtDAs also decreased patients' feelings related to unclear values (MD -10.29; 95% CI -15.03 to -5.55; 12 trials) (Table 3.4).

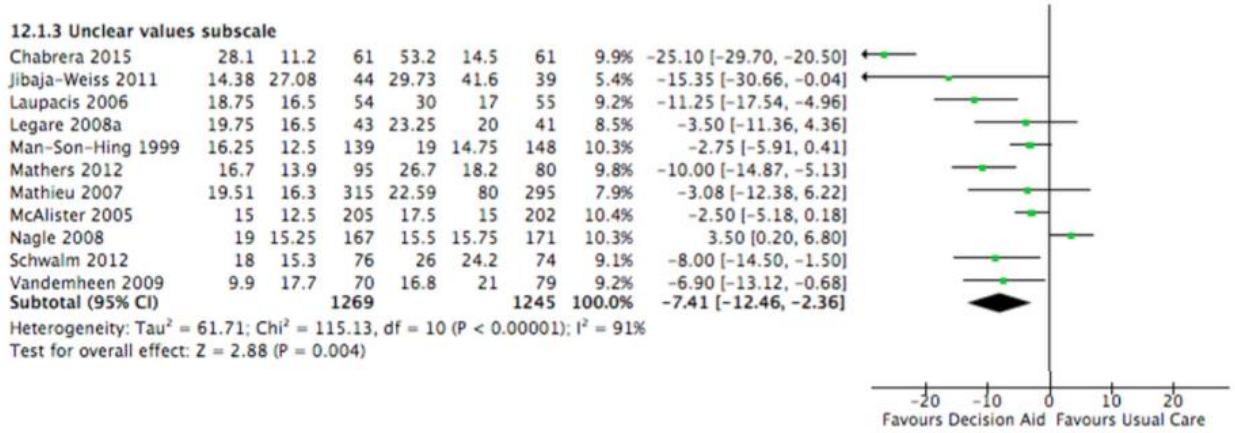

Figure 3.7. Forest plot of the effect of ODSF-based PtDAs on the decisional conflict unclear values subscale.

Unsupported subscale.

Compared to usual care, patients who received the ODSF-based PtDA had greater reduction in feeling unsupported (MD -4.08; 95% CI -7.52 to -0.64; 11 trials) (Figure 3.8). One trial not included in the meta-analysis showed no significant difference in the feeling unsupported subscale compared to usual care (Berry et al., 2013). Compared to usual care, non-ODSF PtDAs also reduced patients feeling unsupported (MD -8.28; 95% CI -11.87 to -4.69; 13 trials) (Table 3.4).

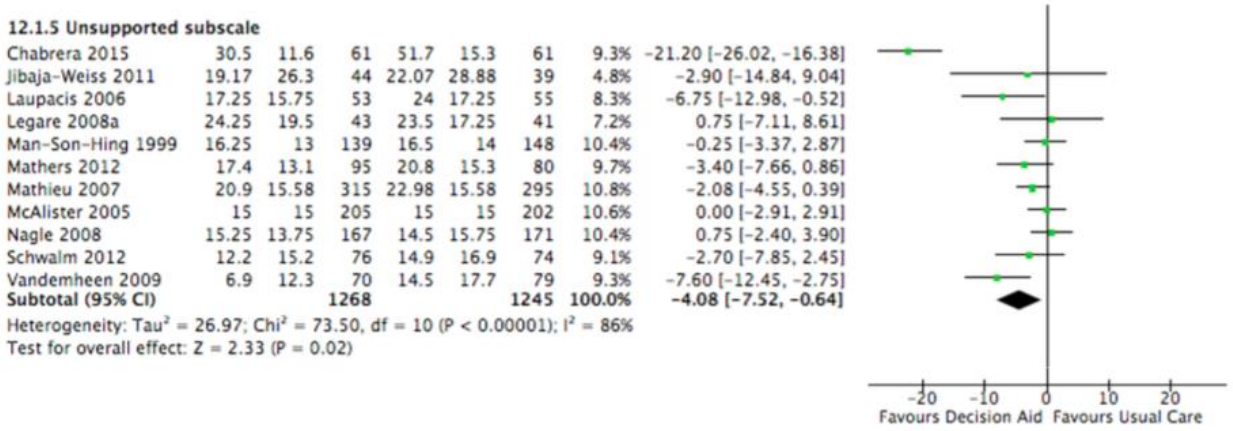

Figure 3.8. Forest plot of the effect of ODSF-based PtDAs on the decisional conflict unsupported subscale.

Ineffective decision.

Ten studies measured the effect of PtDAs on the ineffective decision subscale of the DCS and one did not (Jibaja-Weiss et al., 2011). Compared to usual care, patients who received the ODSF-based PtDA had a reduction in their perception of ineffective decisions (MD -5.56; 95% CI -9.30 to -1.82; 10 trials) (Figure 3.9). Berry et al., (2013) found no significant difference in the ineffective decision subscale compared to usual care. Compared to usual care, non-ODSF PtDAs also reduced the perception of ineffective decisions (MD -6.92; 95% CI -10.48 to -3.36; 14 trials) (Table 3.4).

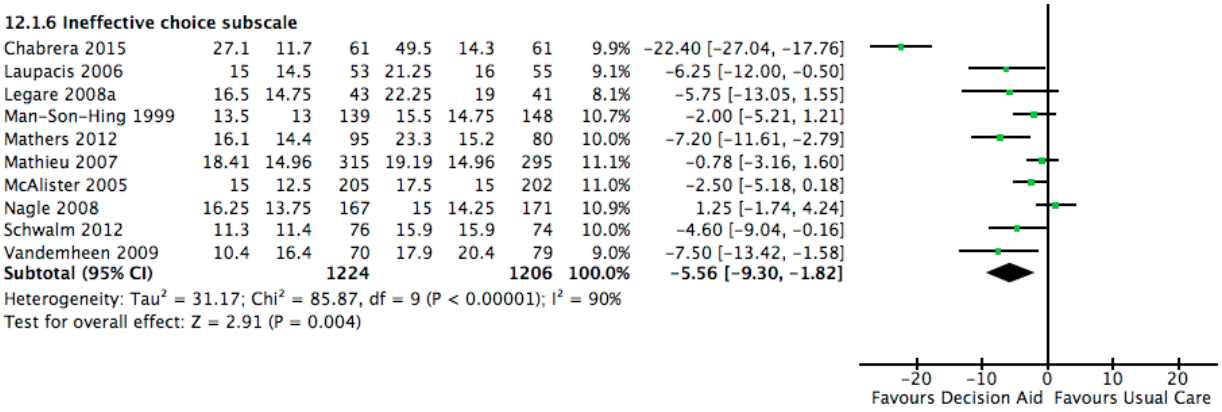

Figure 3.9. Forest plot of the effect of ODSF-based PtDAs on the decisional conflict ineffective decision subscale.

Decision actions: delayed decision-making.

Of 24 trials, 13 examined the effects of ODSF-based PtDAs on the proportion of patients who remained undecided. Compared to usual care, a lower proportion of patients remained undecided after exposure to the ODSF-based PtDA (RR 0.65; CI 0.50-0.83; 13 trials) (Figure 3.10). Compared to usual care, non-ODSF PtDAs also lowered the proportion of patients who remained undecided (RR 0.66; 95% CI 0.48-0.91; 10 trials) (Table 3.4).

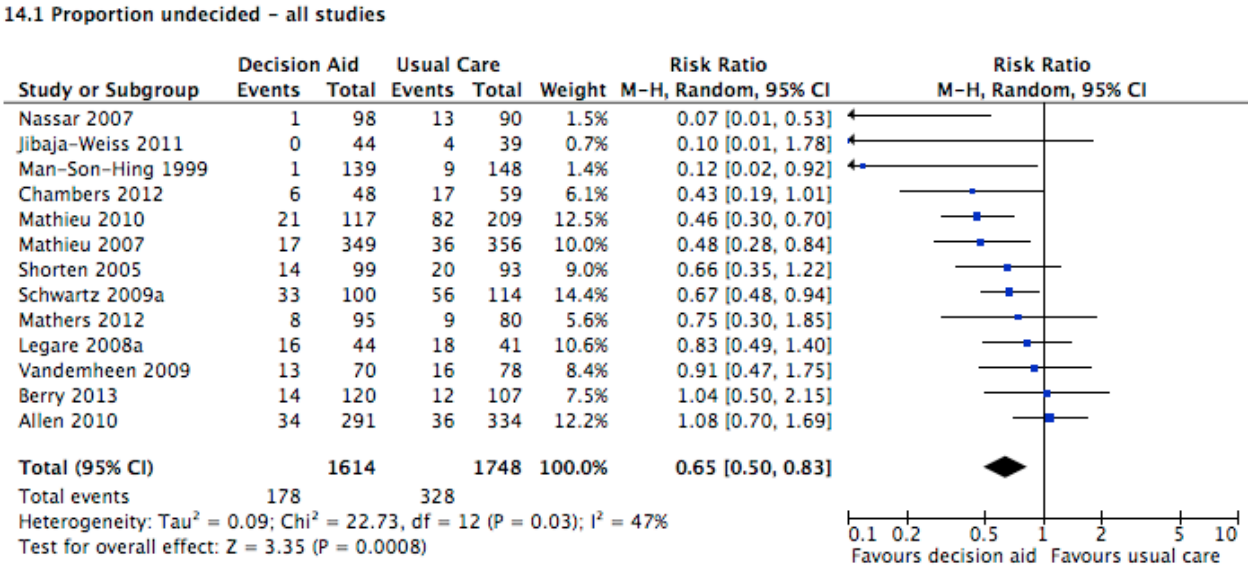

Figure 3.10. Forest plot of the effect of ODSF-based PtDAs on delayed decision-making (proportion undecided).

Secondary Outcomes

ODSF outcomes.

There were a few studies that reported on adherence to chosen option and decisional regret. No studies reported on blame, values-based outcomes, or appropriate use and costs of health services.

Adherence to chosen option.

Of 24 trials, three measured adherences to baseline choice after reviewing the ODSF-based PtDA (Lepore et al., 2012; Man-Son-Hing et al., 1999; Mathers et al., 2012) and one

measured adherence to treatment (Oakley & Walley, 2006). Mathers et al., (2012) reported that compared to usual care, participants who received the ODSF-based PtDA had higher adherence to their baseline choice. Lepore et al., (2012) and Man-Son-Hing et al., (1999) found no difference between groups. Oakley and Walley (2006) reported no difference in adherence to treatment for patients who received the ODSF-based PtDA and patients who received usual care.

In the 2017 Cochrane review, one out of six non-ODSF PtDAs reported improved adherence to baseline choice and two out of nine non-ODSF PtDAs reported improved adherence to treatment compared to usual care (Stacey, Légaré, et al., 2017).

Decisional regret.

One trial used the Decision Regret Scale to measure participants' regret in the decision at six months. There was no difference between participants exposed to the ODSF-based PtDA and the usual care group (Mathers et al., 2012). In the 2017 Cochrane review, five non-ODSF PtDAs reported no effect on decisional regret and one non-ODSF PtDA trial reported a reduction of decisional regret compared to usual care (Stacey, Légaré, et al., 2017).

Other primary outcomes of the 2017 Cochrane review.

Some studies measured the effects on satisfaction with the decision and decision-making, participation in decision-making, and patient-practitioner communication.

Satisfaction with the decision and decision-making process.

There were mixed results evaluating the effect of ODSF-based PtDAs on satisfaction. Of 24 trials, six evaluated the effect of ODSF-based PtDAs on patient *satisfaction with the decision* (Chabrera et al., 2015; Jibaja-Weiss et al., 2011; Laupacis et al., 2006; Leighl et al., 2011; McBride et al., 2002; Nassar, Roberts, Raynes-Greenow, Barratt, & Peat, 2007). Chabrera et al., (2015), Laupacis et al., (2006) and Nassar et al., (2007) found patients had higher satisfaction

with their decision when exposed to the ODSF-based PtDA compared to controls ($p<0.05$). McBride et al., (2002) found that women who received the ODSF-based PtDA were more satisfied with their decision compared to patients who had a delay in receiving the PtDA, but found the opposite finding one month later. Jibaja-Weiss et al., (2011) and Leighl et al., (2011) found no difference in patient satisfaction with the decision between ODSF-based PtDA groups and control groups.

Four out of 24 trials evaluated the effect on *satisfaction with the decision-making process* (Jibaja-Weiss et al., 2011; Man-Son-Hing et al., 1999; Schroy et al., 2011; Schwartz et al., 2009). Compared to controls, Schroy et al., (2011) found patients had higher satisfaction with the decision-making process when patients received the ODSF-based PtDA alone or with a risk assessment tool. Schwartz et al., (2009) also found increased satisfaction with decision-making for patients who were undecided at baseline ($p = 0.002$). However, Man-Son-Hing et al., (1999) and Jibaja-Weiss et al., (2011) found no difference in patient satisfaction with the decision-making process between ODSF-based PtDA groups and control groups.

Participation in decision-making.

Two trials focused on participation in decision-making. Mathers et al., (2012) used the Controlled Preference Scale and found patients who received the ODSF PtDA were more likely to demonstrate autonomy in their decision-making compared to patients who received usual care (64% vs 43%). Man-Song-Hing et al., (1999) found no significant difference in autonomous decision-making compared to usual care, although the trend was in the same direction (62% versus 54.5%).

Patient-practitioner communication.

Only one trial examined the effect of ODSF-based PtDAs on patient-practitioner communication (Lepore et al., 2012). This trial found participants were more likely to report they discussed prostate-specific antigen testing with their practitioner when exposed to the ODSF-based PtDA in preparation for consultation compared to usual care ($p < 0.001$).

Discussion

The purpose of this sub-analysis was to compare the effectiveness of PtDAs developed using the ODSF to usual care. Overall, PtDAs developed using the ODSF were more effective than usual care for improving decision quality, decreasing decision delay, and resolving most decisional needs. These findings for PtDAs developed based on the ODSF were similar to effectiveness of other PtDAs compared to usual care. There were few studies that measured the ODSF secondary outcomes. These results led to three observations.

First, the study results lend support to the ODSF assertion that decision support using PtDAs improves decision quality by addressing decisional needs. Decision quality was improved as exhibited by increased knowledge of the condition and options (MD 13.85) and increased accurate risk perceptions of the likelihood of outcomes (RR 2.41). Patients were also more likely to choose an option that was congruent with their informed values (RR 1.32). This result aligns to the 2017 Cochrane review which concluded that the GRADE quality of the evidence rating was strong for all of these outcomes except for chosen option congruent with values (Stacey, Légaré, et al., 2017). Further research is warranted to strengthen the quality of the evidence for option congruency with values, but trials also need to use more consistent measurement approaches (Sepucha et al., 2013).

As hypothesized, decision delay and decisional needs were reduced as exhibited by the lower proportion of patients who remained undecided about a choice (RR 0.65), lower scores for

total decisional conflict and four of the five decisional conflict subscales. The direction of effect and significance of these findings are consistent with the findings in the 2017 Cochrane review of PtDAs (Stacey, Légaré, et al., 2017). The only decisional conflict subscale that was not significantly reduced in our study was uncertainty. In contrast, non-ODSF PtDAs had a significant reduction compared to usual care. It is possible that the larger number of trials in the latter meta-analysis was better able to narrow the confidence interval of the overall effect estimate below the line of no effect in favour of the PtDA. Even if this were the case, and more ODSF-based PtDA trials narrowed the confidence intervals, the effect on uncertainty remains smaller than in other subscales. According to the ODSF, uncertainty about the best course of action arises from the inherent difficulty of the choice, which can be exacerbated by modifiable factors such as feeling uninformed, unclear about personal values and unsupported (O'Connor, Jacobsen, & Stacey, 2002). Therefore, one cannot expect as much improvement in the uncertainty subscale as the others, because it is still a difficult decision. Timing of implementing the intervention and measurement are also critical. Uncertainty can be raised temporarily if the PtDA is presented to patients who are unaware that they need to make a decision or if they have already made up their minds (Grant, Laupacis, O'Connor, Rubens, & Robblee, 2001; Sepucha et al., 2011). Moreover, uncertainty was typically measured immediately post exposure to the PtDA and uncertainty does not usually decline until after the follow-up consultation with one's practitioner (Collins et al., 2009). The non-significance of the decreases in feelings of uncertainty in this sub-analysis confirms the ODSF intention of PtDAs as adjuncts to consultation with a practitioner and are not intended to replace consultation (O'Connor, Stacey, & Boland, 2015).

Second, there is little evidence to support the hypothesized effects on the secondary ODSF outcome of adherence to the chosen option. The majority of trials in this sub-analysis, as

well as in the 2017 Cochrane review, showed no differences between PtDAs and usual care on adherence to baseline choice (2 of 3 sub-analysis trials; 5 of 6 non-ODSF trials) or to treatment (1 of 1 sub-analysis trial; 7 of 9 non-ODSF trials) (Stacey, Légaré, et al., 2017). These results raise questions about the generalizability of results across decisions and the likelihood that non-adherence may be more influenced by implementation barriers rather than decisional needs (Stacey, Légaré, et al., 2017). The 2017 Cochrane review also noted difficulties in interpreting adherence results due to incomplete data, primarily self-reported data, varying length of follow-ups, and small sample sizes (Stacey, Légaré, et al., 2017). In the case of Man-Song Hing et al., (1999), there was little variation in choice; over 90% of long-term aspirin users decided to stay on aspirin, making it easy for both intervention groups to stay on aspirin. The review also concludes that further research is warranted with better methods and measurement (Stacey, Légaré, et al., 2017). However, before embarking on expensive trials, there needs to be better evidence that primary reasons for non-adherence are related to decision-making outcomes (e.g. decision quality, decisional needs), rather than implementation barriers. A first step might be to analyze primary data from pooled studies that have measured these variables.

Lastly, there is a need to identify if the other ODSF secondary outcomes warrant further research. Of the ODSF-based PtDA trials, only one reported on decisional regret and no trials reported on values-based health outcomes, appropriate use and costs of services, or blame. It is interesting that only one trial reported on decisional regret (Mathers et al., 2012). One of the challenges of using this outcome is the timing (Becerra Pérez, Menear, Brehaut, & Légaré, 2016). Most trials stop collecting data soon after the decision is made, but decisional regret should be measured at multiple time points (Becerra Pérez, et al., 2016). Patients need to have implemented the chosen option and lived with the consequences before regret is measured. There

are over 100 RCTs of PtDAs and funding agencies are unlikely to support expensive trials with long term follow-up unless there are compelling reasons to do so (Stacey, Légaré, et al., 2017).

To date, there have been no trials in the Cochrane review reporting on values or preference-linked health outcomes, and the review recommends that more research is needed on developing validated measures for this outcome (Stacey, Légaré, et al., 2017). The 2017 Cochrane review examined eight trials reporting appropriate use and costs of services, but there was insufficient evidence to draw conclusions, and further research is warranted. The rationale for including blame in the ODSF was based on one study that reported a positive correlation between more blame and more decisional needs (Gattellari & Ward, 2005). There were no evaluations of blame reported in the 2017 Cochrane review or evaluations of litigation, which could have an element of blame. The frequency of this problem in populations may be too low to warrant further study.

Satisfaction, participation in decision-making, and patient-practitioner communication are not outcomes in the updated ODSF (O'Connor, 2018), but were reported as other primary decision-making process variables in the 2017 Cochrane review (Stacey, Légaré, et al., 2017). These variables were evaluated in this sub-analysis for information purposes to see how ODSF-based PtDAs perform regarding other primary decision-making process outcomes included in the larger review. This sub-analysis showed that ODSF-based PtDAs had limited effects on satisfaction with the decision and with the decision-making process, which is consistent with the larger review (Stacey, Légaré, et al., 2017). This lack of effect may have been due to measurement insensitivity related to ceiling effects of satisfaction, the inherent difficulty in the choice itself, and the psychological need to feel comfortable with the decision after it is made. Of note is that PtDAs had no adverse effects on satisfaction. Satisfaction was included in the

original 1998 ODSF, but was excluded in refined versions of the ODSF based on the emerging evidence of what decision support cannot affect (O'Connor et al., 1998; O'Connor, 2018). These results support the continued exclusion of satisfaction from the ODSF as a possible variable that may be positively affected by PtDAs.

The two trials in this sub-analysis that measured participation in decision-making showed a trend toward increased autonomous decision-making (Man-Son-Hing et al., 1999; Mathers et al., 2012). Both trials were included in the 2017 Cochrane review meta-analysis of 15 trials that showed significant increases in autonomous decision-making with PtDAs compared to usual care (RR 1.28; 95% CI 1.05-1.55) (Stacey, Légaré, et al., 2017). One trial reporting on patient-practitioner communication reported that patients who received the ODSF-based PtDA in preparation for a consultation were more likely to discuss PSA testing with their practitioner (Lepore et al., 2012). This result is consistent with three of four non-ODSF PtDAs in the 2017 Cochrane review that also reported a higher proportion of patients discussed the decision with their practitioner compared to usual care (Stacey, Légaré, et al., 2017).

Strengths and Limitations

Two independent team members screened the trials and extracted data on the framework or theory used in the development of the PtDA. The research team included the developer of the ODSF, and those with experience in developing and evaluating PtDAs based on the ODSF.

There are limitations to this sub-analysis. First, our sampling frame was pulled from the Cochrane review. Hence, PtDAs that may have used the ODSF, but did not fit within the Cochrane review's inclusion criteria, were not captured. Also, four included trials used other frameworks along with the ODSF to develop their PtDAs. Second, the search was stopped in 2015 and therefore new trials were not included. Third, as in the 2017 Cochrane review, there is

heterogeneity among the included trials that may be due to varying decision types, study quality, comparison interventions, format and setting (Gentles, Stacey, Bennett, Alshurafa, & Walter, 2015; Stacey, Légaré, et al., 2017). Hence, these results should be interpreted as the best estimate of the average effect on the ODSF outcomes across varying conditions and contexts (Stacey, Légaré, et al., 2017). However, the direction of effect for all studies consistently favours PtDAs over usual care for knowledge and accurate risk perception. Fourth, there is greater heterogeneity in the scales used to measure congruence between chosen option and values, which makes this outcome complex to measure (Munro, Stacey, Lewis, & Bansback, 2016). For outcomes with less precision and wider confidence intervals, they were significant overall, but confidence interval and direction of effect should be considered rather than only using effect size (Stacey, Légaré, et al., 2017).

Conclusions

Using the ODSF is a reasonable approach to developing PtDAs. The findings in this sub-analysis lend support to the ODSF assertion that PtDAs, as decision support interventions, can help resolve key decisional needs, improve decision quality and help the undecided to decide. This is also true in synthesized findings of PtDAs that are not based on the ODSF. Questions remain about the downstream impacts of these improvements in decision-making that warrant further evaluation. Our findings will be used to update the ODSF using current evidence on PtDAs as supportive interventions for quality decision-making.

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Chapter Four

Integrated Discussion

Introduction

For 20 years, the Ottawa Decision Support Framework (ODSF), a theoretical framework, has been used internationally to guide researchers and practitioners to assess patients' decisional needs, develop and use patient decision aids (PtDAs) as decision support interventions, and evaluate the effects on decision outcomes (O'Connor et al., 1998; Chapter 1; Chapter 2). Since it was first published, there have been 45 decisional needs assessment studies guided by the ODSF (Chapter 2) and 24 randomized controlled trials (RCTs) that have evaluated ODSF-based PtDAs (Chapter 3). This thesis has focused on: (a) the decisional needs component of the ODSF and (b) ODSF-based PtDAs as an intervention to improve decision quality and address decisional needs. I will briefly describe a summary of findings from the manuscripts in Chapters Two and Three. Then, I will use Walker and Avant's (2011) concept validation and theory testing steps to frame an integrated discussion on how this thesis contributes to validating the ODSF decisional needs concepts and testing the assertion in the ODSF that PtDAs, as an intervention, address decisional needs and improve decision quality. Finally, I discuss the implications for nurses.

In Chapter Two, I focused on the decisional needs component of the ODSF. Since there had never been a comprehensive review of the decisional needs of patients and families making health or social decisions, I conducted a mixed studies systematic review of ODSF-based decisional needs studies to determine if these needs, and any new needs, emerged in a broader context of decisions and countries. Of 4652 citations, 45 studies were identified as decisional needs assessments based on the ODSF. These studies reported all of the individual ODSF decisional needs concepts in at least 2 studies; the major categories of decisional needs were reported in at least 11 studies (Appendix E). The five most common manifestations of decisional needs were: (1) having inadequate knowledge of benefits, risks and outcomes; (2) having

inadequate access to information about the health condition, options, benefits, risks, or scientific uncertainties; (3) feeling unclear about what is important; (4) feeling unsure about what to choose; and (5) feeling unsupported in decision-making. Nine new manifestations of ODSF decisional needs emerged. These manifestations include: difficulty believing the chances of outcomes applied to them; information overload; lacking access to information about other's experiences with options; being unreceptive to information and/or deliberation due to lack of acceptance of the condition or need for treatment, powerful emotions limiting information processing, or being unmotivated to consider delayed or unpredictable decisions; relationship barriers with the practitioner, difficulty involving family in decision-making and difficultly sharing deliberations with family. These manifestations updated the operational definitions for needs related to unrealistic expectations, inadequate support and resources (information, decisional role and needs), decisional stage needs, and unrealistic expectations, and decisional stage needs.

In Chapter Three, I focused on the assertion in the ODSF that PtDAs, as an intervention, improve decision quality and address decisional needs. Since no comprehensive analysis had been done on PtDAs developed using the ODSF, I conducted a sub-analysis of a systematic review to determine their effectiveness on patients' decision outcomes (decisional needs, decision quality, decision actions). Of 105 eligible RCTs, 24 evaluated PtDAs using the ODSF. When compared to control groups (e.g. usual care or alternative interventions), ODSF-based PtDAs addressed decisional needs (e.g. patients felt more informed, were clearer about values, felt more supported, and had better perceptions of making effective decisions), improved decision quality (e.g. patients had improved knowledge, accurate risk perceptions and were more likely to select an option congruent with their informed values) and helped the undecided to

decide. Questions remain about the downstream impacts of these improvements in decision-making that warrant further evaluation.

Validated Concepts

A concept is, "a word or phrase that summarizes a phenomenon, such as an idea, an observation, or an experience" (Fawcett, 2005, p. 4). Validating concepts is important because concepts describe a phenomenon that is observed in clinical practice, which concerns nursing practice and actions (Walker & Avant, 2011). The decisional needs concepts included in the ODSF were examined in a systematic review (Chapter 2). To guide empirical validation of concepts, Walker and Avant (2011) suggest that: (1) there should be evidence that the concept represents a phenomenon in reality, and (2) there should be evidence that the concept is relevant to practice, in terms of patient needs, clinical outcomes, or other meaningful clinical criteria (Table 4.1).

Evidence that the Concept Represents a Phenomenon in Reality

Since the ODSF decisional needs were first published in 1998, there have been 45 studies describing the reality of patients' decisional needs (Chapter 2). I developed a coding manual of decisional needs including: (a) conceptual definitions; and (b) operational definitions listing behavioural manifestations of each decisional need using structured items from ODSF-based needs assessment interview guides, surveys, and scales. Then, extracted data from each study was coded according to the needs and corresponding behavioural manifestations (Walker & Avant, 2011). All of the decisional needs categories were evident in 24% (11/45) to 91% (41/45) of the included studies (Figure 4.1). At least 4% (2/45) of studies reported all individual decisional need concepts (Appendix E). Hence this is evidence to support all of the decisional needs concepts in the ODSF.

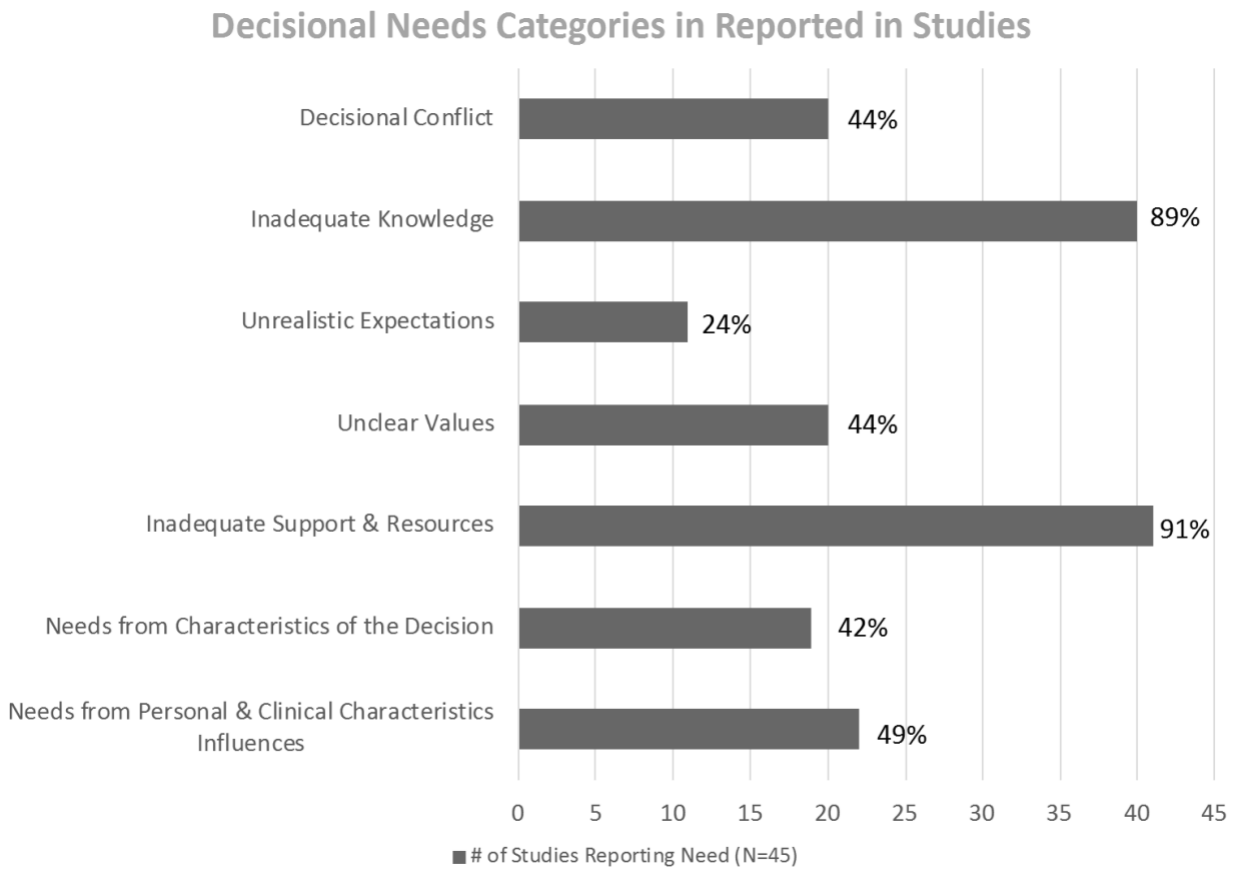

Figure 4.1. Percentage of studies that reported decisional needs categories.

Evidence that the Concepts are Relevant to Practice

The decisional needs in the ODSF are highly relevant to practice in terms of patients' needs, clinical outcomes and nursing practice. Of 45 decisional needs studies from seven countries, 43 were conducted in clinical practice settings and two in large populations (national Canadian survey and survey of disadvantaged suburb in Chile's capital). Patients' decisional needs were reported by patients, families and practitioners. The identified needs affected clinical outcomes. For example, patients reported manifestations such as feeling distressed or upset, cannot get the decision off their minds, feeling physically stressed, or having powerful emotions

that impaired decision-making (Chapter 2). Hence, knowing patients' decisional needs is highly relevant to nursing practice given that key decisional needs are modifiable and nurses can direct their actions towards resolving these needs (Stacey et al., 2009).

Theory Testing

The testability of a theory is important for generating nursing knowledge and for examining if further research is required on the phenomenon being explored (Walker & Avant, 2011). Furthermore, the soundness of a theory is critical when adopting it into clinical practice and when it shapes how problems are thought of in relation to health and nursing care (Walker & Avant, 2011). Theory testing can use qualitative or quantitative methods to determine empirical adequacy (Walker & Avant, 2011). Empirical adequacy can determine if assertions made within the ODSF are congruent with empirical data (Fawcett, 2005).

The main assertion tested in the ODSF was whether or not you are more likely to resolve decisional needs and improve decision quality when you intervene with a PtDA (O'Connor, 2006). In Chapter Three, a meta-analysis was used in the sub-analysis of trials evaluating ODSF-based PtDAs to determine if these interventions resolved patients' decisional needs and improved decision quality. I will use the eight steps for theory testing proposed by Walker and Avant (2011) as a framework to test this assertion in relation to the findings in Chapter Three (Table 4.1).

Table 4.1 *Walker and Avant's Concept Validation Criteria and Theory Testing Steps*

Criteria for Concept Validation	**ODSF Decisional Needs**
1. Evidence that the concept represents a phenomenon in reality	✓
2. Evidence that the concepts are relevant to practice	✓
Steps for Testing the ODSF	**ODSF-based PtDAs as an intervention to address decisional needs**
1. The purpose of the study is to determine the empirical validity of a designated theory's assumptions or propositions (internal theoretical statements)	✓
2. The theory is explicitly stated as the rationale for the theory-testing research	✓
3. The theory's internal structure (key propositions and their interrelationships) is explicitly stated so that its relationship to study hypotheses is clear	✓
4. The study hypotheses are clearly deducted from the theory's assumptions or propositions	✓
5. The study hypotheses are empirically tested in an appropriate research design using sound and relevant instruments and suitable study participants	✓
6. As a result of empirical testing, evidence exists in support of the validity or invalidity of the designated assumptions or propositions of the theory	✓
7. This evidence is considered specifically as it supports, refutes, or explains relevant aspects of the theory	✓
8. The hypotheses used to test a specific theory are designed to put the theory at risk of falsification by virtue of their specificity and compatibility with only a limited set of outcomes	✓

Step one for theory testing is to assess if the purpose of the study is to determine the validity of a designated theory's assumptions or propositions (Walker & Avant, 2011). In Chapter Three, the purpose was to evaluate if ODSF-based PtDAs resolved decisional needs and improved decision quality. This is the main assertion of the ODSF (O'Connor, 2006). Only the effectiveness of ODSF-based PtDAs was evaluated. The effectiveness of other decision support interventions such as, decision coaching or clinical counseling, were not. These other interventions could be tested in future research.

Step two is to ensure the theory is explicitly stated as the rationale for the theory-testing research (Walker & Avant, 2011). The ODSF asserts that "unresolved decisional needs will have adverse effects on decision quality. However, decision support can improve decision quality by addressing unresolved needs with clinical counseling, decision tools, and coaching" (O'Connor & Légaré, 2009, p. 4). The overall aim of the study in Chapter Three was to synthesize the effectiveness of ODSF-based PtDAs on decision quality and decisional needs. As such, there was an explicitly stated rationale for testing the main assertion in the ODSF (Chapter 1). In the sub-analysis, only trials which explicitly stated the ODSF was used in the development of the PtDA were included.

Step three is to assess if the theory's internal structure (key propositions and their interrelationships) is explicitly stated so that its relationship to study hypotheses is clear (Walker & Avant, 2011). Step four is to ensure the study hypotheses are clearly deduced from the theory's assumptions and propositions. In Chapter One, the interrelationship between decisional needs, decision support, and decision outcomes in the ODSF are explained. The premise of the ODSF is described as when decisional needs remain unaddressed, decision quality is adversely affected (O'Connor, 2006). Decision support can improve decision quality by addressing decisional needs

(O'Connor, 2006). In Chapter Three, the meta-analysis of 24 trials showed that ODSF-based PtDAs resolved patients' decisional needs and improved decision quality. The objectives of the sub-analysis were informed by the ODSF propositions regarding decisional needs concepts, decision outcomes, and PtDAs as decision support interventions.

Step five is to evaluate if the study hypotheses are tested in an appropriate research design using sound and relevant instruments (Walker & Avant, 2011). In Chapter Three, the study design was a sub-analysis of RCTs included in the Cochrane review of PtDAs (Stacey et al., 2017). RCTs are considered the *gold standard* for evaluating interventions (Cochrane Consumer Network, 2019; Hariton & Locascio, 2018). Primary outcomes of interest were based on the ODSF, including decision quality, decisional needs, and decision delay. The Decisional Conflict Scale (DCS) was used to measure if decisional needs were resolved in ODSF PtDA trials (Garvelink et al., 2015; O'Connor, 1995). The DCS is a valid and reliable tool and was based on the ODSF. The DCS tool has five subscales that measure patients' perceptions of: feeling uncertain, feeling uninformed, having unclear values, feeling unsure about what to choose, feeling unsupported, and feeling that one has made an ineffective decision (O'Connor, 1995).

The findings from the sub-analysis of ODSF-based PtDAs revealed that trials had been evaluated in different decision contexts and different instruments were used to measure the knowledge and realistic expectations components of decision quality. Furthermore, trials used different approaches to measuring if patients chose an option that was congruent with their informed values. The only consistent instrument used in the majority of RCTs, was the DCS. Fifteen RCTs used the total DCS scale and 11 used some of the subscales only. The use of inconsistent instruments is a limitation in measuring primary outcomes in trials of PtDA

interventions (Kryworuchko, Stacey, Bennett, & Graham, 2008) and in theory testing (Walker & Avant, 2011). Further research is required to measure congruency with informed patients' values due to the quality of the evidence.

Step six is to determine if evidence exists in support of the validity or invalidity of the designated assumptions or propositions of the theory, as a result of testing (Walker & Avant, 2011). The results of the sub-analysis indicated that the primary assertion of the ODSF was supported by the evidence. When compared to usual care, ODSF-based PtDAs: (a) addressed key decisional needs (e.g. patients felt more informed, were clearer about values, felt more supported, and had better perceptions of making effective decisions); (b) improved decision quality (e.g. patients had improved knowledge, accurate risk perceptions and were more likely to select an option congruent with their informed values); and (c) reduced decision delay (helped the undecided to decide). Patients who received an ODSF PtDA had lower uncertainty compared to patients receiving usual care, but the reduction was not statistically significant. Given that a previous trial reported that the uncertainty subscale remained high before and after the PtDA and only reduced after consultation with the practitioner (Collins et al., 2009), this finding is not surprising since all of the ODSF-based PtDA trials included in Chapter Three measured uncertainty before the consultation.

While all outcomes showed improvement in decision quality with ODSF-based PtDAs compared to usual care, stronger evidence on congruency with informed patients' values is required (Chapter 3). This is due to a range of different instruments used to measure congruency, which is a limitation to theory testing (Walker & Avant, 2011). This finding is consistent with the Cochrane review, which states there is an insufficient number of trials to measure this outcome (Stacey et al., 2017).

Step seven is to consider the evidence specifically as it supports, refutes, or explains relevant aspects of the theory. In the sub-analysis (Chapter 3), the evidence supports the use of ODSF-based PtDAs as an intervention for addressing decisional needs in clinical practice, which is a relevant aspect of the framework.

Step eight is to evaluate if the hypotheses used to test a specific theory were designed to put the theory at risk of falsification by virtue of their specificity and compatibility with only a limited set of outcomes (Walker & Avant, 2011). In Chapter Three, the hypothesis used to test the ODSF was to compare the effectiveness of PtDAs developed using the ODSF to usual care. This put the main assertion of the theory – that when you intervene with a PtDA you are more likely to resolve decisional needs and improve decision quality – at risk of falsification. Only a limited set of primary outcomes (decision quality, decisional needs, and decision actions) were used and were based on outcomes of the ODSF. Previous studies on the effectiveness of PtDAs have also shown there is evidence to support this main assertion of the ODSF (Kryworuchko et al., 2008; Stacey et al., 2017).

In summary, the results in Chapters Two and Three lend support for the validation of the ODSF decisional needs concepts and the assertion that ODSF-based PtDAs, as an intervention, resolve decisional needs and improve elements of decision quality. The ODSF decisional needs concepts meet the two criteria – that decisional needs represent a phenomenon in reality and are relevant to nursing practice – for concept validation by Walker and Avant (2011). The ODSF decisional needs are validated by a systematic review of the decisional needs of patients and families making health or social decisions and are relevant to patients' needs and outcomes (Chapter 2). The most frequent decisional needs reported by patients can be addressed using PtDAs developed using the ODSF (Chapter 3). This assertion was tested in a sub-analysis of

ODSF-based PtDAs included in a Cochrane review using the DCS (Chapter 3), meeting all of the eight steps in theory testing by Walker and Avant (2011) (Table 4.1). There was a limitation measuring congruency with informed patients' values due to the various instruments used in trials. Further research is warranted to strengthen the evidence for the assertion that ODSF-based PtDAs improve congruency with patients' values. Walker and Avant (2011) provided a framework for discussing decisional needs concepts and the main assertion in the ODSF. These results will update relevant aspects of the ODSF with recent evidence from various practice settings and seven countries.

Implications for Nursing

Clinical Practice

Nurses in any practice setting will encounter patients and families making health decisions. Providing decision support and identifying patients' needs falls within the scope of nursing practice and related competencies (Canadian Nurses Association [CNA], 2015; Registered Nurses Association of Ontario [RNAO], 2002). The ODSF is relevant to the nursing process and reinforce basic nursing skills: nurses assess, diagnose, plan, implement, and evaluate care (Toney-Butler, 2019).

Assessment is the first step in the ODSF as well as in the nursing process (O'Connor, Stacey, & Boland, 2015; Toney-Butler, 2019). Assessing patients' and families' decisional needs is a critical first step in order to appropriately address them (CNA, 2015; O'Connor et al., 2015). The ODSF can help nurses understand and assess decisional needs, which have been validated in various practice settings across 45 studies in seven countries (Chapter 2). Nurses who are aware of the multiple and complex decisional needs that patients and families experience could be more

likely to diagnose decisional conflict and related decisional needs. The SURE test is a simple four-item tool to screen for these needs (Légaré et al., 2010).

According to the nursing process, nurses should plan care that meets the unique needs of the patient (Toney-Butler, 2019). The ODSF offers a framework for supporting patients and families experiencing decisional needs. The framework also recognizes that decision support should be tailored to meet the patient's needs (O'Connor, 2006). PtDAs developed using the ODSF have been tested in 24 RCTs and are one decision support intervention that nurses could implement to address patients' and families' decisional needs (Chapter 3).

The final stage in the nursing process is to evaluate care (Toney-Butler, 2019). Nurses using the ODSF are encouraged to monitor patients' decisional needs and to facilitate progress in decision-making and implementation (O'Connor, 2006). Nurses can evaluate care by screening for decisional conflict using the SURE test and facilitate implementation of the chosen option using decision coaching and referrals to other required services and consultations (Jull et al., 2019; O'Connor et al., 2015).

Education

The ODSF has been used to inform the development of the Ottawa Decision Support Tutorial as an online training program to improve knowledge in shared decision making, decisional needs, decision support interventions, and patient outcomes (O'Connor, Stacey, & Boland, 2015). A recent publication on the ODSF online tutorial showed it has been used by over 6000 users and is an accessible education intervention that improves practitioners' knowledge about shared decision making and decision support (Boland et al., 2019). Findings from this thesis, should be used to update this tutorial and strengthen the description of the evidence describing the validity of the concepts and the results from testing the main assertion of the

ODSF. Nurse educators in clinical practice settings can also use the ODSF decisional needs concepts to educate front line nurses on potential reasons for patients' and families' indecisiveness or decision delay. Educating nurses on how to use PtDAs with patients can also help provide nurses with decision support tools they can use in practice. For those interested in developing PtDAs, there is an online tutorial based on the ODSF (O'Connor, Stacey, Saarimaki et al., 2015). This tutorial should also be reviewed to ensure it is updated with the findings from Chapters Two and Three.

Leadership and Collaboration

Nurses using the ODSF put the patient at the center of care which is considered best practice (RNAO, 2015). Moreover, there are over 130 organizations in Canada, including the Canadian Nurses Association and the Canadian Medical Association that have endorsed patients at the center of healthcare (Montague et al., 2017). Nursing leaders, formal or informal, can use the synthesized evidence on the decisional needs of patients and families to consider how they and their colleagues can assess and address the decisional needs of patients and families. They can also look for opportunities to use PtDAs as known effective decision support interventions.

Formal nursing leaders can advocate for integrating this evidence in system level care delivery by collaborating with other stakeholders including other practitioners, the public, policy-makers, healthcare insurers, and organizations that support patients with illnesses (Ankolekar, Dekker, Fijten, & Berlanga, 2018; Légaré et al., 2017). For example, nursing leaders can educate stakeholders about the importance of assessing patients' decisional needs and providing decision support to address these needs. Nurses and other practitioners have an ethical duty to help patients reach quality decisions that are informed by the best available evidence and grounded in the patient's values (Légaré et al., 2017; O'Connor et al., 1998). Collaborating with

organizations that support patients with illnesses can help raise public awareness about common decisional needs of patients, as outlined in the ODSF, and the benefits of using PtDAs in decision-making (Ankolekar et al., 2018). Nursing leaders can also collaborate with other stakeholders to advocate for reimbursement incentives that require evidence of shared decision making approaches prior to certain treatments or procedures (Ankolekar et al., 2018). There are already reimbursement incentives being used in the United States of America (Coulter, 2018).

Research

Researchers conducting needs assessments can use the updated operational definitions developed for ODSF decisional needs concepts to assess if these needs are seen in the population they are researching (Appendix D). This thesis focused on patients' needs, however, future research could focus on the needs of practitioners as this population is also a relevant component of the ODSF (O'Connor et al., 1998). The systematic review of ODSF-based decisional needs assessments included patients 18 years of age and older and focused on one condition or illness context (Chapter 2). Future research could also focus on the decisional needs of children and the decisional needs of patients with co-morbidities who need to consider making decisions for multiple illnesses at one time.

The ODSF is the second most common framework used in the development of PtDAs (Vaisson et al., 2019) and the theory has been tested against the assertion that ODSF-based PtDAs address patients' decisional needs (Chapter 3). Developers of new PtDAs can use the ODSF as a framework in the creation of these tools. Given the importance of assessing patients' decisional needs, developers of PtDAs are encouraged to conduct needs assessments for the targeted population of the PtDA (Légaré et al., 2017; O' Connor et al., 2015; Witteman et al., 2015). Further research is needed to synthesize evidence on use of ODSF-based decision

coaching and counselling. The only systematic review for decision coaching was not specific to the ODSF, included only 10 trials, and was published seven years ago (Stacey et al., 2012). A new Cochrane review of decision coaching is underway (Jull, et al., 2019). Other research priorities include re-evaluating which downstream impacts of decision quality should remain in the ODSF for future research such as continuance of chosen option, values-based health outcomes and appropriate use and costs of health services.

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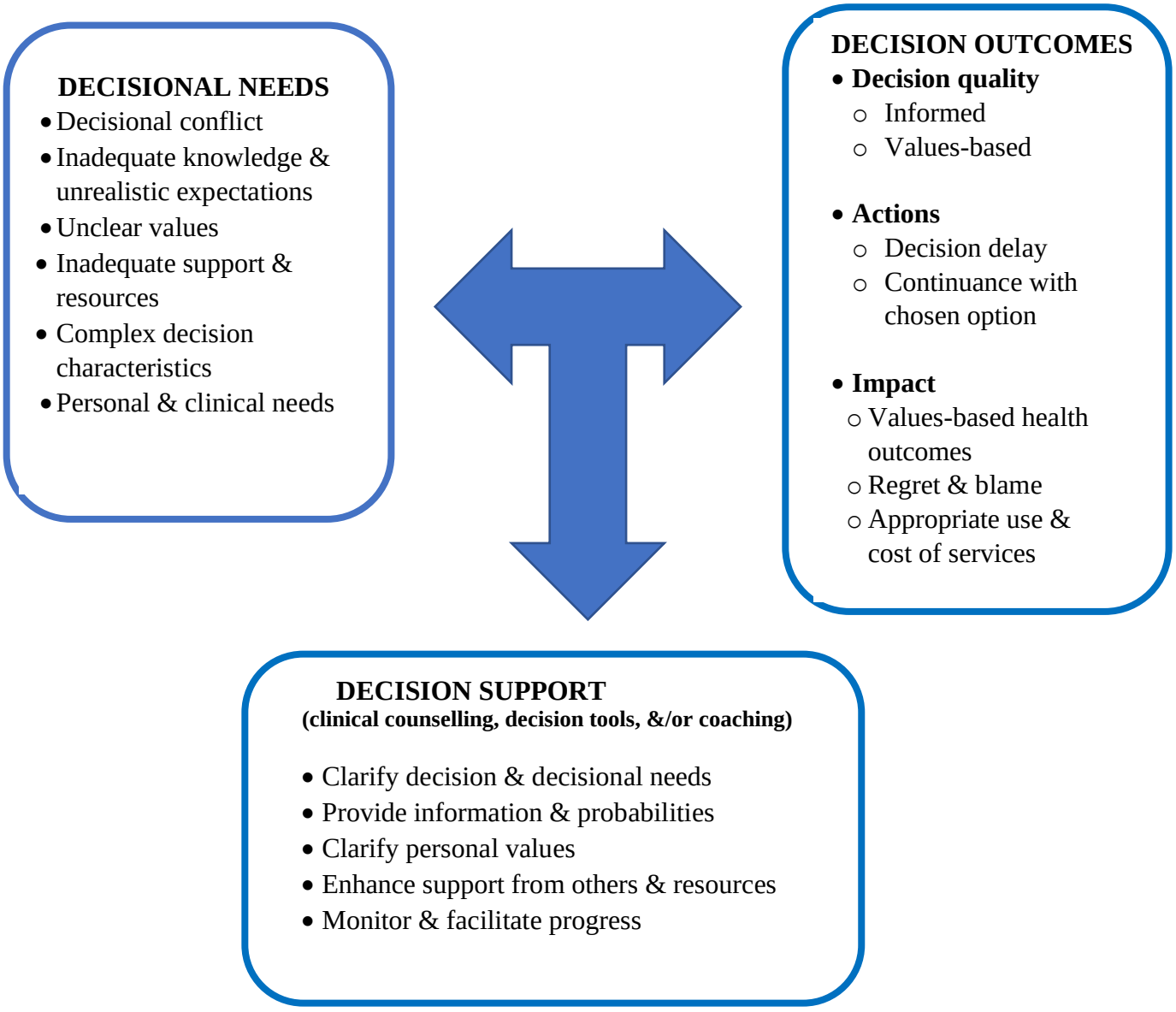
Appendices

Appendix A: The Ottawa Decision Support Framework (O'Connor, 2018)



Appendix B: ODSF Decisional Needs Definitions

Decisional Need: deficit in an essential requirement to make and implement a high quality decision (informed and based on patients' values)

Decisional Conflict: Personal uncertainty about which course of action to take when choice among options involve risk, loss, regret, or challenge to one's personal values

Inadequate Knowledge: Lacks cognizance of the health problem or situation, options, outcomes (e.g. known benefits, harms scientific uncertainties that is essential for decision making)

Unrealistic Expectations: Lack of alignment between facts and perceptions of the likelihood or probability of outcomes (benefits/harms; advantages/disadvantages) of each option

Unclear Values: Lacks clarity regarding desirability or personal importance of outcomes of options (benefits, risks, scientific uncertainties)

Inadequate Support and Resources

- **Unclear/ biased views of others' opinions/ practices:** Lacks clarity about or misperceives what others decide or what others think is the appropriate choice. This may include a person's spouse, family, peers, and practitioner(s).
- **Social Pressure:** Perception of persuasion, influence, coercion from important other(s) to select one option.
- **Inadequate experience:** Lacks previous exposure or experienced negative outcomes related to the condition/situation, options, outcomes and/or the decision-making process
- **Inadequate decisional self-confidence (self-efficacy):** Lacks belief in one's abilities to make a decision (includes participating in decision making and implementing the chosen option)
- **Inadequate decisional motivation:** Lacks desire or willingness to engage in decision making
- **Inadequate decisional skills:** Lacks abilities in making and implementing a decision
- **Inadequate resources:** lacks quantity/quality of accessible available assets to make and implement the decision: information, advice, emotional support, instrumental help, financial assistance, and health and social services. Sources include social networks, professional networks, support groups, voluntary agencies, and the formal healthcare, education, and social sectors

Complex Decision Characteristics

Decision Type: the class or characteristic of a decision, for example, developmental transitions or clinical options to screen, test, treat, or palliate. *Decisional needs may be amplified if the decision has multiple options, scientifically uncertain outcomes, known outcomes that people value differently, and serious or permanent effects*

Decision Timing: the time frame or urgency with which a decision has to be made. *Decisional needs may be amplified if the timing is urgent or delayed.*

Decisional Stage: Stage refers to the phase of decision making: not thinking about options; actively thinking about options; close to making a choice; and taking steps or already implemented the chosen option. (Deciding not to change or to do nothing may be a viable option).
Decisional stage can make one unreceptive to information or deliberation due to denial, hasty decision making, premature closure, or polarized leaning.

Decisional Role: Roles refer to a participant's preferred or actual involvement in decision making; made on their own ; shared with someone else; or delegated to someone else. *Decisional role needs include: unclear decisional role, and mismatches between an informed person's preferred role and actual role.*

Personal and Clinical Characteristics:

Patient: age, developmental stage, gender, education, marital status, ethnicity, socioeconomic status, occupation, locale, diagnosis & duration of condition, health status (physical, emotional, cognitive, social) *Decisional needs may be amplified if support and resources are not tailored appropriately to these characteristics*
Practitioner: age, gender, ethnicity, clinical education, specialty, practice locale, experience, style of communication

Adapted from: 1) ODSF Framework (O'Connor, 2018) ; 2) Jacobsen, M.J., O'Connor, A.M., & Stacey, D. Decisional needs assessment in populations. © 1999 [updated 2013]. Available from www.ohri.ca/decisionaid; and 3) O'Connor, A.M., Stacey, D., & Boland, L. (2015). *Introduction to the Ottawa decision support tutorial*. Ottawa Hospital Research Institute. Retrieved from https://decisionaid.ohri.ca/odst/pdfs/ODST.pdf

PROSPERO
International prospective register of systematic reviews

NHS National Institute for Health Research

Appendix C: PROSPERO Registration

20th anniversary update of the Ottawa Decision Support Framework: a proposed systematic review of the decisional needs of patients and families making health or social decisions

Lauren Hoefel, Laura Boland, Krystina B. Lewis, Annette M. O'Connor, Dawn Stacey

Citation

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Review question

In decisional needs studies based on the Ottawa Decision Support Framework, what are patients and families' decisional needs when facing health or social decisions?

Objectives:

The aim of this systematic mixed studies review is to update the Ottawa Decision Support Framework (ODSF) using a broader range of decisional needs studies and more rigorous review methods. Specific objectives are (a) to synthesize the evidence from ODSF-based studies of patients' and families' decisional needs when facing various health or social decisions, (b) to identify new decisional needs and (c) to validate decisional needs already in the ODSF.

Searches

The following electronic databases will be searched: MEDLINE (via OVID), CINAHL (via EBSCOhost), PsycINFO (via OVID), Cochrane Library (via OVID), Embase (via OVID), AMED (via OVID), Scopus, Web of Science and Social Services Abstracts (via Proquest). A hand-search of the reference list of the only known previous systematic review by Jackson et al., (2008) will be done to identify decisional needs studies that used the ODSF.

Citation searches for prominent literature containing the ODSF will be done in Scopus. This includes: O'Connor et al., (1998), Stacey et al., (2009), O'Connor & Légaré (2009) chapter on Decisional Conflict in the Encyclopedia of Medical Decision Making, and the Decisional Needs in Populations: A Workbook for Assessing Patients' and Practitioners' Decision Making Needs (Jacobsen, O'Connor & Stacey, 2013). A citation search for this workbook will also be done in PubMed.

We will personally contact experts in the field who are known developers and evaluators of patient decision aids from the Facebook list serve to further inquire about studies that may have been missed.

The search strategy was developed with an academic librarian (LS) with expertise in comprehensive literature searching. The MEDLINE search strategy is included below and will be adapted to use for the other listed databases. The authors performing the search are LH (Master of Nursing graduate student) and LS (academic librarian).

The ODSF and related terms (as listed in lines 1 through 6 in MEDLINE example) were used as the keyword search term and all fields were searched. Since this search does not include a large number of articles, we decided not to apply further limitations to the search strategy, such as a date range, for example. MeSH terms were not used since the ODSF is not a MeSH term. There will be no restrictions on geographical location or language.

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily
<1946 to October 6, 2018>
Search Strategy:

1 Ottawa Decision*

Framework.mp. 2 Ottawa

Decision* Support*.mp.

3 Ottawa framework*.mp.

4 ODSF.mp.

5 decision* support* framework.mp.

6 DSF.mp.

7 1 or 2 or 3 or 4 or 5 or 6

Types of study to be included

A mixed studies systematic review will be

conducted. Inclusion Criteria:

Only primary studies published in peer-reviewed journals that list decisional needs assessment as a study objective will be included. These studies can be quantitative, qualitative or mixed-methods studies.

Exclusion Criteria:

Knowledge syntheses of any kind will be excluded. Abstract-only papers and non-peer reviewed studies will also be excluded from this study (e.g. dissertations, commentaries, letters, editorials).

Condition or domain being studied

We are interested in the decisional needs of children, youth and adults making health or social decisions for themselves, a child or a mentally incapable other as studied using the ODSF.

The evidence on the decisional needs component of the ODSF has not been synthesized since the ODSF initially described them in 1998. Individual studies that have used the ODSF to assess the decisional needs of patients facing health or social decisions may provide pertinent insights into this essential concept in the framework. A systematic review inclusive of all decisional need studies guided by the ODSF will identify and synthesize decisional needs across a range of health and social topics. Bringing this evidence together is important because shared decision-making is on the current policy agenda of many countries and assessing decisional needs is the first step in providing adequate decision support that can lead to quality decision outcomes (Coulter, 2018).

The eligibility criteria for this systematic mixed studies review are informed by a PIPOH structure that is defined by population, phenomena of interest, professionals and patients, outcomes and health setting.

Participants/population

Health and social care providers who report on their perspective of the decisional needs of patients and people who report on their needs when making a health or social decision for themselves, a child, or mentally incapable person. No restrictions will be applied.

Intervention(s), exposure(s)

Our phenomenon of interest are the decisional needs of people making health or social decisions as studied by the ODSF or methods guided by the Jacobsen et al., (2013) workbook, Decisional Needs in Populations: A Workbook for Assessing Patients' and Practitioners' Decision Making Needs. Primary studies that look at the decisional needs must be listed as an objective of the study.

Exclusion criteria:

Decisional needs related to hypothetical scenarios (e.g. advance care planning); studies that do not use the ODSF; or studies referencing the Jacobsen et al., (2013) workbook, that do not explicitly state in their methods how this workbook was used.

Decisional needs defined by the ODSF include personal uncertainty about the best choice (decisional conflict), lack of knowledge (condition, options, benefits, risks, probabilities), unrealistic expectations, and unclear values or priorities (personal desirability or importance of benefits vs. harms) (O'Connor & Légaré, 2009; O'Connor et al., 1998; O'Connor et al., 2006; O'Connor et al., 2015). Decisional needs may also include inadequate support and resources. There may also be decisional needs related to characteristics of the patient and of the decision itself (O'Connor et al., 1998; O'Connor et al., 2015).

Comparator(s)/control

Not applicable.

Context

No restrictions will be placed on settings (e.g. hospital, primary care, out-patient clinics, community, health centers, home care, community hospitals, telephone, outreach).

Main outcome(s)

The outcomes of interest for this systematic review will be decisional needs of people facing health or social decisions. For example, decisional needs currently outlined in the ODSF include decisional conflict, knowledge and expectations, values, support and resources, decision (type, timing, stage, leaning) and personal and clinical characteristics. Yet, we anticipate additional decisional needs not yet defined or emphasized in the ODSF, such as complex decision contexts, unreceptive stage of decision-making (fear, anxiety), lack of acceptance and emotional effects of information (Loiselle et al., 2016). These will be reported separately.

Timing and effect measures

Additional outcome(s)

Not applicable.

Timing and effect measures

Data extraction (selection and coding)

The reviewers will not be blind to study information. Using Covidence, two authors will independently screen the title and abstracts of identified articles obtained from the complete search strategy following the PIPOH eligibility criteria. Remaining full-text articles will be assessed by two authors independently. Prior to the formal screening of full-text articles, a pilot test will be done with one or two eligible articles to test and refine the screening questions and inclusion criteria. Disagreements between the two reviewers will be resolved through discussion. If a consensus is not reached, a third reviewer will act as an arbitrator.

Two data extractors will independently use a standardized data extraction grid and compare their data. A pilot test of one or two articles will be used as a calibration exercise to test the grid before starting the formal review. Any disagreements regarding the extracted data will be resolved by discussion and any further uncertainties will involve an arbitrator. If during the data extraction the reviewers come across multiple reports of a single study, the reviewers will only count this as one study.

We will extract data on the characteristics of the article (first author, publication year, country/location, funding), study aim(s), setting, population focus, sample size, duration of study, methodology, study design type and ethical considerations. Decision characteristics such as type, timing and stage will also be collected. Patient characteristics (sex, gender, age, socioeconomic status, education, occupation, ethnicity, marital status, health status (physical, emotional, cognitive, social) and duration of condition) that are included in the articles will be extracted, as well as, provider characteristics (discipline, work setting, years of experience, age, sex, and gender). Results that will be extracted are the decisional needs identified in the studies. Conclusions and limitations of the studies will also be extracted.

Risk of bias (quality) assessment

The Mixed Method Appraisal Tool (MMAT) 2011 version will be used to appraise and describe the methodological quality of included quantitative, qualitative and mixed method studies. We will do a pilot test of one to two articles to ensure homogenous interpretation between the two reviewers. Discrepancies will be resolved through discussion. If further information is required to appraise a particular study, we will attempt to contact the authors by phone or email to a maximum of two attempts over 3 weeks.

Quality scores will be calculated using the MMAT tool, but will not solely determine if studies are of "low" or "high" quality, as a descriptive summary using MMAT criteria will also be considered (Pluye et al., 2009).
The results of studies that score lower will be compared to higher quality studies to determine if this changes the outcomes of our synthesis and interpretations.

Strategy for data synthesis

If similar outcomes are measured, we will pool them using Review Manager (version 5.3) and evaluate heterogeneity across pooled studies using H and I^2 test statistics (Higgins & Thompson, 2002). For example, decisional conflict is a decisional need identified in the ODSF and may be measured in studies using the decisional conflict scale.

Data across studies for other outcomes will be pooled using narrative synthesis. We will adhere to the guidance on narrative synthesis in systematic reviews developed by Popay et al., (2006), which provides guidance on maintaining transparency, trustworthiness and avoiding bias in the composite of findings. This framework identifies four elements of the narrative synthesis process and we will work through elements two through four. (Popay et al., 2006). We will not focus on the first element of theory development on how an intervention works since our review is focused on the decisional needs of patients and families making health or social decisions, and there is no specific intervention being evaluated.

We will work through elements two through four:

Element 2: Developing a preliminary synthesis of findings of included studies

The tools and techniques that will be used are tabulation, groupings and clusters and thematic

analysis. Element 3: Exploring relationships in the data

Concept mapping will be used as a technique to construct a model with relevant themes that focus on what the decisional needs are of patients making health or social decisions.

Element 4. Assessing the robustness of the synthesis

We will include a reflection that will look at the methodology of the synthesis used, the evidence used to support the synthesis, assumptions that were made, any uncertainties and where future research is required.

Analysis of subgroups or subsets

A subgroup analysis may be undertaken, but it is not possible to confirm these groups in

advance. Studies could be grouped according to the decisional needs reported, the setting (e.g. hospital, community), the type of decision being made (e.g. social, health, life-threatening decisions, non-life-threatening decisions, the number of options an individual has to consider), the stage of decision-making, if participants were recalling decisional needs after decision-making or if they reported current needs at the time; and the group whom is offering their perspective on decisional needs (e.g. patients, providers, patients making decisions for themselves, patients making decisions for another).

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Type and method of review

Narrative synthesis, Systematic review

Anticipated or actual start date

01 November 2018

Anticipated completion date

31 May 2019

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University of Ottawa

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Research Chair in Knowledge Translation to Patients from the University of Ottawa

Conflicts of interest

No financial conflicts of interest for any team members included in the study.

DS has given talks on this topic in graduate classes. DS does not speak about conducting

decisional needs assessments or decisional need results in workshops or conferences.

AO is the author of the Ottawa Decision Support

Framework. Yes

Language

English

Country

Canada

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Anniversaries and Special Events; Decision Making; Humans; Learning; Patient Participation

Date of registration in PROSPERO

07 December 2018

Date of publication of this version

07 December 2018

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	
	No	Formal
screening of search results against eligibility criteria	Yes	
	No	Data Extraction
	No	
	No	
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Versions

07 December 2018

Appendix D. ODSF Decisional Needs Coding Manual Conceptual/Operational Definitions

Decisional Need: deficit in an essential requirement to make and implement a high quality decision (informed and based on patients' values).		
Conceptual definitions of Decisional Needs	**Operational Definition:** (new behavioural manifestations are **bolded**)	
	Structured items from ODSF, OPDG, ODSF needs interview guide/survey	**Scale statistic**
Decisional Conflict Personal uncertainty about which course of action to take when choice among options involve risk, loss, regret, or challenge to one's personal values	*Hallmark behavioural manifestation is verbalized uncertainty* ☐ unsure about what to do/choose/best course of action	Uncertainty subscale or item (DCS, SURE)
	Other behavioural manifestations (experienced during the decision-making process or while attempting the decision) ☐ worried what could go wrong; concerns about undesired outcomes when attempting decision ☐ feeling distressed or upset when attempting decision ☐ constantly thinking about decision/can't get off mind ☐ wavering between choices or changing their mind ☐ delaying the decision ☐ questioning personal values or what is desirable/important to them when attempting decision ☐ feeling physically stressed (tense muscles, racing heartbeat, difficulty sleeping when attempting decision)	
Inadequate Knowledge Lacks cognizance of the health problem or situation, options, outcomes (e.g. known benefits, harms scientific uncertainties that is essential for decision making)	☐ unaware that a decision needs to be made (e.g. person never told they had options) ☐ don't know (enough) about the health problem or situation to make a decision ☐ don't know (enough about) options ☐ don't know enough about) benefits, risks (pros/cons, features of options), outcomes and/or scientific uncertainties (includes medical-based outcomes and lifestyle outcomes)	Uninformed subscale or item (DCS, SURE) Knowledge test (% incorrect)
Unrealistic Expectations Lack of alignment between facts and perceptions of the likelihood or probability of outcomes (benefits/harms; advantages/disadvantages) of each option	☐ perceptions of likelihood of outcomes is not aligned with current evidence of the chances of these outcomes (reports chances that are not aligned with current evidence) ☐ don't know chances of benefits/risks ☐ **difficulty believing the chances of outcomes applied to them**	% Inaccurate expectations or risk perceptions
Unclear Values Lacks clarity regarding desirability or personal importance of outcomes of options (benefits, risks, scientific uncertainties)	☐ unclear about what is important to them	Unclear values subscale or item (DCS, SURE)
Inadequate Support and Resources:		
Unsupported in decision making Perceives a lack of support while making a decision	☐ feel unsupported in decision making	Unsupported subscale or item (DCS,SURE)
Unclear/ biased views of others' opinions/ practices Lacks clarity about or misperceives what others decide or what others think is the appropriate choice. This may include a person's spouse, family, peers, and practitioner(s).	☐ don't know the opinions/practices of others involved in the decision (spouse, family, practitioner(s), others involved in the decision) ☐ misperceptions of others' opinions/practices involved in the decision reporting receiving conflicting recommendations from others	

Social Pressure Perception of persuasion, influence, coercion from important other(s) to select one option.	☐ feeling pressure from others involved in the decision (e.g. spouse, family, practitioners, or society) to choose a specific option	
Inadequate Internal Resources: Decisional Experience, Confidence, Motivation, Skills		
Inadequate experience Lacks previous exposure or experienced negative outcomes related to the condition/situation, options, outcomes and/or the decision-making process	**Classification of Type of Experience** ☐ No previous experience ☐ Previous experience with: ○ Condition/situation → specify whether post, neg, mixed _____ ○ Options → specify whether post, neg, mixed _____ ○ Outcomes → specify whether post, neg, mixed _____ ○ Decision making process -> specify whether pos, neg, mixed __ **Classification of need** ☐ lack of experience with _____ ☐ previous experiences had deleterious effect on current decision making, specify ___	
Inadequate decisional self-confidence (self-efficacy) Lacks belief in one's abilities to make a decision (includes participating in decision making and to implement the chosen option	☐ inadequate confidence to participate in decision-making ☐ inadequate confidence to implement chosen option	Decision Self-Efficacy Scale
Inadequate decisional motivation Lacks desire or willingness to engage in decision making	☐ lacking motivation or interest in making a decision	
Inadequate decisional skills Lacks abilities in making and implementing a decision	☐lacking the ability or skill to make a decision ☐ lacking the ability or skill to implement a decision	
Inadequate Social Support (information, advice, emotional support, instrumental help) and Other Resources (financial assistance, health and social services)		
Inadequate information Lacks quantity/quality of information (written, verbal) that is required to make and implement the decision.	☐ lacking access to (did not receive) information ○ options ○ benefits, risks ○ features of options ○ outcomes ○ scientific uncertainties regarding outcomes ○ the chances of benefits and harms/how likely each pro/con ○ **other's experiences with options (procedures, side effects outcomes)** ○ what other decide or recommend ○ health condition ○ other: did not receive **information materials** ☐ poor quality information ☐ **too much information: "information overload"**	
Inadequate access to advice Lacks quality/quantity of advice required to make and implement the decision.	☐ lacking advice from important others involved in the decision ☐ poor quality advice from important others involved in the decision	
Inadequate access to emotional support Lacks quantity/quality of emotional support to make and implement the decision.	☐ lacking emotional support, specify _____	

Inadequate access to instrumental help Lacks quality/quantity of instrumental help to make and implement the decision	☐ lacking instrumental help (e.g. transportation, housekeeping, daycare), specify _____	
Inadequate access to financial assistance Lacks quantity/quality of financial assistance to make and implement the decision.	☐ lacking financial assistance, specify _____	
Inadequate access to health and social services Lacks quantity/quality of health/social services required to make and implement the decision.	☐ lacking health & social services, specify _____	
Inadequate Support and Resources: Decisional Role and Needs		
Difficult Decisional Roles Roles refer to a participant's preferred or actual involvement in decision making; made on their own ; shared with someone else; or delegated to someone else. *Decisional role needs include: unclear decisional role, and mismatches between an informed person's preferred role and actual role.*	ROLE IN DECISION MAKING (DEGNER) ☐ Shared: wanted to share the decision with practitioner or other, specify ____ ☐ Patient-led: wanted to make decision on their own ☐ after considering others' views, specify _____ ☐ without considering others' views ☐ Delegated: wanted practitioner or other to make decision for them ☐ after considering patient's views ☐ without considering patient's views DECISIONAL ROLE NEEDS ☐ Unclear about role in decision making ☐ Mismatch between and informed* person's preferred role and actual role in decision making *Note, preferred roles shift when a person is informed about the nature of the decision (e.g. no clear best answer, best choice depends on what matters most to an informed person) **FAMILY ROLE NEEDS** ☐ **Difficulty involving family member in decision-making** **Contributing Factors:** o **Patient did not want to worry family** o **Family lacked knowledge** ☐ **Difficult sharing deliberations on options with family:** **Contributing Factors:** o **Different information needs** o **Different values** o **Communication barriers** **RELATIONSHIP BARRIERS WITH PRACTITIONERS** ☐ **Difficulty deliberating because patient/family:** ☐ **have not established a relationship with practitioner** ☐ **do not perceive they have positive relationship with the practitioner (e.g. trust, mutual respect, empathy, compassion, honesty, clear communication)**	
Influences of Decision Characteristics and Personal/Clinical Characteristics on Decisional Needs		
Decision Type Influences Type refers to the class or characteristics of the decision, for example, developmental transitions or clinical options to screen, test, treat, or palliate. *Decisional needs may be*	CLASSIFICATION OF DECISION TYPE ☐ Screening/diagnostic ☐ Treatment ☐ Palliate ☐ Location of care ☐ Other	

<table>
<tr><td>amplified if the decision has multiple options, scientifically uncertain outcomes, known outcomes that people value differently, and serious or permanent effects</td><td>CHARACTERISTICS OF DIFFICULT DECISIONS
☐ Multiple options: n=x
☐ Unknown outcomes
☐ Known outcomes:
☐ Serious effects
☐ Permanent effects (irrevocable)
☐ High chance of undesirable outcomes
☐ Valued differently by affected population
☐ Other, specify _____
DECISIONAL NEEDS AFFECTED BY TYPE OF DECISION
☐ Specify decisional need and measure (e.g. number of behavioural manifestations of DC, DCS total scale or subscales, other needs measures):____
☐ Other, specify _____</td></tr>
<tr><td>Decision Timing Influences
Timing refers to the time frame or urgency with which a decision has to be made. Decisional needs may be amplified if the timing is urgent or delayed.</td><td>DECISION TIMING
☐ Timing is urgent
☐ Decision needs to be made soon
☐ Timing is delayed
☐ Timing is unpredictable

DECISIONAL NEEDS AFFECTED BY DECISION TIMING
☐ Stage of decision making
☐ Other, specify _____</td></tr>
<tr><td rowspan="2">Decisional Stage Influences
Stage refers to the phase of decision making: not thinking about options; actively thinking about options; close to making a choice; and taking steps or already implemented the chosen option. (Deciding not to change or to do nothing may be a viable option). Decisional stage can make one unreceptive to information or deliberation due to denial, hasty decision making, premature closure, or polarized leaning.</td><td>STAGE OF DECISION MAKING IN THE EXTRACTED STUDIES
☐ A. In process of making a decision
☐ B. Retrospectively thinking about a decision in the past
☐ A. or B. – participants are either in the process of making a decision or retrospectively thinking about a decision in the past
☐ C. Retrospectively thinking about a decision in the past and reporting on current needs now after they have made the decision

DECISIONAL NEEDS AMPLIFIED BY DECISIONAL STAGE:
☐ Specify decisional need _____

<u>DECISIONAL STAGE NEEDS</u></td></tr>
<tr><td><table><tr><td>Need</td><td>Contributing factors</td></tr><tr><td>☐ Unreceptive to information
☐ Unreceptive to deliberation

☐ Other decisional stage needs</td><td>☐ Lack of acceptance of condition or need for treatment from
☐ Powerful emotions
☐ Lack of clinical symptoms
☐ Clinical condition (e.g. Bipolar)
☐ Powerful emotions affect information processing
☐ Unmotivated because decision too far off in the future or unpredictable
☐ Denial
☐ Hasty Decision Making
☐ Premature closure
☐ Polarized leaning

☐ Other contributing factors</td></tr></table></td></tr>
<tr><td></td><td>☐</td></tr>
<tr><td>Personal and Clinical Influences
Patient: Age, developmental stage, gender, education, marital status,</td><td>CHARACTERISTICS OF PATIENT/PRACTITIONER
☐ See table describing characteristics in specific studies
☐ Special needs considering age, developmental stage, gender, education, marital</td></tr>
</table>

ethnicity, socioeconomic status, occupation, locale, diagnosis & duration of condition, health status (physical, emotional, cognitive, social) *Decisional needs may be amplified if support and resources are not tailored appropriately to these characteristics* **Practitioner:** age, gender, ethnicity, clinical education, specialty, practice locale, experience, style of communication	status, ethnicity, **religion/spirituality**, socioeconomic status, occupation, locale, diagnosis & duration of condition, health status (physical, emotional, cognitive, social): _____ DECISIONAL NEEDS AFFECTED BY PATIENT CHARACTERISTICS ☐ Decisional needs that are amplified by patient characteristics, specify need/characteristic _____ ☐ Need for tailored information or other support & resources according to patient characteristics, specify _____	
Other Needs not mapped on to ODSF		

Appendix E: Frequency of Studies Reporting ODSF Decisional Need Categories, Decisional Needs, and Top 5 Manifestations of Decisional Needs

N	**Decisional Need Category**		**Decisional Need**		**Top 5 Manifestations of Decisional Needs**
N	**Modifiable with decision support**	**Influences on Decisional Needs**	**Modifiable Decisional Needs**	**Influences on Decisional Needs**	
45					
44					
43					
42					
41	Inadequate support and resources				
40	Inadequate knowledge		Inadequate knowledge		
39					
38					
37					
36					
35			Inadequate information		
34					
33					
32					
31					
30					
29					Inadequate knowledge of benefits, risks and outcomes; Inadequate access to information about the health condition, options, benefits, risks, or scientific uncertainties
28					
27					
26					
25					
24					
23					
22		Personal/Clinical Characteristic Influences			
21					
20	Unclear values Decisional conflict		Unclear values Decisional conflict		Feeling unclear about what is important

19		Decision Characteristic Influences			
18					
17					Feeling unsure about what to choose
16				Clinical special needs considering diagnosis & duration, & health status limitations in physical, emotional, social functioning	
15			Feel unsupported in decision making; Inadequate access to health and social services		Feeling unsupported in decision-making
14			Social pressure; Unclear/biased perceptions of others' opinions/practices		
13					
12					
11	Unrealistic expectations		Inadequate experience		
10			Inadequate decision making skills		
9					
8				Decision timing; Personal special needs considering age, gender, education, marital status, ethnicity, occupation, locale, socioeconomic status	
7			Inadequate motivation; Inadequate access to advice	Decision type	
6			Inadequate access to financial assistance;	Decisional stage needs	
5				Need for tailoring according to personal characteristics- age, gender, education, marital status,	

				ethnicity, occupation, locale, socioeconomic status	
4			Mismatch in preferred & actual decisional role	Need for tailored information according to clinical diagnosis & duration, & health status limitations in physical, emotional, social functioning	
3			Inadequate access to emotional support		
2			Inadequate self-confidence; Inadequate access to instrumental help		
1					