Evaluating Interventions to Support Child-Parent Involvement in Health Decisions

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Thesis Abstract

Objective: To explore interventions that support children and parents making health decisions.

Systematic Review: A systematic review was conducted to synthesize evidence on interventions that support children's health decision making. Five studies of variable quality were included. Interventions that improved decision making were decision coaching with or without an educational resource, or education alone.

Pre-/post-test pilot: A pre-/post-test study evaluated the feasibility and acceptability of decision coaching guided by the Ottawa Family Decision Guide for children with type 1 diabetes and their parents. Of 16 families invited, 7 participated. Compared to children/parents who preferred one option at baseline, participants who were unsure of the best option rated decision coaching as more acceptable and had larger decreases in decisional conflict.

Conclusions: Few studies have evaluated interventions supporting children's decision making. The piloted decision support intervention was feasible and acceptable, particularly with children and parents who were unsure of the best option.

Acknowledgements

"Standing on the shoulders of giants"

The accomplishment of great things often occurs at the expense of great people. This is nearly axiomatic within research, and the preparation of a Master's thesis is no exception. As such, there are several 'giants' that I would like to recognize and thank for graciously lending me the support of their shoulders over the past two years.

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List of Abbreviations

Abbreviation	
APN	Advanced Practice Nurse
DCS	Decisional Conflict Scale
ITTT	It Takes Three to Tango
ODSF	Ottawa Decision Support Framework
OFDG	Ottawa Family Decision Guide
PtDA	Patient decision aid
RCT	Randomized controlled trial
SDM	Shared decision making

Chapter One- Introduction

1.1 Relevance/ Problem

Parents and their children/youth can face difficult health decisions which may lead to decisional conflict (Jackson, Cheater & Read, 2008; Lyon at, 2009). Decisional conflict is defined as a state of uncertainty that arises when deciding between two or more options that involve risk, loss, potential for future regret or challenges to personal life values (Ackley & Ladwig, 2006). A nationwide survey of 635 adult Canadians found that 65% had faced a preference-sensitive health decision (lack clear indication as to which outcome is best) and of those, 59% had experienced decisional conflict (O'Connor et al., 2003). Although this survey excluded those under age 18, individuals aged 14 to 21 have been reported to experience decisional conflict when faced with preference-sensitive health decisions (Lyon et al., 2009). One example of a decision that children and their parents may face is whether to use a diabetes pump, standard insulin therapy, or multiple daily injections to manage type 1 diabetes (Children's Hospital of Eastern Ontario, 2009, Wu et al., 2010).

Type 1 diabetes management is an important issue in pediatric health care given its prevalence, potential for future complications, and intensive management. Although there are currently no national estimates available for Canada, provincial estimates range from 15 cases per 100,000 children aged 18 years and under in Quebec (1989-2000) to 35 cases per 100,000 children aged 14 years and under in Newfoundland and Labrador (1987-2005) (Legault & Polychronakos, 2006; Newhook et al., 2008). The Public Health Agency of Canada (2011) reports that there are nearly 26,000 individuals aged 1-19 with diabetes (type 1 and 2) in Canada and an estimated 3,000 new cases diagnosed each year, with type 1 diabetes representing around 95% of these cases (Amed et al, 2010). The incidence of type 1 diabetes has also been increasing worldwide over the last twenty years (DIAMOND Project Group, 2006). Canada is estimated to

have experienced a 5.1% increase in childhood type 1 diabetes from 1990-1999 (DIAMOND Project Group, 2006).

Effective diabetes management is important for prevention of short term complications of hypoglycemia and long term complications such as diabetic retinopathy, kidney failure, nerve damage, cardiovascular disease, and higher mortality (Lipton, 2007; Ryan, Gurtunca, & Becker, 2005). Furthermore, the risk for developing these long-term complications is significantly higher than for individuals with type 2 diabetes, partly due to the early age onset of type 1 diabetes (Public Health Agency of Canada, 2011). Finally, type 1 diabetes management is very intensive and, therefore, can have a significant impact on both child and parent (Alsaleh, Smith & Taylor, 2012; Beléndez, de Wit, & Snoek, 2010; Miller & Drotar, 2007). Children with type 1 diabetes require insulin which must be given by daily injections or an insulin pump, frequent self-blood glucose monitoring, and careful management of diet and physical activity to avoid the short and long-term complications of diabetes.

Several insulin delivery options are available to manage type 1 diabetes. Three common methods include standard insulin therapy (2 or 3 injections per day), multiple daily injections (MDI), and continuous subcutaneous insulin infusion (CSII or insulin pump therapy) (Canadian Diabetes Association [CDA] Clinical Practice Guidelines Expert Committee, 2008). All of these therapies have been demonstrated to be safe and effective; however, CDA guidelines suggest treatment regimens should be individualized at the patient level and as such, health care professionals should account for patient values and preferences in decision making. However, children/youth and parents may have different preferences for diabetes management given that the child or youth is the one receiving the injections or wearing the pump and is, therefore, more likely to focus on short-term benefits and harms, whereas parents are more likely to be motivated

to longer term benefits and harms for their child (Alsaleh, Smith & Taylor, 2012; Low et al., 2005).

Consequently, the process of selecting an intervention that optimizes diabetes management and meets the individual preferences of child and parent(s) may produce a significant amount of decisional conflict. A model of shared decision-making (SDM) whereby parents, children and clinicians participate in decision making through an exchange of information and preferences to reach an agreement on treatment plan is advocated as an ideal method of decision making in health care (Gabe, Olumide, & Bury, 2004). There is evidence that both children and their parents want to be involved in the decision making process (Coyne, 2008; Jackson, et al., 2008; Kools, Gilliss & Tong, 1999), however, it is uncertain whether the views of children are consistently elicited in current practice (Bricher, 2000; Dixon-Woods, Young, & Heney, 1999).

Interventions available to reduce decisional conflict and facilitate SDM include decision coaching and decision aids such as the Ottawa Personal Decision Guide (OPDG) or the Ottawa Family Decision Guide (OFDG) (Arimori, 2006; Stacey et al., 2008). Decision coaching guided by the OPDG has demonstrated effectiveness in reducing decisional conflict in women considering prenatal genetic testing (Arimori, 2006). However, despite the evidence to support the effectiveness of these types of interventions in the adult population, little is known about their use in the pediatric setting where multiple stakeholders (i.e., clinician, parent, and child/youth) are involved (Stacey et al., 2012; Stacey et al., 2011). Although randomized controlled trials have evaluated decision aids for adults with type 2 diabetes, none have evaluated patient decision aids in children with diabetes (Stacey et al., 2011).

1.2 Thesis Objective

The objective of this thesis is two-fold: 1) to review the characteristics and effectiveness of interventions that support the decision making needs of children who are actively considering a health-related decision and, 2) to evaluate the feasibility and acceptability of decision coaching guided by the OFDG with parents and their children who are considering insulin options for type 1 diabetes management.

1.3 Conceptual Frameworks

Frameworks used to guide the research were the Ottawa Decision Support Framework (ODSF) (O'Connor et al., 1998) and 'It Takes Three to Tango' (Gabe, Olumide & Bury, 2004). The ODSF is organized into three steps: 1) assessment, 2) intervention and 3) evaluation (O'Connor et al., 1998).

1) The first step identifies the determinants of decision making that influence the making and implementation of a decision. These decision making needs include aspects such as patient and clinician characteristics, patient perceptions of the decision, perceived involvement of others, and availability of resources for decision making.

2) In the second step, decision support is used to prepare the patient for decision making (O'Connor et al., 1998). Interventions such as clinician counseling, decision coaching and/or decision aids are used to target the patient's modifiable decision-making needs (e.g. inadequate knowledge, unrealistic expectations, unclear values, perceived pressures, lack of support and/or inadequate resources).

3) The third step evaluates decision support by examining the quality of the decision made, the decision-making process and the outcomes of the decision (O'Connor et al., 1998). According to the framework, a quality decision is one that is informed, congruent with personal

values, is implemented and elicits satisfaction from relevant stakeholders. The ODSF describes a quality decision making process as one that includes adequate knowledge, realistic expectations, clear values, alignment between values and actual choice, low decisional conflict, satisfaction with the decision making process and the decision, and implementation of the decision. Outcomes of a quality decision and decision making process may include an improvement in decision adherence, quality of life, satisfaction with care, efficient use of resources, and reduced distress and regret.

The ODSF has been evaluated extensively and has several tools such as the OPDG and the OFDG for use in practice (Legere et al., 2006; O'Connor et al., 1998). For my thesis the ODSF was used to guide the process of development, implementation, and evaluation of the decision coaching within the intervention study. The decision making needs of the patient population were considered, an appropriate intervention to meet these needs was chosen and implemented, and outcomes relating to decision quality and decision making process were used for evaluation of the intervention. It was also used in the systematic review to classify the elements of interventions to support child decision making.

The second framework is called 'It Takes Three to Tango' (ITTT): a framework for understanding patient partnership in pediatric clinics (Gabe, Olumide & Bury, 2004). The ITTT framework advocates a partnership between the child/youth, parent(s) and clinician(s) to facilitate SDM. Partnership, a concept central to the framework and a prerequisite to SDM, includes establishing common goals and mutual respect in the absence of a hierarchical structure. The ITTT also identifies several factors influencing partnership, namely: the organizational and legal setting, the perspectives of decision stakeholders and the types of coalitions that form between those involved in the decision process.

Of particular importance to the identified research problem is the unique perspective of each member of the triad. The success of partnership in pediatrics is threatened by the ability of different members within the triad to impose their perspective and influence the outcome through the exertion of power during the consultation (Gabe et al., 2004). The framework argues that parents hold a significant power differential over children/youth, making executive-like decisions on their behalf. This power differential increases as parents gain knowledge about their child/youth's circumstances. The authors also acknowledge, however, that the parental role within the triad is variable in practice since it also represents the varying dynamics brought from the home environment.

The authors of the ITTT framework note that the clinician is also susceptible in contributing to the power differential (Gabe et al., 2004). They point out that clinicians' assumptions regarding a child/youth's level of competence to make decisions are often tied to the age of the child. Since the assessment of competence lies with the clinician, incorrect assumptions about competence can negatively impact their willingness to involve the child/youth (Gabe et al., 2004). The authors question whether the clinician's inability to communicate effectively with children/youth rather than the child/youth's level of competence, is responsible for their lack of comprehension. Appropriate and relevant means of communication are, therefore suggested in order for an effective information exchange between the clinician and child/youth to occur.

Finally, the ITTT framework values the child/youth's perspective in planning his or her care (Gabe et al., 2004). While it is uncertain in which situations children/youth wish to participate in decision-making, not involving them risks resistance, dissatisfaction and other negative effects (Gabe et al., 2004).

This framework has little empirical evaluation and no tools for use in practice. Rather the framework was used in this thesis as a means of mitigating potential power differentials by establishing a structure within the intervention that ensures each member within the triad (child, parent, clinician) is given an opportunity to express their preferences and have their perspective accounted for.

1.4 Thesis Outline

This thesis is structured according to a series of two papers and an integrated discussion. Chapter 2 is the first paper, entitled "Interventions to Support Children Engaging in Health-Related Decisions: a Systematic Review". This chapter addresses the first objective by synthesizing the evidence on existing interventions available to support the health-related decision making needs of children. Chapter 3 is the second paper, entitled "Decision Coaching using the Ottawa Family Decision Guide with Children and their Parents: A pilot study". It addresses the second objective by reporting on a pilot study that examined the feasibility of a decision coaching intervention using the OFDG and collecting data using several outcome and process measures. Chapter 4 is an integrated discussion of the findings from chapters 2 and 3 and outlines their implications for nursing practice, future health policy development and areas for further research. Additionally, Appendix A: Contributions of Collaborators, outlines the contributions and respective roles of various collaborators involved in this project.

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Chapter Two

Interventions to Support Children Engaging in Health-Related Decisions: A Systematic Review

This chapter is based upon an unpublished manuscript formatted for submission to the journal Pediatrics

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Abstract

Context: Children often need support in health decision making.

Objective: To review characteristics and effectiveness of interventions that support health decision making of children.

Methods: A systematic review.

Data Sources: Electronic databases (PubMed, the Cochrane Library, Ovid, Web of Science, Scopus, Proquest Dissertations and Theses, CINAHL, Psych-INFO, MEDLINE, and EMBASE) were searched from inception until end of March 2012.

Study Selection: Two independent reviewers screened eligibility: a) intervention studies; b) involved supporting children (≤18 years) considering health-related decision(s); and c) measured decision quality or decision making process outcomes.

Data Extraction: Data extraction and quality appraisal conducted by one author and verified by another using a standardized data extraction form. Quality appraisal was based on the Cochrane Risk of Bias tool.

Results: Of 4313 citations, 5 were eligible. Study quality ranged from lower to higher risk of bias. Interventions focused on supporting decisions about risk behaviors (n=3), psycho-educational services (n=1), and end of life (n=1). Three of five studies had statistically significant findings: i) decision coaching alone increased values congruence between child and parent, and child satisfaction with decision making process; i) decision coaching with a co-intervention increased agreement between child's values and chosen behavior; iii) workshop with weekly assignments increased overall decision making quality. The two other studies found no difference in outcomes.

Conclusions: Few studies of variable quality focus on interventions to support child decision making. However, decision coaching with or without co-interventions may improve overall decision making quality, parent-child agreement, values-choice congruence, and satisfaction.

2.1. Introduction

2.1.1 Rationale

There is an expanding consensus among researchers, policy makers and health professionals that children should be encouraged to participate in the process of making decisions regarding their health (Coyne, 2006; Coyne & Harder, 2011; Moore and Kirk, 2010). Shared decision making (SDM) is a decision making process that involves children, parents, and clinicians (e.g. physicians, nurse practitioners) in decision making through an exchange of information and preferences to reach agreement on a treatment plan (Gabe, Olumide & Bury, 2004). When children are involved in SDM, they are reported to experience decreased anxiety and an increased sense of value and control (Moore and Kirk, 2010; Tiffenberg, 2000). Their involvement is also thought to improve communication between children, parents and clinician(s), which is important for child/parent satisfaction, and may also improve adherence with the chosen treatment (Adelman, Kaser-Boyd & Taylor, 1984; McCabe, 1996).

The practice of including children in decision making is also advocated by several prominent organizations. In 1989, the United Nations Convention on the Rights of a Child (UNCRC) provided grounds for a child's right to be involved in decisions regarding his or her health (United Nations, 1989). Article 12 of the UNCRC states "parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child" (United Nations, 1989, p.4). The American Academy of Pediatrics Committee on Bioethics also suggests that children should be included in their decision making to the greatest extent possible (Mercurio et al., 2008).

Despite these mandates studies show that, children are not adequately involved and their preferences are not being elicited as often or consistently as they could (Bricher, 2000; Coyne, 2008; Dixon-Woods, Young, & Heney, 1999; Mårtenson, & Fägerskiöld, 2008). Furthermore, although most clinicians recognize a need to include children in decision making, they have varying opinions about when and how to do so (Vaknin & Zisk-Rony, 2011). Factors such as the child's age, length of illness, previous experiences, clinical condition, behavior, and ability to express oneself are often considered when deciding whether or not to include him or her (Coyne, 2006; Nova, Vegni, & Moja, 2005; Vaknin & Zisk-Rony, 2011). As a result, children are often excluded, which may lead to fear, confusion, and anger on the part of the child (Moore & Kirk, 2010; Runeson et al., 2002).

Although several studies have examined the decision making needs of children faced with decisions, they are primarily focused on the perspective of parents. A systematic review of 149 studies identified three decision support needs of parents: information, communication with others, and a perceived sense of control over the process (Jackson, Cheater, & Reid, 2008). A narrative review of parental preferences and perspectives in the pediatric decision making process noted that parents prefer an active role, encounter various influences, and need support to determine when and how to include their children in treatment decisions (Lipstein, Brinkman, & Britto, 2011). Other studies found that children require access to information, an appropriate means of communication, and support from parents and clinicians to participate in SDM (Coad & Shaw, 2008; Coyne, 2008; Dunsmore & Quine, 1995; Martenson & Fagerskiold, 2007; Moore & Kirk, 2010).

Decision support interventions such as patient decision aids and decision coaching are well tested in the adult population. Patient decision aids are tools that prepare a patient for SDM

with their practitioner by explaining options, clarifying personal values relating to benefits and harms, and facilitating deliberation and communication (O'Connor et al., 1999; O'Connor et al., 2007). A systematic review of 86 trials found that decision aids increase the quality of patient's decisions and the decision making process (Stacey et al., 2011). Decision coaching is a form of non-directive counseling that provides individuals with support to meet their decision making needs in order to prepare them for consultation with the clinician ultimately responsible for sharing in the decision with the patient (Stacey et al., 2012). A systematic review examining the characteristics and effectiveness of decision coaching suggested non-directive decision coaching may be a useful adjunct to patient decision aids (Stacey et al., 2012). However these reviews only examined the use of decision support interventions with adult populations. A review by Ranmal, Prictor and Scott (2012) examined the effects of interventions that enhance general communication between health professionals and children with cancer. Although some interventions demonstrated minimal benefit to children in providing knowledge, psychological support, and reintegration into school and social activities, the communication interventions in this review were not designed to address children's decision making needs. To date, no systematic review has been conducted that specifically explores interventions that support children in their health-related decision making.

2.1.2 Objective

The purpose of this systematic review was to explore the characteristics and effectiveness of interventions that support the decision making needs of children who are actively considering a health-related decision.

2.2 Methods

2.2.1 Design/Protocol

A systematic review was conducted according to a protocol developed a priori. The protocol was guided by the Cochrane Handbook for Systematic Reviews of Interventions (Cochrane Handbook) (Higgins & Green, 2011). Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement guidelines were used to format the reporting of findings (Moher, Liberati, Tetzlaff, & Altman, 2009).

2.2.2 Eligibility Criteria

Studies including children aged 18 and under who were actively facing a health-related decision with or without their parent(s)/guardian(s) were considered for inclusion (see Table 2.1). Studies needed to evaluate an intervention that addressed an identified decision making need of the child. All study designs were included (e.g. randomized controlled trials (RCT's), non-randomized controlled trials (non-randomized CT), interrupted time series (ITS), and controlled before-and-after (CBA) designs). Comparator groups could have been usual care or any alternative intervention and included doing nothing. Study outcomes needed to address either the quality of the decision (e.g. knowledge, values-choice agreement) or the decision making process (e.g. decisional conflict, satisfaction) for children. These outcomes are based on the International Patient Decision Aids Standards (Elwyn et al., 2006; International Patient Decision Aids Standards, 2005) and are consistent with systematic reviews of interventions to support adults and parents in making health decisions (Jackson et al., 2008; Stacey et al., 2011).

Table 2.1: Inclusion/Exclusion Criteria

	Included	Excluded
Participants	• Children (≤18 years) who are facing a health-related decision • Decisions about participation in health research	• Children not treated as active participants in decision making or decisions not directly pertaining to their health • Hypothetical decisions
Interventions	• Interventions to support children's decision making needs.	• Interventions that support only the information needs of children
Design	• Randomized controlled trials • Non-randomized controlled trials • Interrupted time series • Controlled before-and-after	• Qualitative studies, descriptive studies, cohort studies • Editorials, opinion articles
Outcomes	• Outcomes that affect the *quality* of the decision or the decision making *process* for children/youth	• Studies that do not report at least one of the outcomes relating to the quality of the decision or the decision making process
Language	• English or French	• Other languages
Publication status	• Published • Peer-reviewed	• Unpublished studies • Non peer-reviewed

2.2.3 Information Sources

The following electronic databases were searched to the end of March 2012: Evidence-Based Medicine Reviews (Ovid) (Cochrane Database of Systematic Reviews (March 2012), Database of Abstracts of Reviews of Effects (1st quarter 2012), Cochrane Central Controlled Trials Register (2005 to March 2012)); MEDLINE (Ovid) (1966 to present); MEDLINE (PubMed) (1945 to present); CINAHL (via EBSCOhost) (1981 to present); Psych-INFO (1806 to present); Web of Science (1898 to present); Scopus (1960 to present); Proquest Dissertations and Theses (1861-present); EMBASE (Ovid, 1974 to present). The Agency for Healthcare Research and Quality (AHRQ) website (under Children's Health) and Google Scholar were also searched informally using the main key words from the search strategy. Finally, reference lists of relevant articles and review articles were scanned.

2.2.4 Search Strategy

The search strategy included keywords related to the intervention (e.g. intervention, patient participation, social support, health communication), decision support techniques (e.g. decision making--computer-assisted, decision trees), and decision making (see Table 2.2). Some limits were applied relating to study types (e.g. clinical trials, or randomized controlled trials, or evaluation studies), language (English or French only), and participant types (must include child or adolescent).

Table 2.2: Search strategy used for PubMed

Group	Terms
1	intervention* OR intervene* OR "Health Knowledge, Attitudes, Practice"[Mesh] OR "Social Support"[Mesh] OR "Family"[Mesh] OR "Patient Participation"[Mesh] OR "Health communication"[Mesh] OR "Health education"[Mesh] OR "Decision Support Techniques"[Mesh] OR "Decision Making, Computer-Assisted"[Mesh])
2	("Decision Making"[Mesh])
3	(Humans[Mesh])
4	(Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp] OR Review[ptyp] OR Classical Article[ptyp] OR Comparative Study[ptyp] OR Controlled Clinical Trial[ptyp] OR Evaluation Studies[ptyp] OR Historical Article[ptyp] OR Journal Article[ptyp] OR Multicenter Study[ptyp] OR Patient Education Handout[ptyp] OR Validation Studies[ptyp])
5	(English[lang] OR French[lang])
6	(infant[MeSH] OR child[MeSH] OR adolescent[MeSH])
7	NOT (aged[MeSH Terms]) OR adult[MeSH Terms]
8	Limits: Preschool Child: 2-5 years, Child: 6-12 years, Adolescent: 13-18 years

2.2.5 Study Selection

After removing duplicates, retrieved article citations were entered into a web-based tool designed to facilitate screening. The screening process involved three levels: title only, title plus abstract and full-text screening. Levels one and two were completed by BF and at least one other reviewer (LB, DS, ML, JK) to judge the citation as ‘include’, ‘exclude’ or ‘unsure’. All citations rated as ‘include’ or ‘unsure’ by at least one reviewer were advanced to the next level. Full-text versions were obtained and reviewed for final inclusion (BF, LB). Disagreements between reviewers were resolved by consensus with a third member (DS) of the review team. Study

investigators were contacted regarding missing data or when clarification was required to confirm study eligibility.

2.2.6 Data Collection Process

Data extraction was conducted by one review author (BF) and verified by a second review author (LB). The process was guided by a data extraction form (Appendix B) based on a template provided by another systematic review of decision support interventions (Stacey et al., 2011). The data extraction sheet was piloted with a randomly selected study chosen for inclusion and necessary revisions to the form were made. Disagreements between review authors regarding data extraction were resolved by discussion. When unresolved, a third reviewer (DS) arbitrated the decision.

2.2.7 Data Items

The following information was extracted from each study (as per the data extraction sheet): a) characteristics of child participants (location, age, gender, ethnicity, diagnosis, and stage of illness), b) study methods (aims, design, allocation, recruitment, inclusion/exclusion criteria, informed consent, ethical approval, funding, and statistical methods), c) interventions and control intervention(s) (enrollment and attrition of participants, type(s), co-interventions, content, mode of delivery, timing, frequency, duration, provider, training, and elements of decision support), e) outcomes (primary and secondary measures, definition(s), methods of follow-up, timing, validity of instruments used and adverse events), f) results (according to study type), and g) limitations and conclusions.

2.2.8 Risk of Bias Assessment for Individual Studies

The Risk of Bias tool from the Cochrane Handbook was used to assess RCT's (Appendix C) (Higgins & Green, 2011). Risk of Bias tables adapted using guidelines developed by the

Cochrane Effective Practice and Organization of Care Review Group (2011) were used to assess studies with non-randomized CT, ITS and CBA designs (Appendix D).

Quality assessment was completed independently by two reviewers (BF, and a research assistant). Disagreement was resolved through discussion, and if unsuccessful, a third reviewer (DS) arbitrated. As suggested by the Cochrane Handbook, the following types of bias were assessed as "high risk", "low risk", or "unclear risk": a) selection bias (random sequence generation and allocation concealment), b) performance bias (blinding of participants and personnel), c) detection bias (blinding of outcome assessment), d) attrition bias (incomplete outcome data), e) reporting bias (selective reporting), and f) other bias.

2.2.9 Summary Measures

The primary outcomes of interest for this systematic review were those that improved decision quality: knowledge regarding the decision and options, accuracy of perceptions regarding benefits and harms of treatment options, and agreement between values and chosen option. Secondary outcomes were those that improved the decision making process: satisfaction with process, decisional conflict, participation in decision making process, communication with practitioner and parent(s)/guardian(s), and proportion undecided.

2.2.10 Methods of Analysis

A limited number of eligible studies and heterogeneity made combining outcomes impractical. A descriptive synthesis was conducted. The synthesis of findings was structured using the following domains: characteristics of studies, interventions, and outcome measures, and impact of interventions. Studies with similar interventions were grouped together. The following intervention categories were used: a) decision coaching only (coaching), b) coaching plus an educational aid, and c) education only. Essential elements of decision support

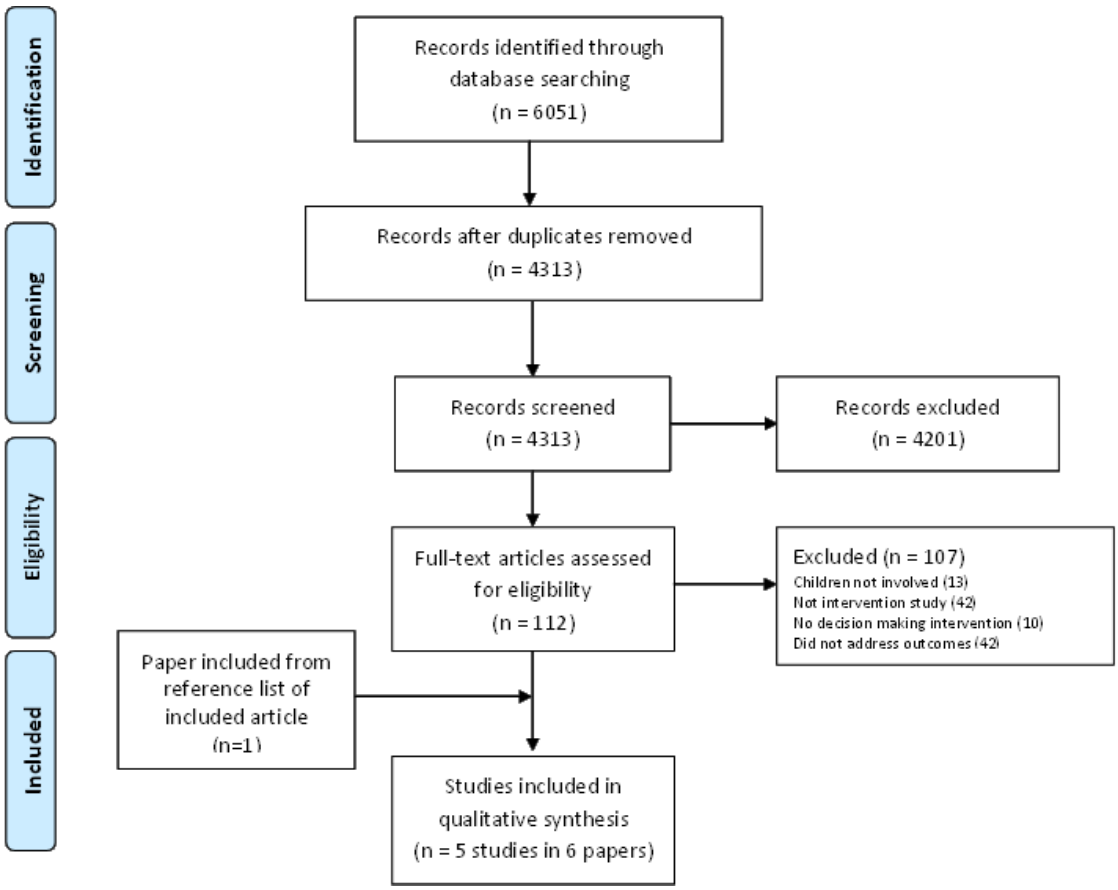
interventions were identified with criteria previously used to evaluate decision support technologies and general SDM interventions (Elwyn et al., 2009; Kryworuchko, 2012; Makoul & Clayman, 2006; & Stacey et al., 2012).

2.3 Results

2.3.1 Study Selection

The search identified 6051 citations. After removing 1738 duplicates, 4313 original articles remained for screening (see Figure 2.1). Of these, 4201 citations were removed after title and abstract screening because they did not meet the inclusion criteria. The full text reports of 112 citations were retrieved and 107 citations were excluded. The results of one study were published in two papers; therefore, the second article was retrieved to determine all reported outcomes.

Figure 2.1: Flow Diagram of Study Selection Process



2.3.2 Study Characteristics

Table 2.3 summarizes the characteristics of the five included studies. All studies were conducted in the United States and published in English. Three studies published since 2008 were RCTs (Adams, Norman, Hovell, Sallis & Patrick, 2009; Lyon, Garvie, McCarter, Briggs, He & D'Angelo, 2009; Rhee, Hollen, Belyea & Sutherland, 2008), and two studies published before 2000 were a non-randomized CT (Adelman, MacDonald, Nelson, Smith & Taylor, 1990), and a CBA study (Hollen, Hobbie & Finley, 1999). Studies included a variety of decision types including participating in risk behaviors, choosing a psycho-educational service to overcome learning problems, and end of life planning. Four studies were conducted in a clinical setting (Adams et al., 2009; Adelman et al., 1990; Lyon et al., 2009 (a, b); Rhee et al., 2008) and one

was conducted in a day camp (Hollen et al., 1999). Three studies were conducted with children who had a chronic medical condition (Hollen et al., 1999; Lyon et al., 2009 (a, b); Rhee et al., 2008) and two were conducted with children without any previous medical history (Adams et al., 2009; Adelman et al., 1990).

2.3.3 Risk of Bias within studies

Risk of bias was higher in the two older studies that were not RCTs (Adelman et al., 1990; Hollen, et al., 1999) (see Table 2.3). Of the five included studies, two of the RCTs were rated as lower risk of bias, one RCT had unclear reporting to judge risk of bias, and two non-RCTs had higher risk of bias.

Table 2.3: Characteristics of Included Studies (N=5)

Author (Year)	Study design	Decision	Participants (n) and Setting	Comparisons	Primary Outcome(s)	Quality Assessment		
Rhee, 2008	RCT	Partaking in risk behaviors	41 children with asthma (20 + 21); 4 rural outpatient clinics and 1 high school	Coaching and computer based program v. attention placebo	Feasibility of the decision making program	**1**: Low Risk **2**: Low Risk **3**: Low Risk	**4**: Low Risk **5**: Unclear **6**: Unclear	**7**: Low Risk
Lyon, 2009 (a, b)	RCT	End of life decision making	40 children with HIV and their parents (21 + 19); 2 hospital outpatient clinics	Coaching v. attention placebo	Communication quality, congruence of treatment preferences, decisional conflict satisfaction	**1**: Low Risk **2**: Low Risk **3**: Unclear	**4**: Unclear **5**: Low Risk **6**: Unclear	**7**: Low Risk
Adams, 2009	RCT	Sun exposure vs. sun protection	819 children (395 + 424); primary care physicians office	Coaching + computer program v. attention placebo	Sun protection behaviors, pros for protection, pros for exposure, decisional balance	**1**: Unclear **2**: Unclear **3**: Low Risk	**4**: Unclear **5**: Unclear **6**: Unclear	**7**: Low Risk
Hollen, 1999	CBA	Partaking in risk behaviors	64 cancer-surviving children (21 + 43); campground	Workshop + weekly assignments v. no intervention	Decision making, risk motivation, risk behaviors	**1**: High Risk **2**: High Risk **3**: High Risk	**4**: Unclear **5**: Unclear **6**: Low Risk	**7**: Low Risk
Adelman, 1990	Non-randomized CT	Psycho-educational decision making	85 families (child, parent) (32 + 33 + 20); university clinic	Pre-conference coaching v. attention placebo v. no intervention	Child participation	**1**: High Risk **2**: High Risk **3**: High Risk	**4**: High Risk **5**: Unclear **6**: High Risk	**7**: Low Risk

Quality Assessment Legend

1: Random sequence generation
2: Allocation concealment.
3: Blinding of participants AND personnel
4: Blinding of outcome assessment
5: Incomplete outcome data
6: Selective reporting
7: Other sources of bias

2.3.4 Characteristics of Decision Support Interventions

Interventions included support in the form of decision coaching (Adams et al., 2009; Adelman et al., 1990; Lyon et al., 2009 (a, b); Rhee, 2008) or an educational workshop (Hollen et al., 1999), and were accompanied by computer programs, workbook exercises, telephone follow-ups, and information packages (see Table 2.4). Controls received no intervention (Hollen et al., 1999) and/or an attention placebo such as a computer program, coaching, or information package on another topic not related to the decision (Adams et al., 2009; Adelman et al., 1990; Lyon et al., 2009 (a, b); Rhee, 2008). Of 12 essential elements of decision support interventions, one study addressed 11 elements (Lyon et al., 2009a,b), three studies addressed six elements (Adams et al., 2009; Hollen et al., 1999; Rhee et al., 2008), and one study addressed four elements (Adelman et al., 1990) (see Table 2.5).

Four studies used interventions that were delivered in stages, ranging from 1 week to 3 months apart (Adams et al., 2009; Hollen et al., 1999; Lyon et al., 2009 (a, b); Rhee, 2008), and one study used an intervention delivered at one time (Adelman et al., 1990). Total length of time for main interventions in four studies ranged from a 2-3 minute session to three sessions totaling 180 to 270 minutes, and one day for the camp workshop. Co-interventions (e.g. computer programs, workbook exercises, information packages) ranged from 30 to 90 minutes, although two studies did not specify their length of time. Two of the three attention placebos were comparable in length of time to the main experimental intervention. Length of time was not specified for all other controls (Lyon et al., 2009a,b; Rhee et al., 2008).

Table 2.4: Characteristics of Decision Support Interventions (N=5)

Study (Year)	Group	Description of the Decision Support Program	Group Summary and Frequency	Length of Time
Rhee, 2008	Decision support	Coaching guided by risk behavior fact sheet. Computer-based decision making module Intervention boosters: computer based decision making module, workbook, and substance prevention computer program	Main intervention plus CD-ROM intervention booster at 2 and 4 mo. post-intervention	Coaching= 10 min, Computer= ~ 1-hour, 2 mo. booster= ~1.5 hours, 4 mo. booster = ~ 30 min
	Control	Sham computer program of comparable length featuring study skills No booster	Computer program only	Comparable to the intervention program minus the booster
Lyon, 2009 (a,b)	Decision support	3 semi-structured interviews: 1. *Lyon Family Centered Advance Care Planning Survey*, 2. The *Respecting Choices* patient centered-ACP interview, 3. *Five Wishes* legal directive	3 sessions, 1 week apart	180- 270 min. (for three sessions)
	Control	3 sessions re: 1. Non-medical developmental history, 2. Safety information, 3. Career planning	3 sessions, frequency not specified	Comparable to the intervention
Adams, 2009	Decision support	Brief coaching from clinician, interactive computer sessions, telephone assessments, printed tailored feedback, a brief printed manual, mailed tip sheets, and samples of SPF 15 sunscreen	Main intervention at baseline and 12 months. At 3, 6, 15, and 18 mo. children phoned for the expert system assessments	Coaching session= 2 to 3 min. Sun Smart System= ~20 min Follow up assessments= not specified
	Control	Computer program coupled with monthly stage-matched telephone calls, printed manual and mail for 24 mo. Information related to physical activity, sedentary behavior, total intake of fat, and servings per day of fruits and vegetables	Stage matched to intervention group	Not specified
Hollen, 1999	Decision support	Camp workshop integrating survivorship, quality decision making skills, children risk behaviors, and social support from peers and health professionals. Follow up workbook exercises with audio-tape	Workshop plus 4 weekly assignments	Workshop= 1 day. Weekly assignments= not specified
	Control	No intervention	Not specified	Not specified
Adelman, 1990	Decision support	Pre-conference coaching encouraging and facilitating child's participation in the conference	Main intervention only	5 to 15 min
	Control	1. Attention placebo-expanded neutral explanation of the conference process. 2. Non-intervention- no intervention	Control 1: Explanation only Control 2: Not specified	Control 1: Not specified Control 2: Not specified

Table 2.5: Elements of the Decision Support Interventions (N=5)

Intervention Item	Rhee, 2008	Lyon, 2009 (a, b)	Adams, 2009	Hollen, 1999	Adelman, 1990
Intervention Type					
Coaching only		✓			✓
Coaching + educational aid	✓		✓		
Education only				✓	
Elements of Decision Support					
Problem defined/explained	✓	✓		✓	✓
Assess/discuss patient's decision making needs		✓	✓		
Options (including alternatives) presented	✓	✓	✓	✓	
Benefits of options discussed	✓	✓	✓	✓	
Risks of options discussed	✓	✓		✓	
Understanding assessed/clarified		✓	✓		
Values/preferences discussed	✓	✓	✓	✓	
Build skills in deliberation, communication, and accessing support		✓			✓
Ability/self-efficacy to enact plan discussed					✓
Decision made or explicitly deferred		✓			
Facilitate progress in decision making	✓	✓	✓	✓	✓
Follow-up arranged		✓			
Total Elements	**6**	11	**6**	**6**	**4**

✓= intervention type present/ decision support element present

2.3.5 Characteristics of Outcome Measures

Four studies had one or more primary outcomes related to decision quality (Adams et al., 2009; Adelman et al., 1990; Lyon et al., 2009 (a, b); Hollen et al., 1999) and two studies had one or more outcomes related to the decision making process (Adelman, 1990; Lyon et al., 2009 (a, b)) (see Table 2.3). One study had only one secondary outcome related to decision quality (Rhee et al., 2008). Quality of decision making was measured as an outcome in two studies using the Decision Making Quality Scale. Satisfaction with the decision making process was an outcome measured in two studies using different scales. All other decision making outcomes (agreement

between values and chosen option, congruence of treatment preferences between child and parent, participation in decision making process, decisional conflict, and communication) were measured just once (Adams et al., 2009; Adelman et al., 1990; Lyon et al., 2009 (a)).

Outcomes not related to decision quality or decision making process were also identified in several studies: actual sun protection behaviors (Adams et al., 2009), motivational readiness and future motivation (Adelman et al., 1990), risk motivation and actual risk behaviors (e.g. smoking, alcohol use, and illicit drug use) (Hollen et al., 1999; Rhee et al., 2008), and feasibility of a decision making program (Rhee et al., 2008).

2.3.6 Impact of Interventions

2.3.6.1 Decision coaching only v. Attention Placebo/no Intervention (n=2 studies)

Of the five included studies, Adelman et al. (1990) and Lyon et al. (2009a, b) compared coaching with an attention placebo or no intervention (Table 2.3). Lyon et al. (2009a) reported a statistically significant increase in values congruence between parent and child when compared to the control group ($p=0.028$). Lyon et al. (2009 b) found that children were significantly more satisfied with the decision making process compared to controls ($p=0.001$), while Adelman et al. (1990) reported no difference between groups. Lyon et al. (2009a) found no significant difference in decisional conflict scores (except for one sub-score relating to feeling informed, $p=0.001$), and no significant difference in the quality of patient-interviewer communication. Adelman et al. (1990) found no significant differences in the child's level of participation in decision making between the three experimental groups.

Table 2.6: Summary of Findings (N=5)

Comparisons	Coaching only v. Attention placebo/No intervention	Coaching + Aid v. Attention placebo/No intervention	Education only v. Attention placebo/No intervention
Trials	Lyon 2009 (a, b), Adelman 1990	Adams 2009, Rhee 2008	Hollen, 1999
Decision Quality			
Overall Quality of Decision Making		1/1 no diff: decision making quality [R]	1/1 ↑ decision making quality at 1 and 12 months. [H]
Agreement between values and chosen option		1/1 ↑ agreement between values and chosen behavior [A]	
Congruence of treatment preferences between child and parent	1/1 ↑ value congruence in cognitive impairment scenario [L (a)]		
Decision Making Process			
Satisfaction with DM process	1/1 ↑ child satisfaction with process [L (b)] 1/1 no diff: satisfaction with process [A]		
Participation in DM process	1/1 no diff: participation in DM process [A]		
Decisional conflict	1/1 no diff: decisional conflict except for ↑ informed sub-score [L (a)]		
Communication	1/1 no diff: quality of patient-interviewer communication [L (a)]		

2.3.6.2 Coaching + Educational Aid v. Attention Placebo/no Intervention (n=2 studies)

Two studies compared coaching combined with a co-intervention with an attention placebo or no intervention (Adams et al., 2009; Rhee et al., 2008). Adams et al. (2009) reported a positive increase in agreement between participants' values and their chosen behavior related to the intervention group, while Rhee et al. (2008) found no difference in overall quality of decision making compared to the control group.

2.3.6.3 Education only v. Attention Placebo/no Intervention (n=1 study)

One CBA study compared a workshop and weekly assignments with an attention placebo or no intervention (Hollen et al., 1999). This study reported a statistically significant increase in

decision making quality scores compared to the control group at one month (p=0.02). The difference between groups was not statistically significant at 6 months post intervention but was subsequently statistically significant again at 12 months (p= 0.001).

2.4 Discussion

This systematic review was designed to evaluate the characteristics and efficacy of interventions that support the decision making needs of children who are actively considering a health-related decision. A total of five unique studies of variable quality were identified. Decision support interventions included decision coaching with or without a co-intervention aid (e.g. computer programs, workbook exercises, information packages) and education only.

Three studies had statistically significant findings: coaching alone increased values congruence between child and parent and child satisfaction with the decision making process (one RCT), coaching with educational aids increased agreement between participant's values and chosen behavior (one RCT), and education only increased overall decision making quality (one CBA study). The two other studies found no difference in decision making quality, satisfaction with the decision making process, and child participation in decision making (one RCT, one non-randomized CT).

2.4.3 Lack of interventions tested

Although the eligibility criteria used in this systematic review were relatively broad, only five studies were included. This points to a scarcity of research in this area, despite a growing consensus among researchers, policy makers and health professionals to include children in the process of making decisions regarding their health (Coyne, 2006; Coyne & Harder, 2011; Moore and Kirk, 2010). Although interventions to support decision making in the adult setting have been well tested (Stacey et al., 2011), the evaluation of formal interventions within pediatrics is

lacking. Since current literature has established that decision support interventions such as decision aids and decision coaching are effective in adult populations, future research should seek to address whether these interventions are effective within the pediatric context. As was noted, three of the five studies included in this review were published within the last five years. This may indicate a recent interest in supporting the decision making of children and is promising for continued research in this area.

2.4.1 Coaching as an intervention

A coaching component was part of the decision support interventions in four of five studies. The study by Lyon et al. (2009a,b) which was one of the higher quality studies that met most elements of decision support used a coaching only intervention for end-of-life decision making. It reported increased values congruence between child and parent, and increased child satisfaction with the decision making process compared to controls. Interestingly, this study coached both parents and children together, whereas the remaining studies only coached children. Decision coaching with both children and parents is important within the context of SDM as it can prepare all stakeholders who may have an impact on the outcome and implementation of the decision (Gabe et al., 2004; Legare et al., 2011). These findings are consistent with a systematic review of decision coaching interventions that found adults had improved knowledge and more satisfaction when decision coaching was used alone or in conjunction with patient decision aids (Stacey et al., 2012). In summary, although few studies were identified, decision coaching may benefit children's decision making especially in regards to value congruence between child and parent, agreement between values and chosen behavior, and satisfaction with the decision making process.

2.4.2 Education resources as adjuncts to coaching

Two of the studies tested coaching provided together with educational resources such as computer programs, workbook exercises, and information packages (Adams et al., 2009, Rhee et al., 2008). Adams et al. (2009) found this multifaceted approach increased agreement between participants' values and chosen behavior, while Rhee et al. (2008) found no difference. A similar type of intervention known as patient decision aid (ptDA) is a tool that helps prepare individuals to make a decision with their health practitioner (Stacey et al., 2011). They are available in a variety of formats including, pamphlets, videos/DVDs, or web-based tools. Like the educational aids used in Adams et al. (2009) and Rhee et al. (2008), ptDAs may help address the decision making needs of children and parents. A systematic review of the decision making needs of parents concluded that parents require timely, reliable, and current information in a format that also accounts for the preference-sensitive nature of many decisions (Jackson et al., 2008). Educational aids such as ptDAs appear to be a feasible method of meeting these needs. A recent review evaluating their use with adults found that ptDAs increase knowledge, accuracy of risk perceptions, and the consistency of decisions with values (Stacey et al., 2011). PtDAs also lower decisional conflict- related to feeling uniformed and having unclear values, decrease undecidedness, and increase participation in decision making. Since these interventions are successful with adult populations, it is possible that educational aids such as ptDAs may also be a reasonable intervention for use with children. However, similar to decision coaching, little research has been conducted regarding their use with either children and/or their parents.

2.5 Limitations

There are a number of important limitations that should be considered when interpreting the results of this systematic review. First, on an individual study level, there were few studies

from which to draw firm conclusions. Furthermore, included studies lacked homogeneity with regards to patient context, interventions used, outcomes, and outcome measures, thereby preventing the use of meta-analysis. As previously indicated, the overall quality of studies included ranged from lower to higher, with few studies adequately meeting the risk of bias criteria. Reporting of details of interventions was also poor. This may have prevented an accurate assessment of the elements of decision support. Therefore, these findings should be interpreted with caution.

On a review level, although a thorough and systematic approach was used to search the literature with two independent reviewers screening citations, it is possible that relevant studies were missed. Data extraction was completed by one reviewer and verified by a second reviewer, which may have introduced bias (Higgins & Green, 2011). This review may also be limited by restricting the search to English and French articles (Shea et al., 2007).

2.6 Conclusions

Only five studies have evaluated interventions to support children in making health decisions, with most of these studies published within the last five years. The results suggest that decision support interventions in the form of decision coaching with or without educational resources may be effective in assisting children to make health-related decisions. More specifically, decision quality outcomes such as values congruence between children and parents, and decision making process outcomes such as satisfaction were improved. This systematic review also affirms a need for future research on targeted interventions that support the involvement of children in SDM.

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Chapter Three

Decision Coaching using the Ottawa Family Decision Guide with Parents and their Children: A Pilot Study

This chapter is based upon an unpublished manuscript formatted for submission to the journal Patient Education and Counseling

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Abstract

Objective: To evaluate the feasibility and acceptability of decision coaching for children and parents considering insulin options for type 1 diabetes management.

Methods: Pre-/post-test design. Eligible participants were children (<18 years) with type 1 diabetes, and their parents at a diabetes clinic in a tertiary children's hospital. The intervention consisted of decision coaching guided by the Ottawa Family Decision Guide. Questionnaires were collected at baseline (T1) (preferred option, decisional conflict), post-coaching (T2) (perceived involvement in decision making) and <2 weeks (T3) (satisfaction, decisional conflict). Analysis was descriptive.

Results: Seven of 16 invited families consented. Questionnaires were all completed at T1, T2. At T3, questionnaires were missing for one family (parent, child). Compared to children and parents who were decided about their insulin delivery method (n=4), participants undecided at baseline (n=2) rated decision coaching as more acceptable and had larger decreases in decisional conflict. All participants felt involved in sharing the decision making with their practitioner.

Conclusion: Decision coaching with children and parents considering insulin options for type 1 diabetes management was feasible to deliver and measure. Coaching was more acceptable for participants who were undecided. Further evaluation is required.

Practice Implications: Decision coaching is a promising intervention to help involve children in decision making.

3.1 Introduction

According to the United Nations Convention on the Rights of the Child (UNCRC), parents are required to hold the 'best interests' of children as their primary concern when raising their children and it is only when children reach the age of majority that they assume this responsibility for themselves[1]. As children develop skills necessary for decision making such as abstract thought, problem solving, and inductive and deductive thinking, parents and clinicians must assess what level of involvement children ought to have in various decisions [2,3]. Like adults, children have personal preferences regarding options for various health-related decisions [4,5]. Consequently, unless parents and clinicians actively involve children in a process of shared decision making (SDM) whereby children, family members and clinicians exchange information and treatment preferences to reach an agreement on a treatment plan, they risk making choices that lack concordance with the values and preferences of the child [5,6].

Involving children in health care decisions has been found to improve their treatment adherence, perception of competence, and understanding of the illness [7-9]. Qualitative interviews with children of various medical backgrounds also suggest that their inclusion may decrease anxiety about what will happen to them and may increase a sense of value and control [10,11]. However, there is evidence to suggest that children are not consistently consulted and/or are not involved in SDM about their health care as much as they could be [3]. A review of physicians' and other health care providers' perceptions of barriers to implementing SDM in clinical practice with adults, identified time constraints, lack of resources, unfamiliarity with the processes of SDM, and insufficient reimbursement [12]. Similar barriers may exist for health care professionals implementing SDM with children.

Interventions such as decision coaching and patient decision aids may address some of these barriers and facilitate SDM with children. Decision coaching is a process of non-directive support by a trained facilitator to help patients develop skills in preparation for decision making with their physician [13]. Coaching alone or in conjunction with patient decision aids is effective for improving knowledge, improving satisfaction, and reducing costs [13]. Patient decision aids are tools (e.g. pamphlets, videos/DVDs, web-based) that help patients consider options and their associated outcomes, clarify personal values relating to these outcomes, and proceed through the steps of deliberation and communication with their health care provider [14]. Decision aids can effectively reduce decisional conflict which is defined as a state of uncertainty related to a feeling uninformed, having unclear personal values, a lack of support in decision making, or feeling unsure about the best choice [15,16].

Although many condition specific decision aids have been tested with adults, given the high number of possible health decisions, generic decision aids are available that can be used with any decision type [16,17]. When accompanied by decision coaching, the generic decision aid, the Ottawa Personal Decision Guide (OPDG), has been shown to decrease decisional conflict in women considering prenatal testing [17]. The Ottawa Family Decision Guide (OFDG) is a version of the OPDG adapted for families [18]. However, to date, decision coaching and decision aids have only be been evaluated with adults. Little is known about their use in the pediatric context where multiple stakeholders (child, parent(s), and clinician) are involved.

Type 1 diabetes is a common pediatric condition with incidence rates as high as 35 cases per 100,000 children aged 14 and under in Canada [19]. Children with type 1 diabetes and their parents may have differing preferences for diabetes management options. Children, who must receive daily injections or wear the insulin pump, may be more likely to focus on short term

benefits and harms of options, while parents may be motivated by longer term outcomes of options [20,21]. The process of deciding on an option that satisfies the individual preferences of child and parent(s) and optimizes the management of type 1 diabetes may, therefore, produce a significant amount of decisional conflict. The objective of this pilot study is to evaluate the feasibility and acceptability of decision coaching guided by the OFDG with children and parents who are considering insulin options for type 1 diabetes management.

3.2 Methods

3.2.1 Study design

A pre-test/post-test study design was used. The Ottawa Decision Support Framework guided the development of the study intervention and selection of evaluation measures. The Ottawa Decision Support Framework (ODSF) has three key process elements; a) assessment to identify a patient's modifiable decision making needs; b) intervention designed to address modifiable needs; and c) evaluation of the decision support provided (e.g. *quality* of the decision; decision making *proces*s) [22].The study received ethics approval from the research ethics board at the Children's Hospital of Eastern Ontario (# 11/76X, Appendix E).

3.2.2 Participants and recruitment strategy

Children and parent(s) considering insulin delivery options for management of type 1 diabetes were recruited from a diabetes clinic at a tertiary children's teaching hospital. This hospital serves a population of 1.5 million and in 2010 had over 60,000 emergency department visits and over 166,000 visits to ambulatory clinics [23,24]. Families were invited to participate in the study prior to a scheduled insulin pump assessment or at an insulin pump information evening. At the pump assessment, a diabetes nurse educator and dietitian discussed information

about pump therapy and other insulin delivery options, and assessed the child's eligibility for an insulin pump.

3.2.3 Intervention

All participants received decision coaching guided by the OFDG (Figure 3.1) from one of two social workers on the diabetes team, who had been trained in decision coaching (see Appendix F). Decision coaching was provided according to a detailed protocol (Appendix G). In brief, the decision coach guided the child and parents(s) through sections of the OFDG including, making explicit the decision, clarifying values for benefits and harms of options, identifying the patients' preferred treatment option, assessing for pressures from others, and assessing for other remaining decision making needs. To facilitate child involvement, the child was asked questions prior to their parent(s). The decision coach then facilitated a discussion between parent and youth of the areas of agreement/disagreement on values for benefits and harms of options. The family was also offered a completed copy of the OFDG.

The OFDG was pre-populated with benefits and harms relating to three common options for insulin delivery: insulin pump therapy, standard insulin therapy (2 or 3 injections per day), and multiple daily injections (MDI). Pre-populated items were based on Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada [25]. The OFDG was peer-reviewed by a Pediatric Endocrinologist and several Diabetes Nurse Educators before being used in this study.

Figure 3.1 OFDG pre-populated with insulin options for type 1 diabetes management

Date: _____ Participant IDs: _____ (child/youth) _____ (parent)

Ottawa Family Decision Guide

For Families Facing Tough Health or Social Decisions

❶ Clarify the decision.

What decision do you face?	Should I/my child get an insulin pump?
What is your reason for making this decision?	
When do you need to make a choice?	

❷ Explore your decision.

	Reasons to Choose this Option (Benefits / Advantages / Pros)	How much it matters Add ★s! Child / Youth	Parent	Reasons to Avoid this Option (Harms / Disadvantages / Cons)	How much it matters Add ★s! Child / Youth	Parent
Option #1 **Insulin pump therapy**	• More flexibility with daily activities and meals. • Less likely to have severe low blood sugar reaction. • May improve A1c levels. • Easier to adjust insulin for illness, sports and other activities. • Fewer injections. •			• Need to check BG 4-10 times/day (including overnight). • Need to do accurate carb counting at every meal /snack. • Pump tubing can block without you noticing – ↑ risk for DKA. • Parents/caregivers need to be more involved with diabetes care. • Others more likely to notice you have diabetes. •		
Option #2 **Standard insulin therapy (2 or 3 injections per day)**	• Do not have to think about diabetes as often. • Record keeping is simpler. • Least expensive regimen. •			• Probably won't control blood sugar as well as a pump or MDI. • Higher risk of severe low blood sugar than with pump or MDI. • Needs consistent timing of meals/snacks and carb content. •		
Option #3 **Multiple daily injections (MDI)**	• May improve A1c levels. • Can use insulin pens with each injection. • May decrease risk of low blood sugars overnight. • Less expensive than pump. •			• More injections (with every meal and snack). • Less flexibility with food and activity than with a pump. • Need to do carb counting at every meal and snack. • Need to check BG 4 times/day plus some post meal BGs. •		

	Child / Youth				Parent			
Which option do you prefer?	❑ #1	❑ #2	❑ #3	❑ Unsure	❑ #1	❑ #2	❑ #3	❑ Unsure

Support Who else is involved in this decision?	**Child / Youth** Option you think this person prefers? #1	#2	#3	Unsure	**Parent** Option you think this person prefers? #1	#2	#3	Unsure
	❑	❑	❑	❑	❑	❑	❑	❑
	❑	❑	❑	❑	❑	❑	❑	❑
	❑	❑	❑	❑	❑	❑	❑	❑

	Child / Youth		Parent	
Are you choosing without pressure from others?	❑ Yes	❑ No	❑ Yes	❑ No

Date: _____ Participant IDs: _____ (child/youth) _____ (parent)

❸ **Identify your decision making needs.**

			Child / Youth		Parent	
	**Knowledge**	Do you know the benefits and harms of each option?	❑ Yes	❑ No	❑ Yes	❑ No
	**Values**	Are you clear about which benefits and harms matter most to you?	❑ Yes	❑ No	❑ Yes	❑ No
	**Support**	Do you have enough support and advice from others to make a choice?	❑ Yes	❑ No	❑ Yes	❑ No
	**Certainty**	Do you feel sure about the best choice?	❑ Yes	❑ No	❑ Yes	❑ No

People who answer "No" to one or more of these questions have decision making needs. They are more likely to delay their decision, change their mind, feel regret about their choice or blame others for bad outcomes.

❹ **Plan the next steps based on your needs.**

Decision making needs	Things you would like to try...
Knowledge If you feel you do NOT have enough facts	❑ Find out more about the options and the chances of benefits and harms. ❑ List your questions and note where to find the answers (e.g. library, health professionals, counsellors):
Values If you are NOT sure which benefits and harms matter most to you	❑ Review the stars in the balance scale to see what matters most to you. ❑ Find people who know what it's like to experience the benefits and harms. ❑ Talk to others who have made the decision. ❑ Read stories of what mattered most to others. ❑ Discuss with others what matters most to you.
Support If you feel you do NOT have enough support	❑ Discuss your options with a trusted person (e.g. health professional, family, friends). ❑ Find help to support your choice (e.g. funds, transport, child care).
If you feel PRESSURE from others to make a specific choice	❑ Focus on the opinions of others who matter most. ❑ Share your guide with others. ❑ Ask another person involved to complete this guide. Find areas of agreement. When you disagree on facts, agree to get more information. When you disagree on what matters most, respect the person's opinion. Take turns to listen to what the other person says matters most to them. ❑ Find a neutral person to help you and others involved in the decision.
Other factors making the decision DIFFICULT	List anything else you need:

Children's Hospital of Eastern Ontario Family Decision Services www.cheo.on.ca/en/DecisionServices
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3.2.2 Procedures

During the initial telephone contact by a diabetes nurse educator, participant eligibility for the study was assessed, and if eligible, the study was explained. Participants were given an opportunity to ask questions and if they agreed, they were provided with an information sheet. Written informed consent was obtained from parent(s) and children by the researcher responsible for the study (Consent forms-Appendix H).

Data was collected at three points during the study: baseline (T1), after decision coaching (T2) and, within two weeks after decision coaching (T3) (Appendix I). Children and parent(s) completed the baseline questionnaire (T1) that included a demographic survey, the Decisional Conflict Scale (DCS), and the Preferred Option Scale (Appendix J). Decision coaching using the OFDG was then conducted with parent(s) and children according to the protocol. Immediately after decision coaching, the T2 measure (Dyadic OPTION Scale) was administered to the child, parent(s), and decision coach. After completing the T2 measure, the method for T3 data collection (telephone, email or post) was arranged with participants. Participants choosing data collection by post were provided with T3 measures in a prepaid, self-addressed envelope and were asked to mail them within two weeks of the decision coaching session. T3 measures included the DCS, an acceptability questionnaire, and questions about actual choice and follow up with a health practitioner. Children and parent(s) were asked to complete all measures independently.

3.2.4 Outcome measures

The outcomes measured in this study are consistent with the International Patient Decision Aids Standards (IPDAS) [26,27]. The primary goals for this study were to test feasibility of the study design and acceptability of the intervention. Feasibility was measured by

proportion of participants recruited and proportion of missing questionnaire items completed by children and parents. Acceptability of the intervention was indicated by a questionnaire that assessed child and parents' satisfaction with decision coaching, and questions relating to the helpfulness of decision coaching, participants' willingness to recommend it, and other general comments. A single item also assessed child and parents' perceptions of decision coach neutrality [28]. The Genetic Counseling Satisfaction Scale was used to measure satisfaction with decision coaching [29]. This scale has face validity and a reliability coefficient of alpha= 0.80 to 0.90 in genetic counselling contexts with adults, however; it has not been tested with children [29,30].

Secondary outcomes included child and parent decisional conflict; child and parent preferred option and actual choice; child, parent, and clinician perceptions of involvement in SDM; child and parent values for outcomes of options; and values concordance between parent and child. Decisional conflict was measured using a 10-item, low literacy version of the Decisional Conflict Scale (DCS) [28]. Compared to the original DCS that has 16-item statements and a 5-point agreement scale, the low literacy DCS has a 3-point response scale of 'yes', 'unsure', 'no' for 10 items expressed as questions. The original DCS has been validated with parents in the paediatric context and has been used with youths making health related decisions [29,30]. Preferred option was measured using the 15-point Choice Predisposition Scale that indicates a patient's inclination toward a given option, with a score of 1 indicating a strong preference for option A, 15 indicating a strong preference for option B and the centre of the scale indicating no preference (unsure). Since there were three options, this question was repeated three times, comparing options A with B, B with C, and C with A. When tested with post-menopausal women considering hormone replacement therapy, the scale was found to be

sensitive to change in undecided responses and has a test-retest coefficient >0.90 [34]. One to two weeks after the insulin pump assessment meeting, children and parents were asked if they had made a choice about an insulin delivery method with their attending clinician and if so, what their choice was. Parent, child and decision coach perceptions of involvement in decision making was measured by the researcher using the dyadic OPTION scale [35]. The dyadic version of the OPTION scale has been shown to be valid and reliable with family medicine patients [36]. Since the original scale was developed for use with family physicians and their patients, three items (sources of information discussed, ways to manage health problem discussed, preferred option chosen) were modified to be within the scope of practice of non-physicians involved in the process of decision making. Values for outcomes of options was measured using the balance scale method that is included within the OFDG. This 5-point scale helps participants evaluate the desirability of benefits and harms relating to options [37,38]. Adaptations of this scale have been used with a variety of situations such as women considering options for osteoporosis, lung cancer patients considering treatment options, and women considering hormone therapy [19,36,37]. Test-retest coefficient results range from 0.79 to 0.91 [34].

3.3 Analysis

Data from questionnaires were entered into an Excel database. A process of data verification was completed using double data entry. Less than 1% of data were entered incorrectly. When data was provided by both parents, the parent with a complete data set was included and if there was a complete data set for both parents, one set was randomly chosen for analysis using a random numbers table.

Descriptive analysis was used. The DCS was standardized out of 100 to allow for comparisons with other studies [41]. The ‘yes’, ‘unsure and ‘no’ response categories were

assigned a numeric value of 0, 2, and, 4, respectively. The total score was then calculated by summing items 1-10, dividing by 10, and multiplying by 25. Values concordance was measured by taking the absolute difference between parent and child values for each item.

To examine the influence of child and parent stage of decision making on study outcomes, data were grouped according to baseline DCS results with adults, and preferred option results with children. DCS scores were used for adults since this scale has been found to be a covariate of stage of decision making in adults; earlier stages are associated with higher decisional conflict and later stages associated with lower decisional conflict [42,43]. Consequently, those with a DCS score of $\leq$25 were included in the 'decided' group given that they are more likely to follow through with their choice [22]. Although children aged 12 to 21 have been found to understand and respond to the DCS, it appears to have been more limited for capturing decisional conflict with this population, and a different measure has been recommended [32]. Therefore, the child's strength of preferred option on the scale of 1 to 15 was used to group them. Children rating their preferred option between 3 and 13 points were grouped as 'undecided'.

3.4 Results

3.4.1 Participants

Of 16 families approached to participate, 12 agreed (response rate, 75.0 %; Table 3.2), and 7 were able to attend the decision coaching session (attendance rate, 58.3 %) (Figure 3.2). Reasons families did not receive decision coaching were: families were unable to attend (n=2), and decision coach was unavailable (n=3) (Table 3.2; Appendix K).

Seven families, including 17 family members (7 children and 10 parents) participated in the study but only 7 children and 7 parents were included in the analysis. Four children were

male and three were female with an age range of 9 to 17 (Table 3.1). Three parents were male and four were female with an age range of 29 to 54 and an education ranging from some high school to university graduate. Four families had both parents participate in the decision coaching and three had only one parent participate (Table 3.2). Of 7 families, 2 were 'undecided' and 5 were 'decided' about the best insulin delivery method at baseline.

Figure 3.2: Diagram of study flow

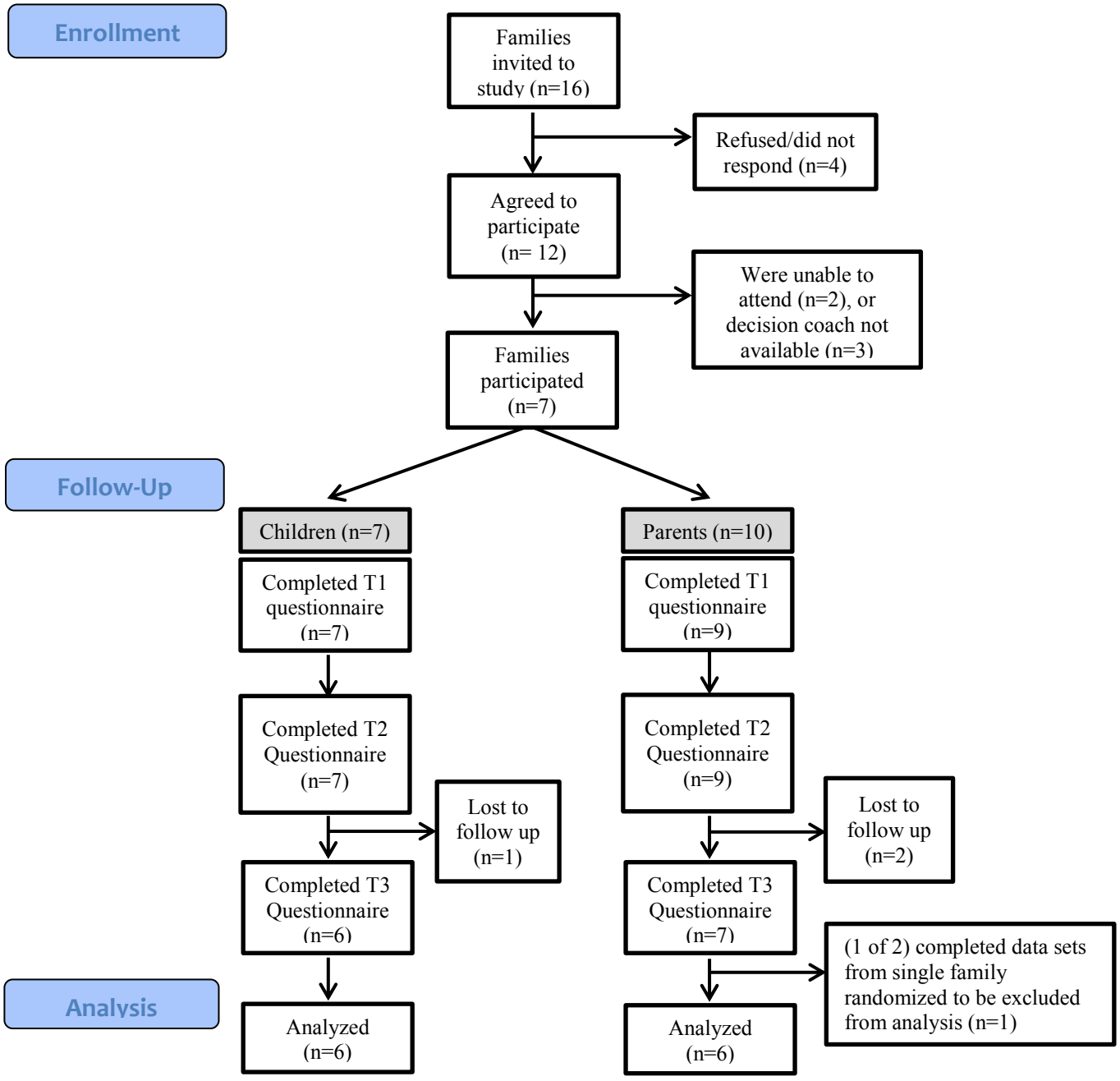

Table 3.1: Characteristics of participants (n=7 children, n=7 parents)

Demographic characteristics	Frequency
Children	**(n= 7)**
Age (in years)	Median: 15, (Range: 9,17)
≤9	1
10-14	2
15-19	4
Sex:	
Male	4
Female	3
Primary Language:	
English	6
French	1
Other	0
Education:	
Child- Grade Level	
≤4	1
5-8	2
9-12	4
1st Year University/College	0
Duration of Type 1 Diabetes:	
>1 month to 6 months	1
>6 months to 1 year	2
>1 year to 5 years	2
>5 years	2
Parents	**(n= 7)**
Age (in years)	Median: 44, (Range: 29,54)
25-29	1
30-34	0
35-39	0
40-44	4
45-49	2
Sex:	
Male	3
Female	4
Marital Status:	
Married/Common-law	6
Divorced/Separated	1
Primary Language:	
English	6
French	1
Other	0
Adult- Highest Education	
Some High school	3
High school diploma	1
Trade cert./diploma	0
University-undergraduate degree	2
University-graduate degree	1

3.4.2 Feasibility of the decision coaching intervention

Both undecided families reported that the decision coach did not suggest or recommend a specific option to influence their decision (Table 3.2). The parents of 2 of 4 decided families indicated that the coach suggested a specific option.

3.4.3 Feasibility of data collection

All parents and children completed the T1 and T2 questionnaires and 6 families completed the T3 questionnaire (85.7% response rate). Missing questionnaire items were: 5 of 340 for children (1.5%), and 1 of 349 for parents (0.3%) (Table 3.2).

Table 3.2: Feasibility of recruitment, data collection, intervention delivery

Feasibility of study design	**Percentage (n/N)**			
Recruitment				
Families recruited	75.0 % (12/16)			
Families who attended decision coaching	58.3 % (7/12)			
Questionnaire response rates	**Child**		**Parent**	
T1 (baseline)	100% (7/7)		100% (7/7)	
T2 (immediately after coaching)	100% (7/7)		100% (7/7)	
T3 (less than 2 weeks following coaching)	85.7% (6/7)		85.7% (6/7)	
Missing data on study questionnaires	1.5% (5/340 items)		0.3% (1/349 items)	
Decision coaching intervention				
Coach availability				
Decision coach not available	25.0 % (3/12)			
Decision coach available	75.0 % (9/12)			
Coach neutrality	*Undecided*		*Decided*	
	Child	**Parent**	**Child**	**Parent**
Did the decision coach suggest or recommend a specific option to influence your decision?				
Yes	0	0	0	2
No	2	2	4	2
Not answered	0	0	1	1
Length of time	*Median (range)*			
(n= 4) Sessions	35 minutes (21-38 minutes)			
Parental presence during Decision Coaching				
One parent:				
Mother	3			
Father	0			
Both parents	4			

3.4.4 Acceptability of intervention

The 2 families who were undecided at baseline strongly agreed that the decision coaching session was acceptable for most items, except one child somewhat agreed it was valuable and one parent somewhat agreed the session helped him/her come to a preferred option (Table 3.3). For the 4 decided families who completed the questionnaire, the parents strongly or somewhat agreed that the intervention was acceptable. Although the decided children's responses ranged from disagree to strongly agree on acceptability items, 3 of the 4 children would recommend the coaching intervention to others.

Four of 7 decision coaching sessions were timed (Table 3.2). The median time was 35 minutes (range 21-38 minutes). Both undecided families agreed the decision coaching was the right length of time. For decided families, 1 child and 2 parents agreed that it was the right length of time, 2 parents were neutral, and 3 children disagreed. Members of one decided family wrote: "the session was a little too long for our 9 year old daughter" and his/her child stated "It was too long."

Table 3.3: Acceptability of decision coaching session

Acceptability of the decision coaching	Undecided		Decided	
	Child (n=2)	Parent (n=2)	Child (n=5)	Parent (n=5)
The decision coach seemed to understand the stresses I was facing.				
Agree Strongly	1	2	1	3
Agree Somewhat	0	0	1	1
Uncertain	0	0	2	0
Disagree Somewhat	0	0	0	0
Strongly Disagree	0	0	0	0
Not answered	1	0	1	1
The decision coach helped me to identify what we needed to know to make decisions about what would happen to me.				
Agree Strongly	2	2	2	2
Agree Somewhat	0	0	0	2
Uncertain	0	0	0	0
Disagree Somewhat	0	0	1	0
Strongly Disagree	0	0	1	0
Not answered	0	0	1	1
I felt better about my decision after meeting with the decision coach.				
Agree Strongly	1	2	0	2
Agree Somewhat	0	0	1	2
Uncertain	0	0	1	0
Disagree Somewhat	0	0	0	0
Strongly Disagree	0	0	2	0
Not answered	1	0	1	1
The decision coach was truly concerned about my well-being.				
Agree Strongly	2	2	3	3
Agree Somewhat	0	0	0	1
Uncertain	0	0	0	0
Disagree Somewhat	0	0	1	0
Strongly Disagree	0	0	0	0
Not answered	0	0	1	1
The decision coaching session was valuable to me.				
Agree Strongly	1	1	0	1
Agree Somewhat	1	0	1	2
Uncertain	0	0	0	0
Disagree Somewhat	0	0	2	1
Strongly Disagree	0	0	1	0
Not answered	0	1	1	1
How helpful was the decision coaching in helping you come to a preferred option?				
Very helpful	2	1	0	2
Somewhat helpful	0	1	0	2
A little helpful	0	0	3	0
Not helpful	0	0	1	0
Not answered	0	0	1	1

Table 3.3: Acceptability of decision coaching session (cont.)

Acceptability of the decision coaching (cont.)	Undecided		Decided	
	Child (n=2)	Parent (n=2)	Child (n=5)	Parent (n=5)
Would you recommend decision coaching to other people who are facing the same decision?				
I would definitely recommend it	2	2	0	2
I would probably recommend it	0	0	3	2
I would probably not recommend it	0	0	1	0
I would definitely not recommend it	0	0	0	0
Not answered	0	0	1	1
The decision coaching session was about the right length of time.				
Agree Strongly	2	1	1	0
Agree Somewhat	0	1	0	2
Uncertain	0	0	0	2
Disagree Somewhat	0	0	1	0
Strongly Disagree	0	0	2	0
Not answered	0	0	1	1
Did this session prepare you for a follow up with your health care provider (family doctor, nurse practitioner, etc.)?				
Yes	2	2	4	4
Unsure	0	0	1	0
No	0	0	0	1

3.4.5 Decisional conflict

At baseline, among undecided children (n=2), 1 child was not in decisional conflict and the other was for subscales of feeling informed, values clarity, certainty, and overall (Table 3.4). Undecided parents (n=2) indicated higher decisional conflict at baseline on the values clarity subscale, certainty subscale, one item on the support subscale (have enough advice), and overall. At T3, undecided parents and children showed no decisional conflict on any item except for 1 parent and 1 child who felt some pressure from others to choose a specific option.

At baseline, decided children (n=5) showed no total decisional conflict but did have decisional conflict on 2 items (knowing the risks and side effects of each option, being clear about values associated with these risks). Decided parents (n=5) at baseline showed no decisional conflict on subscales or for the total. These parents indicated decisional conflict for 1 item about

clarity of values for benefits of options. At T3, decided parents (n=4) and children (n=4) showed no decisional conflict on any item or overall.

Table 3.4: Decisional conflict before and after decision support

Subscale	Items	Baseline				T3 (less than 2 weeks following coaching)			
		Undecided Item median, (range)		**Decided** Item median, (range)		**Undecided** Item median, (range)		**Decided** Item median, (range)	
		Child (N=2)	**Parent (N=2)**	**Child (N=5)**	**Parent (N=5)**	**Child (N=2)**	**Parent (N=2)**	**Child (N=5)**	**Parent (N=5)**
Informed	Do you know which options are available to you?	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)
	Do you know the benefits of each option?	25 (0,50)	0 (0,0)	0 (0,50)	0 (0,50)	0 (0,0)	0 (0,0)	0 (0,50)	0 (0,0)
	Do you know the risks and side effects of each option?	25 (0,50)	0 (0,0)	50 (0,100)	0 (0,50)	0 (0,0)	0 (0,0)	0 (0,100)	0 (0,0)
	Subscale median (range)	17 (0,33)	0 (0,0)	17 (0,50)	0 (0,17)	0 (0,0)	0 (0,0)	0 (0,50)	0 (0,0)
Values Clarity	Are you clear about which benefits matter most to you?	50 (0,100)	50 (50,50)	0 (0,100)	25 (0,50)	0 (0,0)	0 (0,0)	0 (0,50)	0 (0,0)
	Are you clear about which risks and side effects matter most to you?	25 (0,50)	75 (50,100)	50 (0,50)	0 (0,50)	0 (0,0)	0 (0,0)	0 (0,100)	0 (0,0)
	Subscale median (range)	38 (0,75)	63 (50,75)	25 (0,75)	0 (0,50)	0 (0,0)	0 (0,0)	0 (0,75)	0 (0,0)
Support	Do you have enough support from others to make a choice?	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)
	Are you choosing without pressure from others?	0 (0,0)	50 (0,100)	0 (0,0)	0 (0,0)	50 (0,100)	50 (0,100)	0 (0,0)	0 (0,0)
	Do you have enough advice to make a choice?	25 (0,50)	50 (50,50)	0 (0,50)	0 (0,50)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)
	Subscale median (range)	8 (0,17)	33 (17,50)	0 (0,17)	0 (0,17)	25 (0,50)	17 (0,33)	0 (0,0)	0 (0,0)
Certainty	Are you clear about the best choice for you?	25 (0,50)	50 (50,50)	0 (0,50)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,50)
	Do you feel sure about what to choose?	25 (0,50)	50 (50,50)	0 (0,50)	0 (0,50)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,50)
	Subscale median (range)	25 (0,50)	50 (50,50)	0 (0,50)	0 (0,25)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,50)
Total DCS Score		20 (15,25)	33 (30,35)	5 (0,40)	0 (0,20)	5 (0, 15)	5 (0, 10)	0 (0,30)	0 (0,10)

Responses to items= ‘yes’, ‘unsure’, ‘no’. Standardized scores range from 0 (low decisional conflict) to 100 (high decisional conflict); those with scores $\leq$25 are likely to implement their decision

3.4.6 Preferred option/actual choice

At baseline, 7 children and 6 parents preferred insulin pump therapy and 1 parent was unsure (Table 3.5). After coaching, 1 child switched his/her preference to 'unsure' and the 1 parent remained unsure. The undecided child had not implemented a decision by T3. The undecided parent implemented the insulin pump therapy option.

Table 3.5: Preferred Option before and after Decision Support

Preferred option (Baseline)	Preferred option (T2)							
	Child				**Parent**			
	Option #1	Option #2	Option #3	Unsure	Option #1	Option #2	Option #3	Unsure
Option #1 (Insulin Pump Therapy)	6	0	0	1	6	0	0	0
Option #2 (Standard Insulin Therapy)	0	0	0	0	0	0	0	0
Option #3 (Multiple Daily Injections)	0	0	0	0	0	0	0	0
Unsure	0	0	0	0	0	0	0	1

3.4.7 Perceived involvement in SDM

Families indicated that most elements of shared decision making occurred within the decision coaching session (Table 3.6). Elements rated as not present by 2 or more participants (child, parent, decision coach) were: discussed different sources of information and the possibility of returning for subsequent session with the coach.

Table 3.6: Perceived involvement in SDM (at T2)

Item	Frequency (n/N)								
	Child (n=7)			Parent (n=7)			Decision Coach (n=7)		
	Yes	Unsure	No	Yes	Unsure	No	Yes	Unsure	No
A health problem/situation was identified.	7	0	0	6	1	0	7	0	0
Different options (including the possibility of doing nothing) were discussed.	5	1	1	6	0	1	6	0	1
If available, different sources of information (e.g. leaflets, websites, contact with other people) to help make the decision were discussed.	4	0	3	3	1	3	2	3	2
The advantages, disadvantages and possible outcomes of options were discussed.	7	0	0	7	0	0	7	0	0
Ideas or expectations about the options were discussed.	6	1	0	7	0	0	7	0	0
Concerns or worries about the options were discussed.	7	0	0	6	1	0	7	0	0
It was made sure that information had been understood.	6	1	0	7	0	0	7	0	0
There were opportunities to ask questions.	7	0	0	7	0	0	7	0	0
The preference to take part in the decision (or not) was respected.	7	0	0	7	0	0	7	0	0
During the consultation, a preferred option was discussed/identified.	7	0	0	6	0	1	7	0	0
The possibility of coming back to the decision coach was discussed.	4	0	3	4	1	2	4	0	3

3.4.8 Values for outcomes of options.

Values for outcomes of options were rated by all families for insulin pump therapy, by three families for standard insulin therapy, and by six families for multiple daily injections. Their responses indicated higher values for benefits compared to harms and scores were consistent between parents and children (Table 3.7). Values for the benefits and harms of other options (standard insulin therapy and multiple daily injections) were more variable.

At the individual child/parent dyad level, 5 of 7 dyads were in concordance with their ratings of benefits and harms for insulin pump therapy and 2 dyads had differences of 2.5 to 3 points on four items (Table 3.8). Four of 6 dyads were in concordance with the ratings of benefits and harms for multiple daily injections and two had differences of 2.5 to 5 on two items.

Table 3.7: Values scores relating to type 1 diabetes management options

Values			Values score (0-5) Median (range)	
			Child (n=7)	**Parent 1** (n=7)
Option #1 (Insulin Pump Therapy)	Benefits	• More flexibility with daily activities and meals.	4 (3,5)	5 (3,5)
		• Less likely to have severe low blood sugar reaction.	5 (3,5)	5 (4,5)
		• May improve A1c levels.	5 (4,5)	5 (3,5)
		• Easier to adjust insulin for illness, sports and other activities.	5 (3,5)	5 (4,5)
		• Fewer injections.	5 (4,5)	5 (3,5)
	Harms	• Need to check BG 4-10 times/day (including overnight).	1 (0,3)	1 (0,3)
		• Need to do accurate carb counting at every meal /snack.	3 (0,4)	3 (1,5)
		• Pump tubing can block without you noticing – ↑ risk for DKA.	4 (1,5)	3 (1,5)
		• Parents/caregivers need to be more involved with diabetes care.	1 (0,2)	1 (0,4)
		• Others more likely to notice you have diabetes.	1 (0,4)	0 (0,1)
			Child (n=3)	**Parent 1** (n=3)
Option #2 (Standard Insulin Therapy)	Benefits	• Do not have to think about diabetes as often.	3 (3,4)	3 (2,5)
		• Record keeping is simpler.	1 (0,4)	3 (2,3)
		• Least expensive regimen.	3 (0,5)	2 (0,5)
	Harms	• Probably won't control blood sugar as well as a pump or MDI.	3 (3,3)	4 (2,4)
		• Higher risk of severe low blood sugar than with pump or MDI.	4 (4,5)	4 (4,5)
		• Needs consistent timing of meals/snacks and carb content.	3 (1,5)	3 (1,4)
			Child (n=6)	**Parent 1** (n=6)
Option #3 (Multiple Daily Injections)	Benefits	• May improve A1c levels.	3 (3,4)	5 (3,5)
		• Can use insulin pens with each injection.	3 (0,5)	5 (3,5)
		• May decrease risk of low blood sugars overnight.	3 (3,5)	3 (2,5)
		• Less expensive than pump.	3 (1,5)	4 (0,5)
	Harms	• More injections (with every meal and snack).	5 (3,5)	5 (3,5)
		• Less flexibility with food and activity than with a pump.	4 (1,5)	5 (1,5)
		• Need to do carb counting at every meal and snack.	3 (0,5)	3 (0,5)
		• Need to check BG 4 times/day plus some post meal BGs.	2 (1,3)	3 (2,4)

N.B. Preferred Option of all participants (except one) before decision coaching= Option #1 (Insulin Pump Therapy)

Table 3.8: Values concordance between child and parent

Values			Absolute difference of value score between child and parent						
Family #			**1**	**2**	**3**	**4**	**5**	**6**	**7**
N=7									
Option #1 (Insulin Pump Therapy)	Benefits	• More flexibility	1	1	0	1	0	1	1
		• Low blood sugar less likely	0	0	0	2	0	1	X
		• May improve A1c	2	1	0	1	3	1	0
		• Easier to adjust insulin	1	1	1	0	0	0	0
		• Fewer injections.	0	0	0	0	0	2	0
	Harms	• Check BG 4-10 times/day	0	1	0	2	0	0	0
		• Accurate carb counting	3	0	1	2	1	0	0
		• Pump tubing can block	1	0	1	0	1	0	1
		• ↑ Parental involvement	2.5	0	0	1	2	0	1
		• Visibility of diabetes	0	0	0	1	3	0	0
N= 3									
Option #2 (Standard Insulin Therapy)	Benefit	• Less thinking about diabetes	0					1	1
		• Simpler record keeping	2.5					.5	1
		• Least expensive regimen.	0					X	0
	Harms	• May not control blood sugar as well	1					1	1
		• ↑ risk of severe low blood sugar	0					0	0
		• Consistent timing of meals/snacks	2					X	0
N= 6									
Option #3 (Multiple Daily Injections)	Benefits	• May improve A1c		2	1	1	0	1	0
		• Can use insulin pens		2	5	1	1	2.5	0
		• Less low blood sugars overnight.		0	1	0	0	X	1
		• Less expensive than pump.		1	2	1	1	X	0
	Harms	• More injections		2	2	0	0	0	1
		• Less flexibility		0	1	0	0	1	0
		• More carb counting		2	0	0	0	3	0
		• Check BG 4 times/day		2	1	0	0	.5	1

LEGEND:
Blank cell= Option not considered by participants
X= Value missing
Highlighted cell= difference between child and parent greater than 2.5

3.5 Discussion

This pilot study informed the acceptability of the intervention and feasibility of a study design to evaluate decision coaching using the OFDG with parents and children. Results indicated that, overall, the decision coaching intervention and study questionnaires were feasible

and the intervention was acceptable with parents and children who indicated they were unsure about the best treatment option for them. While decisional conflict was low for most participants prior to the intervention, total median DCS scores decreased post-test. Decision coaching did not change participants' preferred option or actual choice. The values of participants regarding benefits and harms of options were consistent with their implemented decision. After the intervention, parents and children indicated that they felt involved in the decision making process. Finally, two-thirds of children and parents demonstrated a high level of concordance between their values ratings for benefits and harms of options listed on the OFDG.

3.5.1 Acceptability of decision coaching

Although children and parents generally responded positively to the decision coaching, acceptability results differed based on participants' stage of decision making. Participants who were more undecided about their options responded to the acceptability questionnaire positively, while those who were more decided, especially children, provided mixed feedback. Level of acceptability, therefore, seemed to reflect the point in the decision making process when participants received decision coaching; those who received it earlier in the process appeared to be more satisfied, whereas participants recruited from a list of families scheduled for an insulin pump assessment with a diabetes nurse educator were less likely to be satisfied. Attendance at an insulin pump assessment is required step for initiation of insulin pump therapy through this diabetes clinic. Children and parents attending this assessment may, therefore, have already decided to initiate the insulin pump option thereby decreasing their receptivity to the intervention. This is supported by the strong option preference of children and parents for insulin pump therapy at baseline, as well as relatively low DCS scores at baseline for those who were more decided. Previous research has found that adults with DCS scores lower than 25 are likely

to implement their decision, while individuals with scores exceeding 37.5 are likely to delay their decision or feel unsure about implementation [22]. As one participant noted "…I think 'decision coaching' could be helpful to those who are truly undecided, but for us it wasn't too helpful as we had made up our minds about going on a pump." Two other children echoed this sentiment stating "…I allready (sic) made my desison (sic) about wich (sic) I want. I want a pump now" and, "My choice was all ready (sic) made".

It is also plausible that variations in satisfaction ratings among children may be in part, age-related. Literature regarding what children think of participating in health-related decision making is scarce, although some studies suggest children do desire to be involved in decision making [3]. However, children's willingness and ability to participate in decision making is thought to be tied to factors such as level of clarity regarding legal rights to participation, parental influences, and experience with their health condition [44,45,3]. It is possible that such factors may only be present at younger age, thus influencing a child's willingness to participate. For example, younger children (age 8, 9) are reported to envisage participation in health decisions at an age of 14 or 15 years of age, while older children (age 13, 14) believe participation can occur as young as age 13 [44]. Future research in this area, therefore, should seek to examine the influence of age-related barriers and facilitators to participation in SDM.

3.5.2 Feasibility of decision coaching

Although decision coaching can be provided by someone either internally or externally to the clinical setting, in order to enhance the likelihood of its sustainability, the intervention was designed to be provided by staff already working within the diabetes program [46]. Additionally, this model of delivery may allow for greater patient-centeredness as patients do not need to seek

counseling outside the clinical setting, and they may also experience an increased level of trust with a provider familiar to them and/or with the clinical area [46].

However, challenges to this model include increased time constraints on clinicians, as well as difficulty in maintaining neutrality in instances where providers are familiar with the patient and family [46]. A challenge encountered in this study was some difficulty in consistently coordinating the availability of a decision coach due to competing demands and pressures for the diabetes social workers' time and resources. These social workers are not routinely involved in the pump assessment process at this pediatric hospital, a practice which differs from many other pediatric pump programs. In addition, the implementation of decision coaching at an earlier point in a family's decision making process may require additional resources and establishment of a process that will accommodate patient and family needs for support in timely fashion. A possible solution may include a shift to a third party model whereby a health professional such as an Advanced Practice Nurse that is committed to providing 'on call' or scheduled decision support, is more likely to have a non-directive approach, and may assist with the overall feasibility of the intervention [46].

3.5.3 Stakeholder presence

The success of decision support in pediatric care where multiple stakeholders are involved (child, and one or more parents/guardians) may necessitate that relevant individuals are present during decision coaching. In this study, it was noted that in four of seven families, two parents were present at the decision coaching (though not all participated in completing questionnaires). However, for the remaining three families, only the mother was present. Since there are certain challenges to arranging the presence of both parents, it is perhaps more important that families and clinicians ensure the most appropriate stakeholders are present. Often

a single stakeholder such as parent, family member, or guardian may assume various roles in the child's decision making process including that of 'information gatherer' or 'interpreter', 'coach', 'negotiator', and 'caretaker' [6]. Of particular importance to the pediatric context is the caretaker role as this task supports and reinforces a particular treatment decision [6]. Consequently, the long term success of decision support may require, at minimum, that the parent/guardian primarily responsible for assisting the child in treatment implementation be present with the child.

3.5.4 Time of the intervention

The results also indicated that the decision coaching session may have taken too long. Quantitative responses were mixed in response to the statement "The decision coaching session was about the right length of time". Notably, more children than parents in the undecided group indicated a negative response to this statement. The median time of decision coaching sessions was 35 minutes, which may have exceeded the attention span of most children for this type of an exercise. Finding ways to reduce the length of time of the decision coaching may need to be explored. It is also possible that designing more stimulating techniques for decision coaching may make the time less noticeable for children.

3.5.5 Limitations

There are three potential limitations to this pre-/post-test study design that should be considered when interpreting the results. First, since this study is a pilot study with a small, non-random sample aimed at piloting the feasibility and acceptability of the intervention, the results need to be interpreted with caution. Second, there is a possibility of maturation effect which occurs in response to natural changes or processes that occur over time apart from the effect of a study intervention [47]. After completing the DCS, participants may have been sensitized to their

decision making needs and took steps to support these needs before completing the DCS again two weeks later. Third, self-selection bias may have occurred as a result of families motivated and willing to participate in decision coaching being the only ones who agreed to participate in the study, thereby limiting the generalizability of the findings. However, we were able to include participants that were of both sexes, and were of variable age, diabetes duration, and education levels. Future research should consider collecting data on ethnicity.

3.5.6 Practice implications

Despite these limitations, there are several implications for practice that can be drawn from this study. First, this study is unique in that it presents a feasible and acceptable method of incorporating the child's perspective into the decision making process. The discordance in values between parents and children that we observed in this study suggest that children may have different values for outcomes of options and preferences than their parents thus leading to treatment choices that if made solely by parents, may not be congruent with children's values and preferences. Furthermore, literature suggests that health care professionals should consider how decision making might best be facilitated among multiple stakeholders (children, parents, and clinicians) and to employ interventions that successfully meet the needs of all those involved [48,3]. The intervention presented in this study ensures that children are not only actively involved in the SDM process, but that the treatment choices which ultimately affect them are consistent with their values and preferences.

Second, the OFDG used in this study demonstrated promise as a decision making tool, especially when used as an adjunct to decision coaching. The Ottawa Personal Decision Guide (OPDG) has demonstrated effectiveness in reducing decisional conflict in women considering prenatal testing, however, unlike the OPDG, the OFDG accounts for the perspectives of multiple

stakeholders (parents and children) [17]. Furthermore, while patient decision aids have been tested extensively within the adult population, few studies have tested their use with children [16]. The positive acceptability results reported in this study, especially among individuals at an earlier stage of decision making, are encouraging for further use and testing of the OFDG with this population. Additionally, since the OFDG is a generic decision aid, it could be used with other pediatric decisions. This is particularly important given the limited availability of condition specific decision aids that have been developed for the pediatric population [18].

3.6 Conclusion

The findings of this pilot study indicate that it was feasible to evaluate decision coaching using the OFDG with children and parents considering insulin options for type 1 diabetes management. However, the acceptability of the intervention may be improved if used with families at an earlier stage in the decision making process.

The findings can also inform a larger scale effectiveness study. Although interventions such as decision coaching and decision aids are shown to be acceptable and beneficial in various clinical settings within the adult population, relatively little is known about their use within pediatrics. Future research should explore other clinical areas where decision support may benefit children and parents and field test decision support interventions within these populations. Examining the barriers and facilitators to implementation, as well as long-term outcomes such as treatment adherence, patient compliance and cost-efficacy may also help inform the use of decision support within pediatrics.

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Chapter 3 References

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Chapter Four

Integrated Discussion and Conclusion

4.1 Introduction (summary of thesis)

The overarching aim of this thesis was to evaluate interventions that support children and their parents in making health decisions. It consists of two studies: a systematic review (Chapter 2) and a pilot feasibility study to evaluate an intervention (Chapter 3). In this chapter, I will summarize the findings of these studies and discuss a number of important considerations that have resulted from the development of this thesis, implications for nursing practice, and areas for future research.

The systematic review examined the characteristics and effectiveness of decision support interventions that support children in their decision making (Chapter 2). Findings revealed that although there is growing support among researchers, healthcare professionals, and professional organizations to develop and implement ways of including and supporting children in decision making, only five studies examining decision making interventions of variable quality and heterogeneous characteristics were found. The synthesis of articles concluded that coaching-based interventions with or without educational resources appear to improve decision making outcomes for children. These outcomes included values-choice congruence, parent-child agreement, satisfaction with the decision making process, and overall quality of decision making. None were conducted with children with type 1 diabetes and their parents.

In order to address the decision making needs of children with type 1 diabetes and their parents, a pilot study was conducted that evaluated the feasibility and acceptability of decision coaching guided by the Ottawa Family Decision Guide (OFDG) (Chapter 3). The intervention in this study employed decision coaching together with a decision aid that was similar to interventions showing some promise in the systematic review (Chapter 2). However, the decision aid used moved beyond the simple patient education resources evaluated in the studies of the

systematic review. Our decision aid made explicit that a decision needed to be made, provided a values clarification exercise, and guided the child and his/her parent(s) through a stepped approach to thinking about the decision. Although we only conducted a pilot study, the results indicated that the intervention was acceptable and the study design was feasible. This study can, therefore, be used to inform a larger-scale study to evaluate the effectiveness of this multifaceted intervention. The decision support intervention was also found to be more acceptable to participants who were more undecided at baseline, thereby indicating who will need to be targeted for future recruitment in the study. Subsequent evaluation of the intervention should be designed in such a way to ensure recruitment occurs at the optimal time in the process of care.

4.2 Lessons Learned from Thesis

The process of conducting a systematic review and an intervention study focused on decision support for children has highlighted three important considerations: a) supporting children to be involved in decision making is a novel area of research, b) interventions for use by multiple stakeholders are different from those designed solely for the patient, and c) although children progress through stages of development, interventions can facilitate their involvement at younger ages in discussions about treatment options with their parents.

4.2.1 Novelty of Decision Support Studies with Children

This thesis has demonstrated that the development and testing of decision support interventions with children is still a novel area of research. Our systematic review identified only five studies. This contrasts quite dramatically with the adult population where research evaluating decision support interventions is far more established (Coulter & Ellins, 2007). Much of the literature discussing decision support for children appears to be weighted towards considering the philosophical and ideological underpinnings to including children in decision

making; and having established this basis, authors have also examined the legal, ethical and practical implications of this practice (Barfield et al., 2010; Coad & Shaw, 2008; Moore & Kirk, 2010; Turner, 2010; Walker & Doyon, 2001; Waxse, 1995). However, the systematic review (Chapter 2) revealed that there appears to be a growing interest over the last five years to evaluate actual interventions that may support the needs of children. In fact, the setting where the pilot study took place recently received funds from the Canadian Institutes of Health Research (CIHR) to implement and evaluate a pediatric hospital-based family decision service (CIHR, 2012). Therefore, the systematic review and results of the pilot study in my thesis are being used to inform what may one day become common practice across pediatric services within this setting.

My thesis is also novel in that we evaluated one of the first studies to test an intervention that supports multiple stakeholders in their decision making (Lyon et al., 2009 a,b). Although decision support with multiple stakeholders has been discussed in the adult (Charles et al., 1997) and pediatric context (Gabe, Olumide & Bury, 2004), there is a dearth of research regarding actual interventions to support this. Results from our systematic review (Chapter 2) indicate that of the five included studies, only one conducted an intervention with both children and their parents (Lyon et al., 2009 a, b). It is interesting that this study reported higher satisfaction among parents and children, and increased congruence of values between parents and children. Therefore, the intervention evaluated in our pilot study (Chapter 3) may similarly produce positive outcomes with multiple stakeholders when tested on a larger scale.

4.2.2 Complexities of the dyad/triad relationship

My thesis has also elucidated some of the many complexities and challenges that the child-parent dyad and the child-parent-clinician triad present. The dyadic nature of relationships is thought to have a unique influence on the cognitions, emotions and behaviors of individuals within the dyad (Cook & Kenny, 2005). The concept is arguably further complicated in the pediatric context as there is a potential for three sets of dyadic relationships (child-parent, parent-clinician, clinician-child) with each dyad potentially influencing the other (Gabe, et al., 2004).

Measuring the outcomes of dyads presents several challenges for researchers (Cook & Kenny, 2005). One challenge is that the interdependence between two individuals may affect the scoring of questionnaires. For example, individual scores within the dyad are likely to be correlated and cannot be analyzed independently. The correlation of responses is likely due to a similarity in relational characteristics such as background and context (Kenny, 1996). This effect may have been amplified in the pilot study (Chapter 3) particularly during the values clarification exercise. Children and parents expressed their values in front of one another which conceivably could have influenced the values scores of the other. Although the child was asked first, the very presence of the parent may have influenced the child's response. Conversely, having heard the child's values rating, the parent(s) may also have modified his/her response accordingly. It is therefore, possible that *actual* congruence of values of options between child and parent may have been lower than reported. Accounting for the dyadic nature of these relationships should be considered in future research (Legare et al., 2012a).

The dyadic relationship may also be complicated by differing values relating to outcomes of options, differing decision making needs, and differing learning styles that children and parents have. The results of our pilot study indicated that although children and parents had

similar values for outcomes of options for most items, several differences did occur. Although minor, these differences may become problematic in cases where children and parents do not agree on the preferred treatment outcome. In such cases, there is a potential for perceived power structures to control the outcome of the decision making process (Gabe et al., 2004). Consequently, decision support interventions using a neutral, non-directive individual such as a decision coach may be particularly useful to mitigate these imbalances. In our study, to help minimize the potential parent-child power imbalance, we asked the child to respond first to all questions. Finally, having the child respond first is in keeping with the IP-SDM model in which the patient's values are central to the decision making process, but given that the values of others are influential, both sets of values are meant to be made explicit and shared (Legare et al., 2011).

The systematic review and pilot study also raise questions regarding the best method to provide decision support in the context of the parent-child dyad. Traditional decision aid mediums used with adults include pamphlets, booklets, and DVD's (Stacey et al., 2011). Although the intervention in the pilot study used a traditional method, we acknowledge that children and parents may be somewhat diverse in their learning styles and their comfort level with various media (D'Alessandro & Dosa, 2001). In an increasingly digitalized society, children are becoming more technologically adept and as a result may prefer other mediums such as web-based tools, computer programs, or digital applications (Barfield et al., 2010; Izenberg & Lieberman, 1998). Applying information technology to decision support may be useful for both children and parents provided it is adapted to the cognitive ability of the child and accompanied by skills training when needed (Johnson, 2001). However, as we were developing the process for the decision coach to use a web-based version of the OFDG, we realized this medium directed

the conversation to the computer application rather than among participants. For this reason we chose to use a paper-based OFDG in the study.

4.2.3 Success of Interventions with Younger Participants

Given that decision support with children and with multiple stakeholders is still a novel area of research, we found the intervention worked unexpectedly well. Although children are at varying stages of development, interventions can involve them in discussions with their parents about treatment options at young ages. In the systematic review, the ages of children in the included studies ranged from 5.8 to 21, while the ages of children in the pilot study ranged from 9 to 17. The children in the pilot study completed questionnaires with minimal missing information, and according to study findings, they were successfully able to participate in the various steps of the decision coaching session. This indicates that not only do children have the capacity to participate in decision making from an early age, but they may also have their own decision making needs and be able to develop and communicate preferences for options.

However, challenges exist in recruiting children capable of participating in decision making for research. Of 16 families approached in the pilot study, 7 participated (44%). Potential barriers to participation for adolescents and young adults are reported to include time commitments involved with research and having too much to think about at time of recruitment (Read et al., 2009). When working with this age group, researchers should explore ways of minimizing the time required for participant involvement and facilitating the process of informed consent to enhance recruitment (Read et al., 2009).

4.3 Implications for Nursing

The results from the systematic review and the pilot study have several implications for nurses, and in particular the role of the Advanced Practice Nurse (APN) (see Table 4.1). An APN

is a nurse who has a graduate-level education in nursing and demonstrates an advanced level of clinical practice in a specialty area (Canadian Nurses Association [CNA], 2008). The five core competencies of the APN role are direct clinical practice, education, consultation, leadership, and research. Each of these competencies can be used to further implementation and evaluation of decision support interventions such as decision coaching and decision aids with children.

Table 4.1: Implications of Systematic Review and Pilot Study Results for APN's

APN Competency	Implications of thesis findings for APN's
1. Direct Clinical Practice	• Assess child's and parent's decision making needs. • Assess continuum of care and where decision coaching and/or decision aids might best be positioned. • Tailor and implement decision support interventions. • Facilitate the process of SDM through decision coaching and generic (OFDG) or specific decision aids.
2. Education	*Patients and Families* • Discuss the benefits of including children in the decision making process *Healthcare providers* • Discuss the benefits of including children in the decision making process • Increase HCP's awareness of children's lack of involvement in SDM • Provide training in decision support (decision coaching and decision aids) • Explore IP-SDM model's relevance to children
3. Consultation	• Consult with interprofessional team to determine, when and how the team might realistically incorporate decision coaching or decision aids into their practice. • Consult with other health care professionals about what decision support interventions may be most appropriate, least appropriate.
4. Research	• Evaluate decision coaching using the OFDG in decision making re: insulin delivery options to establish effectiveness. • Evaluate the effectiveness of decision coaching and decision aids such as the OFDG in *other clinical areas*. • Refine current decision support interventions • Assess barriers and facilitators to participation
5. Leadership (clinical, professional, systems)	• Demonstrate SDM with children by pioneering decision support interventions in champion clinics/areas. • Pilot decision coaching and decision aids in novel clinical areas. • Advocate for support to implement these interventions.

4.3.1 Direct Clinical Practice

The clinical practice competency of the APN includes expert nursing practice in a specialized clinical area and knowledge of related sciences (CNA, 2008). APNs are therefore likely to have a detailed and holistic understanding of the needs of the patient population they work with. This competency also requires them to "assess trends or patterns that have health implications for individuals, groups or communities" (CNA, 2008, p.23). This puts the APN in an ideal position to conduct a detailed needs assessment of a patient population's decision support needs, determine interventions that best meet these needs, and identify an ideal point in the continuum of care where interventions can be introduced. Within this competency, the APN is also able to "guide decision making in complex clinical situations" and, therefore, can tailor and implement decision support interventions with the child and family (CNA, 2008, p.23).

4.3.2 Educator

As educator, the APN is involved in the education of patients, families and health care providers (HCPs) (Hamric, Spross & Hanson., 2009). This competency, also referred to as 'expert coaching and guidance', promotes the development of evidenced-based knowledge and skills within these groups (Ervin, 2005; Hamric et al., 2009). The APN has an opportunity to educate patients and families about the benefits of including children in the decision making process, and make them aware of interventions that may facilitate this process. The APN, can also educate nurses and other HCPs regarding the benefits of including children in decision making, and raise awareness about their lack of involvement in practice. Training other HCPs in using patient decision aids, and providing decision coaching could be facilitated by the APN. Finally, by educating HCPs about interprofessional models of SDM (Legare et al., 2011), the

APN can streamline the process of involving children in decision making across the continuum of care.

4.3.3 Consultant/Collaborator

The consultant competency entails that the APN "demonstrate knowledge and skill in communication, negotiation and conflict resolution, including the ability to analyze, manage and negotiate conflict" (CNA, 2008, p. 27). An inter-professional model of SDM advocates for a collaborative approach between disciplines involved in a patient's care in order to deliver an integrated decision making process (Legare et al., 2011). Within this competency, the APN is well-positioned to be an integral part in this model. The APN can consult with the rest of the team regarding roles and responsibilities in supporting patient's various decision making needs, and discuss with them the appropriateness and timing of appropriate interventions.

4.3.4 Leader

As leaders in their organizations, APNs affect change by continually seeking new ways to improve practice and the delivery of care (CNA, 2008). This may occur in the realms of clinical practice or nursing professionalism, on a systems/organization level, or in the public sphere. As a leader, the APN can demonstrate SDM by including children in decision making, and pioneering decision support interventions in champion clinics/areas. The APN may also be involved in lobbying for policy changes and advocating for shifts in the organizational culture that will facilitate the involvement of children in SDM.

4.3.5 Researcher

As a researcher, the APN is concerned with the generation and translation of evidence relevant to nursing (CNA, 2008). Other competencies within this role suggest participation in the identification, collection, evaluation, critiquing and presentation of knowledge (CNA, 2008).

Furthermore, knowledge should be disseminated to nurses and the rest of the health-care system through the available channels of communication (CNA, 2008). Areas of further research that the APN could be involved in are discussed below.

4.4 Areas for Further Research

The results of this thesis have provided direction for further research in several areas relating to involving children in decision making. First, although the decision support needs of parents have been identified and examined in a number of studies, relatively little is known about the decision making needs of children (Byrnes, 2002; Jackson et al., 2008). In order to best tailor decision support interventions to children and to meet the International Patient Decision Aid Standards for developing and evaluating patient decision aids (Elwyn, 2006; IPDAS, 2005), it is important that researchers are clear about the decision making needs of children. The influence of factors such as child's age and experience with a condition on the child's ability to participate should also be considered. Further, given that children are growing up in a technology dependent world, traditional approaches to decision aid formats may not be adequate (Barfield et al., 2010; Izenberg & Lieberman, 1998).

Second, further evaluation of actual decision support interventions with children is required. Given that the pilot study in my thesis primarily examines feasibility of the study design and acceptability of the intervention, the effectiveness of decision coaching guided by the OFDG on outcomes will require further testing using a more rigorous design. Ideally, these types of interventions should be evaluated in randomized controlled trials to minimize risk of bias (Higgins & Green, 2011). It is estimated that a sample size of 45 participants is required in a pre-/post-test study design in order to detect a statistically significant (alpha <0.05, power $(1-\beta) = 0.80$) change in decisional conflict. To ensure recruitment of a sufficient number of participants

in a timely manner, future studies may need to be multi-centred. In our systematic review (chapter 2), four of the five included studies recruited patients from multiple sites (Adams et al. 2009; Hollen et al., 1999; Lyon et al., 2009; Rhee et al., 2008).

There may also be other diabetes related decisions where specific decision support interventions could be provided. For example, several diabetes team members identified the type of insulin pump that children use as a future point of decision support since several pump options are available, each with various pros and cons. Furthermore, the use of the decision support interventions should be evaluated in other clinical settings within pediatrics. Long term outcomes, such as treatment adherence, quality of life, and decisional regret could also be explored in these settings (Stacey et al., 2011). Although these outcomes have been measured in the adult population, it is unknown if they are also relevant to pediatric patients.

Finally, once research has verified the effectiveness of the intervention with children, it is important to consider implementing it as part of usual care through a process of knowledge translation. Knowledge translation involves the exchange, synthesis and application of knowledge occurring between producers and users to improve health outcomes (Canadian Institutes of Health Research, 2008; Graham & Tetroe, 2007). Previous knowledge translation research indicates that passive dissemination of evidence-based interventions is often not enough to ensure uptake into routine use (Bero et al., 1998). More successful knowledge translation may involve a barriers assessment and the use of interventions to overcome barriers to using evidence in practice (Grimshaw et al., 2012). More specifically, within decision aids related research, effective interventions include training the health care professional with or without audit and feedback, and using the decision aid within consultation with the practitioner (Legare et al., 2010; Legare et al., 2012). The use of a decision aid within the consultation is similar to how the

intervention was implemented with the decision coach in the pilot study. Rather than using a decision coach external to the practice, the intervention was intended to be used by a member of the interprofessional team within the diabetes program. By using someone who is within the team and within the context of a trusted patient-provider relationship that is integrated with care, patient-centeredness may be improved (Woolf et al., 2005).

4.5 Conclusion

My thesis has sought to evaluate interventions that support children and their parents in making health decisions. Although there appears to be a growing interest in supporting the decision making of children in health care, the systematic review (Chapter 2) identified a significant need for more intervention studies in this area. Higher quality studies that address this area of research are greatly needed to provide direction for health care professionals as to how children can best be included and supported in making decisions that affect their health.

The intervention study (Chapter 3) is, therefore, quite timely. Although it is a pilot study, the results will be used to inform a larger scale study and may already provide some direction for health care practice. Decision coaching using the Ottawa Family Decision Guide was found to be an acceptable intervention with children and parents who were undecided about the best insulin delivery method for type 1 diabetes management, and appears to be a promising intervention for supporting their decision making needs, however, further evaluation is required.

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Appendices

Appendix A

Contributions of Collaborators

Research Team Collaborators

Several authors were involved in the various aspects of this thesis. Bryan Feenstra RN, BScN, MScN(c) (BF) conceived, participated in and led all aspects of this research project in fulfilling the requirements for a Master's Degree in Nursing at the University of Ottawa. BF is a registered nurse at the Ottawa Hospital.

Three thesis committee members, Dawn Stacey RN, PhD (DS) (supervisor), Dr. Margaret Lawson MD, MSc, FRCP (ML), and Denise Harrison RN, PhD (DH), were also involved in several stages of the thesis including development of the proposal, development and refining of the intervention, regular consultation throughout the research process, contributing to the process of editing the drafted manuscript, and approving the final manuscript content (see Table).

DS is a nurse and an Associate Professor at the University of Ottawa in the Faculty of Health Sciences (School of Nursing). She is also a Scientist at the Ottawa Hospital Research Institute Clinical Epidemiology Program. She has extensive experience in decision support, patient education, continuing education for nurses, knowledge translation, and the development and evaluation of patient decision aids. She has completed doctoral studies at the University of Ottawa in population health and holds several awards including the 2009 Young Researcher Award, and a doctoral research award from the Ontario Ministry of Health and Long-term Care and the Canadian Institutes of Health Research (CIHR).

ML is a pediatric endocrinologist at the Children's Hospital of Eastern Ontario (CHEO), a Senior Investigator at the CHEO Research Institute, and an Associate Professor of Pediatrics at the University of Ottawa. She has expertise in shared decision making and the development of

decision aids in pediatric endocrinology. She has received funding from the Ontario Ministry of Health and Long-term Care Innovation Fund and the CIHR to implement and evaluate a decision support program at CHEO.

DH is the Chair in Nursing Care of Children, Youth and Families at CHEO and an Assistant Professor at the University of Ottawa in the Faculty of Health Sciences (School of Nursing). She has extensive pediatric research experience in several areas including knowledge translation, pain management, and sucrose analgesia in diverse populations of infants and children. In 2011, she was named a Mayday Pain and Society Fellow (New York, United States).

Several other individuals were involved in various aspects of this thesis including a speech language pathologist, a Librarian, diabetes social workers, diabetes nurse educators, and a technical administrator. Laura Boland (LB), MSc, SLP-C is a trained decision coach and former research associate at the CHEO Research Institute. She assisted with the development and initial testing of the decision coaching intervention and protocol, and was also involved in several stages of the systematic review. Michelle R LeBlanc (MRL) is a Librarian specialized in Nursing and Rehabilitation. She developed the search strategy for the systematic review. Jennifer Kryworuchko RN, PhD (JK), an Assistant Professor at the University of Saskatchewan College of Nursing, screened citations for the systematic review. Annick Constant MSW, RSW and Maura Manuel MSW, RSW are Social Workers at the CHEO diabetes clinic. They were involved in the delivery of the decision coaching intervention for the study. Edgar Belanger RN, BScN and Genevieve Parent RN, BScN are Certified Diabetes Nurse Educators at CHEO who helped with participant recruitment for the study. Anton Saarimaki, MCS, is a technical administrator and analyst for the Patient Decision Aids Research Group at the Ottawa Hospital

Research Institute. He assisted with the development of the web-based screening tools used for the systematic review.

Summary of Collaborator Contributions

	Chapter 1 General Introduction	**Chapter 2** Systematic Review of Interventions	**Chapter 3** Intervention Pilot Study	**Chapter 4** Integrated Discussion
Conception and Study Design	BF	BF DS DH ML LB	BF DS DH ML	BF
Designing the intervention			BF DS ML LB	
Collect Data	BF	BF JK LB DS MRL	BF	BF
Analyze and Interpret Data	BF	BF DS	BF DS	BF
Draft Manuscript	BF	BF	BF	BF
Edit and Revise for Important Intellectual Content	BF DS DH ML	BF DS DH ML	BF DS DH ML LB	BF DS DH ML
Responsible for Overall Content	BF	BF	BF	BF

Appendix B

Data Extraction Template

Study Info

Variables / items / questions	Data value - standardized, coded	Data comment, description, source - text
Review Details	(Text)	
Reviewer completing this form		
Date form completed		
Article Details	(Text)	
Article Title		
First Author		
Year (YYYY)		
Country		
Journal		
Author contact information		
Risk of Bias	choice (low risk, high risk, unclear risk)	***See Risk of Bias tab (RCT,CBA, or ITS) for definitions of the criteria for low, high and unclear***.
Selection Bias		
Random sequence generation		
Allocation concealment.		
Performance Bias		
Blinding of participants AND personnel		
Detection Bias		
Blinding of outcome assessment		
Attrition Bias		
Incomplete outcome data		
Reporting Bias		
Selective Reporting		
Other sources of bias.		
Other		

Methods

Variables / items / questions	Data value - standardized, coded	Data comment, description, source - text
Aim of intervention/study	(Text)	
(As stated in the trial's report. What was the problem that this intervention was designed to address?)		p. 1476
Study design	(Choice)	
(RCT, non-randomized CT, interupted time series, controlled before/after)		p. 1478
Methods of recruitment of participants	(Text)	
How were potential participants approached and invited to participate?)		p. 1480
Inclusion/exclusion criteria for participation in study	(Text)	
Inclusion		p. 1479
Exclusion		p. 1479
Informed consent obtained?	(Choice)	
(Yes/No/Unclear)		
Ethical approval	(Choice)	
(Yes/No/Unclear)		p. 1480
Funding	(Text)	
(including source, amount, if stated)		p. 1475
Statistical methods and their appropriateness (if relevant)	(Text)	
List all statistical meathods used		p. 1481

Participants

Variables / items / questions	Data value - standardized, coded	Data comment, description, source - text
1. Description of those involved in study	(Yes/No/Unsure)	
a. Child patients		
b. Carers;		
c. Parents/Guardians of patients		
d. Health professionals		
e. Other		
2. Geographic location	(Text)	
a. Country		
b. City		
3. Setting	(Text)	
(eg. Community, home, primary health centre, acute care hospital, extended care facility)		
4. Number *of (where applicable):*	(Number)	
a. Eligible,		
b. Excluded,		
c. Refused to take part,		
d. Randomised to intervention,		
e. Randomised to control,		
f. Excluded post randomisation,		
g. Withdrawn,		
h. Lost to follow up,		
i. Died,		
j. Included in analysis,		
k. Included for each outcome		
5. Age (of children):	(Enter Value)	
a. Range		
b. Mean (standard deviation)		
6. Age (of parents):	(Enter Value)	
a. Range		
b. Mean (standard deviation)		
7. Other characteristics	(Text)	
a. Gender:		
b. Ethnicity:		
c. Principal health problem or diagnosis (if relevant):		
d. Other health problem/s (if relevant):		
e. Stage of problem/illness (if relevant)		
f. Other social/demographic details *(eg. literacy or reading level):*		

Intervention(s)/Control(s)

	Intervention - Main Decision Support Intervention (MDSI)		Control Group/Usual care 1 (if applicable)	
Variables / items / questions	**data value - standardized, coded**	**Data comment, description, source - text**	**data value - standardized, coded**	**Data comment, description, source - text**
Details of Intervention	(Text)		(Text)	
Type of Intervention				
Theoretical basis (with key references)				
Goals/objectives of intervention stated (e.g. to improve knowledge, enhance patients control)?				
Content of intervention				
Format(s) (e.g. media)				
Source of intervention				
Setting				
Main Difference between comparison group intervention and main decision support intervention.				
number of eligible subjects enrolled (#)				
number of subjects completing trial (#)				
Included decision support materials? (yes/no)				
Delivery of Intervention	(Text)		(Text)	
Stages? (y/n- if yes, describe)				
Frequency				
Duration				
In person or remotely (telephone or Internet)?				
Details of Providers	(Text)		(Text)	
Who administered?				
Number of providers				
Training of providers delivering intervention				

Outcomes

Variables / items / questions	Data value - standardized, coded	Data comment, description, source - text
Outcomes (as identified by authors)	(Text)	
Primary		
Secondary		
Details of Outcomes		
Administered to chidren AND parents?		
Methods of assessing outcome measures *(eg, phone survey, questionnaire, physical measurements (for each outcome))*		
Validity and reliability of outcome measures		
Methods of follow-up for non-respondents		
Timing of outcome assessment:		
a. Frequency,		
b. Length of follow up		
Adverse events (*eg complaints, levels of dissatisfaction, adverse incidents, side effects))*		

Dichotomous Measures

			Intervention arm - MDSI					Intervention arm - CG1					Intervention arm - CG…					Notes
Variable	Measure - description	Comment, description, source	Timing of Outcome assessment (days/moths)	Raw Score	Standardized score (%)	N in arm (Total)	# Events	Time Point	Raw Score	Standardized score (%)	N in arm (Total)	# Events	Timing of Outcome assessment (days/moths)	Raw Score	Standardized score (%)	N in arm (Total)	# Events	

Continuous Measures

			Intervention arm - MDSI						Intervention arm - CG1						Intervention arm - CG…						Notes
Variable	Measure - description	Comment, description, source	Timing of Outcome assessment (days/moths)	Raw Score	Standardized score (%)	N in arm	Mean	SD	Timing of Outcome assessment (days/moths)	Raw Score	Standardized score (%)	N in arm	Mean	SD	Timing of Outcome assessment (days/moths)	Raw Score	Standardized score (%)	N in arm	Mean	SD	

Conclusions and Limitations

Variables / items / questions	Data value - standardized, coded	Data comment, description, source - text
Conclusions		
1. Provide a brief summary of study author's main findings/conclusions:		
Limitations		
1. Describe any study limitations listed by the author.		
2. If applicable, describe any study limitations not reported by the author.		
Reasons for exclusion		
1. Provide reasons for exclusion after data extraction process		

Appendix C

Risk of Bias Table (for RCT's)

Domain	Review authors' judgement	Support for judgement
Random sequence generation*	***High risk*** ***Unclear*** ***Low risk***	**Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.** Quasi-RCTs and Controlled Before and After (CBA) studies must be rated as 'High Risk' for random sequence generation as the methods were not, by definition, truly random.
Allocation concealment	***High risk*** ***Unclear*** ***Low risk***	**Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.** CBA Studies should be rated 'High Risk. Quasi-RCTs are likely to be rated 'High Risk but there may be some exceptions.
Blinding of participants and personnel *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	**Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.**
Blinding of outcome assessment *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	**Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective**. If the outcome is objective (eg. length of hospital stay) the rating should be 'Low risk.
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	**Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review**

		authors.
Selective reporting	***High risk*** ***Unclear*** ***Low risk***	**State how the possibility of selective outcome reporting was examined by the review authors, and what was found.**
Other sources of bias See the *Cochrane Handbook* 8.15.1 for further examples of potential threats to validity, as well as 16.3.2 for issues relating to cluster trials and 16.4.3 for cross-over trials.	***Note: all answers should follow the format:*** ***High risk*** ***Unclear*** ***Low risk***	**State any important concerns about bias not addressed in the other domains in the tool.** **If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.**

Appendix D

Risk of Bias Tables- Amended for use with CBA and ITS studies

2.5.2.1 Assessing risk of bias for CBA studies

Inclusion criteria:
The EPOC Review Group specifies that, to be included in a systematic review, the CBA study design must meet three key criteria. These are:

- There must be at least two intervention sites and two control sites (note, this is a new criterion added in 2009).
- The timing of the periods for study for the control and intervention groups should be comparable (that is, the pre- and post- intervention periods of measurement for the control and intervention groups should be the same).
- The intervention and control groups should be comparable on key characteristics.

CBA studies that do not meet these criteria should be excluded from a Cochrane review.

Risk of bias assessment:
If CBA studies meet these criteria, they are eligible (at least based on study design criteria) for inclusion in a systematic review and so need to be systematically assessed for their risk of bias.
The standard Risk of Bias tool for RCTs should be utilised for this purpose, and a form suitable for use on CBAs is shown in the table.

Adapted from Cochrane Handbook Table 8.5.a: The Cochrane Collaboration's tool for assessing risk of bias; adapted using EPOC's criteria for studies other than RCTs

Domain	Review authors' judgment	Support for judgement
Random sequence generation*	***High risk*** ***Unclear*** ***Low risk***	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. CBA studies must be rated as 'High risk'. Score 'unclear' if not specified in the paper.
Allocation concealment	***High risk*** ***Unclear*** ***Low risk***	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment. CBA should be scored 'High risk'. Score 'unclear' if not specified in the paper.
Blinding of participants and personnel *Assessments should be made for each main outcome (or class of*	***High risk*** ***Unclear*** ***Low risk***	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.

outcomes).		
Blinding of outcome assessment *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.
Incomplete outcome data* *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.
Selective reporting*	***High risk*** ***Unclear*** ***Low risk***	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.
Other sources of bias* For example: - Were the intervention and control groups comparable at baseline (note, if groups were not reasonably equivalent and this was not adjusted through analysis, the study should be excluded). - Have measures been taken within the study to protect against contamination? See the *Cochrane Handbook* 8.15.1 for further examples of potential threats to validity.	***Note: all answers should follow the format:*** ***High risk*** ***Unclear*** ***Low risk***	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.

* If some primary outcomes were imbalanced at baseline, assessed blindly or affected by missing data and others were not, each primary outcome can be scored separately.

Action:

- *Rate included CBA studies on each of the risk of bias assessment criteria. Each criteria should be rated as low risk (done), high risk (not done), or unclear, with a description given.*
- *Authors should rate **Random sequence generation** as 'high risk' and **Allocation concealment** as 'high risk' (as indicated in the table above).*
- *Authors should pay particular attention to the element relating to baseline comparability of intervention and control groups under the **Other sources of bias** heading, and there is a high risk of groups being unbalanced in CBA designs.*

2.5.2.2 ASSESSING RISK OF BIAS FOR ITS STUDIES

The EPOC Review Group specifies that, to be included in a systematic review, studies of the ITS design must meet two key criteria. These are:

- There must be a clearly defined point in time at which the intervention occurred, and this should be reported by the researchers.
- There should be collection of at least three data points before and three after the intervention was introduced.

ITS studies that do not meet these criteria should be excluded from a Cochrane review.

If ITS studies meet these criteria, they are eligible (at least on study design criteria) for inclusion in a systematic review and so need to be systematically assessed for their risk of bias.

The EPOC guidelines for risk of bias assessment of ITS studies are available on their website.

Note that the scope of EPOC focuses more on healthcare structures and organisational aspects than does the scope of the Consumers and Communication Review Group. Review authors should bear this in mind, and will need to **adapt** the EPOC guidance to suit the needs of their specific review question.

Adapted from Cochrane Handbook Table 8.5.a: The Cochrane Collaboration's tool for assessing risk of bias; adapted using EPOC's criteria for ITS studies and CCRG input

Domain	Review authors' judgment	Support for judgement
Was the intervention independent of other changes?	***High risk*** ***Unclear*** ***Low risk***	Score "Low risk" if there are compelling arguments that the intervention occurred independently of other changes over time and the outcome was not influenced by other confounding variables/historic events during study period. *If Events/variables identified, note what they are.* Score "High Risk" if reported that intervention was not independent of other changes in time.
Was the shape of the intervention effect prespecified?	***High risk*** ***Unclear*** ***Low risk***	Score "Low Risk" if point of analysis is the point of intervention OR a rational explanation for the shape of intervention effect was given by the author(s). Where appropriate, this should include an explanation if the point of analysis is NOT the point of intervention; Score "High Risk" if it is clear that the condition above is not met

Was the intervention unlikely to affect data collection?	***High risk*** ***Unclear*** ***Low risk***	Score "Low Risk" if reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention); Score "High Risk" if the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported).
Blinding of participants and personnel *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.
Blinding of outcome assessment *Assessments should be made for each main outcome (or class of outcomes).****	***High risk*** ***Unclear*** ***Low risk***	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.
Were incomplete outcome data adequately addressed? Assessments should be made for each main outcome (or class of outcomes). ***	***High risk*** ***Unclear*** ***Low risk***	Score "Low Risk" if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the pre- and postintervention periods or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result). Score "No" if missing outcome data was likely to bias the results. Score "Unclear" if not specified in the paper (Do not assume 100% follow up unless stated explicitly).
Are reports of the study free of suggestion of selective outcome reporting? *Assessments should be made for each main outcome (or class of outcomes).*	***High risk*** ***Unclear*** ***Low risk***	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.
Was the study free from other risks of bias?	***High risk*** ***Unclear*** ***Low risk***	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were prespecified in the review's protocol, responses should be provided for each question/entry. Score "Low Risk" if there is no evidence of other risk of biases.

		e.g. should consider if seasonality is an issue (i.e. if January to June comprises the pre-intervention period and july to December the post, could the “seasons’ have caused a spurious effect).

*** If some primary outcomes were assessed blindly or affected by missing data and others were not, each primary outcome can be scored separately.

Appendix E

Ethics approval letter

Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

CHEO RESEARCH ETHICS BOARD APPROVAL – DELEGATED REVIEW

Principal Investigator:	Dr. Margaret Lawson
Proposal Number:	[redacted]
Protocol Title:	Effectiveness of Decision Coaching Using the Ottawa Family Decision Guide for Health Decision-Making in the Pediatric Context
Department or PSU:	Endocrinology and Metabolism, Pediatrics
Approval date:	October 4, 2011
Valid Until:	October 3, 2012
Documents reviewed and approved:	• Protocol Amendment #2, May 17, 2011 • Parental Consent form, Version #2, September 21, 2011 • Child/Youth Consent form, Version #2, September 21, 2011 • Recruitment Poster (Parent/Child) and Staff and Online Advertisement for Facebook, Kijiji, September 21, 2011

This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval to the above named research study on the date noted above. Your project was reviewed under the delegated review stream, which is reserved for projects that involve no more than minimal risk to human subjects.

Final approval is granted for the above noted study, with the understanding that the investigator agrees to comply with the following requirements:

- The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.
- The investigator must not implement any deviation from, or changes to, the protocol without the approval of the REB, or when the change involves only logistical or administrative aspects of the study (e.g., change of telephone number or research staff).
- The investigator must, prior to use, submit to the Board changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials.
- For all other research studies, investigators must promptly report to the REB all unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches).
- Investigators must submit an annual renewal report to the REB 30 days prior to the expiration date stated above.
- Investigators must submit a final report at the conclusion of the study.
- Investigators must provide the Board with French versions of the consent form, unless a waiver has been granted.

[redacted]

Dr. Carole Gentile, C.Psych.

[redacted]

CG/smeh 04/10/2011
c.c. CHEO RI Administration
Laura Boland
Bryan Feenstra

This is an official document. Please retain the original for your file *2010 version*

[redacted]

Appendix F

Interprofessional Shared Decision Making (IP-SDM) Training for Healthcare Professionals
(Tutorial plus ½ day workshop)

Dawn Stacey RN, PhD, Associate Professor, University of Ottawa; Director, Patient Decision Aids Research Group, Ottawa Hospital Research Institute, Ottawa, Canada
Margaret Lawson MD, MSc, Children's Hospital of Eastern Ontario; Associate Professor of Pediatrics, University of Ottawa

Online Tutorial:

Prior to attending the workshop, participates are expected to complete the Ottawa Decision Support tutorial (~1.5 hours) available at https://decisionaid.ohri.ca/ODST/. It is designed to help practitioners **strengthen their knowledge** in shared decision making and decision coaching. Upon completing the tutorial, participants should be able to:

- describe concepts of decision support
- identify complex decisions requiring decision support
- explain how to assess patients' decisional needs
- screen for decisional conflict
- discuss tailoring decision support to patients' needs
- explain how to use patient decision aids
- discuss how to evaluate decision support interventions

At the end of each section of the tutorial, there are self-assessment questions that provide immediate feedback on learning. There is a final test at the end of the tutorial and those who achieve ≥75% on their first attempt at the final test, receive a Certificate of Completion.

Interprofessional Decision Coaching Skills Building Workshop

The 3.5 hour skills building workshop will focus on applying the knowledge gained through the tutorial in hands-on interactive learning exercises. It is designed to help healthcare professionals **enhance their skills** in shared decision making and decision coaching. Upon completion of the workshop, participants should be able to:

- Explain key elements of interprofessional shared decision making (IP-SDM)
- Use evidence- and theory-based tools to support individuals making decisions
- Demonstrate skills in supporting patients making health or social decisions
- Develop appraisal skills for evaluating shared decision making
- Discuss factors influencing the provision of shared decision making/IP-SDM in clinical practice.

Evidence to support the tutorial and workshop

The tutorial has been used by over 1200 health care professionals in Canada, USA, UK, Chile, and other countries. It has been evaluated in two randomized trials and one pre-/post-test study with health care professionals. It significantly improves knowledge of decision support. When it is combined with a skills building workshop, it improves the quality of decision support provided to simulated patients. The skills building workshop has also been

used with many health care professionals as part of studies to implement shared decision making within the processes of care.

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Appendix G

Protocol for study recruitment and Decision coaching using the Ottawa Family Decision Guide (OFDG) pre-populated with Insulin Delivery Options

1. Recruitment to the study	
1.1 Invite potential participants via phone from list of families scheduled to attend a pump assessment at least two weeks in advance OR telephone call to confirm decision coaching session with families recruited from a pump information evening. 1.2 Introduce her/himself and provide a brief description of the process (i.e., families come to CHEO for decision coaching, etc). 1.3 Assess families' eligibility for study using eligibility criteria checklist. 1.4 Schedule appointment for decision coaching at CHEO within appropriate time frame (based on when the decision needs to be made) OR to coincide with families scheduled pump assessment.	
2. Decision Coaching	
Protocol steps	**Decision coaching elements**
2.1 Introduce and explain the OFDG. Be prepared to record directly onto the OFDG.	Provide information
2.2 Review/establish decision to be made and ensure decision is consistent between the parent and youth.	Assess/discuss decision-making needs
2.3 Ask reason for making the decision, timing for when they want to reach a decision and determine where they are at in the process of decision making (not thinking about it to already made a decision).	Assess/discuss decision-making needs Assess understanding
2.4 Discuss/review information on options, benefits and harms related to the decision (pre-populated in the decision aid. 2.5 Ask if there are other benefits or harms to add. Prompts: Associated cost; side effects; effectiveness of intervention; natural course; speed of recovery; logistical issues, etc.	Provide information (e.g. options, benefits, harms) Assess understanding Build skills in deliberation, communication, and accessing support

2. Decision Coaching continued	
Protocol steps	**Decision coaching elements**
2.6 Ask the child first and then the parent, to rate the importance of each of the benefits and harms on a scale of 0 to 5. 2.7 Ask the child and then the parent, which option they prefer considering what is most important in the decision.	Clarify values Build skills in deliberation, communication, and accessing support.
2.8 Ask the child first and then the parent who else is involved in the decision, the option that other person may prefer, and whether or not they feel pressure from anyone in choosing a specific option.	Assess/discuss decision making needs.
2.9 Highlight areas of agreement/disagreement between the youth and parent for values, pressure and support.	Build skills in deliberation, communication, and accessing support.
2.10 Re-assess decisional needs using the SURE scale items.	Assess/discuss decision making needs.
2.11 Facilitate development of a plan for next steps that fit with both the child and the parent's unresolved decisional needs. 2.12 Discuss sharing their preferences with the health care practitioner(s) involved.	Facilitate progress in DM Screen for implementation Needs.
2.13 Provide parent and youth with the decision coach's contact information and invite to contact the decision coach if they would like to further discuss the decision.	Facilitate progress in DM.
2.14 Print and provide copies of the OFDGs to youth and parent to take to their next appointment. 2.15 Include a copy of the completed OFDG in the patient's clinic chart.	

Decision coaching elements (Stacey et al., 2012)

1. Assess/discuss patient and family's decision-making needs
2. Provide information (e.g. options, benefits, harms)
3. Assess understanding
4. Clarify values
5. Build skills in deliberation, communication, and accessing support
6. Facilitate progress in decision-making (DM)
7. Screen for implementation needs

Stacey D, Kryworuchko J, Bennett C, Murray MA, Mullan S, Legare F. Decision coaching to prepare patients for making health decisions: A systematic review of decision coaching in trials of patient decision aids. Med Decis Making. In press 2012.

Appendix H

Information and consent form for children

Letter of Information and Consent Form (for Youth/Child)

Effectiveness of Decision Coaching Using the Ottawa Family Decision Guide for Health Decision-Making in the Pediatric Context

Principal Investigator:
Bryan Feenstra, RN, MScN (Student)

Co-investigators:
Dawn Stacey, RN, MScN, PhD, Margaret Lawson, MD, MSc, FRCP, Denise Harrison, RN, MScN, PhD

You and your parent/guardian are being asked to take part in a study to test if decision coaching using the Ottawa Family Decision Guide (OFDG) helps you and your parent/guardian with health decisions. Please read this information to help you decide if you would like to take part in this study.

Why is this study being done?

When a health decision has more than one option, the right choice for each person is not always clear. A "decision coach" can guide people in the decision-making process and can prepare them to talk about the decision with their doctor or health care team. Decision coaches in this study are health professionals who have received extra training in decision coaching. Sometimes the decision coach will use a decision aid (i.e., a booklet that provides information on options and helps people clarify what is important to them). Decision coaching using decision aids has been shown to be helpful when used with adults, by helping to decrease conflicts about decisions. However this has not been tested with parents and children/youth. We are doing the study to see if decision coaching helps to reduce your conflict about your decision.

Who may take part in the study?

You can join this study if:

- □ You are age 17 or younger and are making a decision with your parent or legal guardian.
- □ You and your parent/legal guardian are currently working through a health-related decision that involves you
- □ The decision involves choosing between two or more reasonable options (including the option of doing nothing).

- □ You are *capable* of contributing to the decision-making process. For example, you are considered *capable* if:
  - You can read and speak English or French
  - You can think about and ask questions related to the decision and communicate how you feel about the different options
- □ You live in the area served by the Children's Hospital of Eastern Ontario (CHEO).
- □ You and your parent/guardian sign the informed consent form.

You cannot join this study if:

- □ Your parent/guardian wants to make a decision for or without you.
- □ You want to make a decision without the help of your parent/guardian.
- □ You are not capable of contributing to the decision-making process.
- □ You and/or your parent/guardian are unable to read and/or speak either English or French.

  Even though the study will take place at CHEO, you don't need to be a CHEO patient to join the study. A total of 45 parents and youth will take part in this study.

What will I have to do in the study?

1. The decision coach will ask your parent/guardian a few questions by telephone or in person. This will take about 5 to 10 minutes.
2. At a time agreed upon by you, your parent/guardian and the decision coach (either immediately or later), you and your parent/guardian will meet with the decision coach at CHEO. During the session, you and your parent/guardian will be asked to sign this consent form and will discuss the decision to be made. You and your parent/guardian will be asked some questions that will help you think about the decision. At the end of the visit, you will be given a summary of the decision and this summary along with a progress note, will be sent to your doctor in preparation for discussing the decision at your next visit.
3. One week later, you and your parent/guardian will be asked to answer some questions by telephone, email, or on a form that can be mailed back to the researchers. This will take about 5 to 10 minutes.

What are the risks for this study and how are the risks different from the standard of care?

The risks of taking part in this study are low. However, it is possible that you and your parent/guardian may have concerns and/or problems when participating:

Time commitment

- The decision coaching session will take about 45 minutes.
- The telephone calls before and after the coaching session will take about 5 to 10 minutes.

Psychological

- When the decision coach asks you and your parent/guardian to think about the benefits and harms of each option, it is possible that you and your parent/guardian may feel more unsure about what to do and/or may feel worried.
- If you and/or your parent/guardian feel more unsure and/or worried, the decision coach can arrange for you to see another health care professional at CHEO (for example, a social worker or mental health professional).

What are the benefits to taking part in the study?

You and your parent/guardian may or may not benefit from taking part in this study. You and your parent/guardian may feel more sure about your decision, feel you know better what is involved in the decision, and feel more clear about what is important to both of you in making your choice.
The findings from this study will help improve the way we use decision coaching and decision aids with other parents and children/youth.

If I chose, how would I withdraw from the study?

Taking part in this study is up to you. You may withdraw at any time and there will be no penalty to you or your parent/guardian. Your decision about taking part in this study will not affect the care that you receive at CHEO.

What other treatment options are there if I do not participate in the study?

If you or your parent/guardian choose not to participate in this study, there are other options that can assist you in your decision. CHEO Family Decision Services' website (see www.cheo.on.ca/en/DecisionServices) has a number of decision aids that are readily available, free of charge, and which may be useful for you. You and your parent/guardian may also be able to get support in making the decision you are facing from your doctor.

What about confidentiality and privacy?

Information talked about and forms filled out as part of the study, will be kept strictly confidential except as required or allowed by law (e.g., cases of child abuse and neglect). Your names will not be written on study forms. All the data will be coded so that you and your parent/guardian cannot be known by name. The only forms that will be shared with your doctor are a summary report (that you will receive at the end of the decision coaching visit) and a progress note written by the decision coach.

All paper forms will be stored in a locked file and/or office. All electronic records will be stored in the CHEO server and secured by a user password known only by the researchers responsible for the study.

The results of this study may be published and presented at scientific meetings. However, you and your parent/guardian will not be known in any publication or presentation of this study. Members of the CHEO Research Ethics Board may have

access to your and your parent/guardian's study forms to be able to make sure we followed the approved procedures.

Compensation

- You will be compensated $13.00/day for parking fees at the hospital

Other Information

We will inform you of any new information that might influence your and your parent's/guardian's decision to continue to participate in this research project. At your request, you and your parent/guardian can receive a copy or a summary of the study results at the end of the study. A copy of the signed consent form will be given to you and your parent/guardian.

For more information concerning this study, please contact the researcher responsible for conducting it.

The CHEO Research Ethics Board (REB) has reviewed and approved this research project. The CHEO Research Ethics Board is a committee of the hospital that includes individuals from different professional backgrounds. The Board reviews all research that takes place at the hospital. Its goal is to ensure the protection of the rights and welfare of people participating in research. The Board's work is not intended to replace a parent or child's judgment about what decisions and choices are best for them. You may contact the Chair of the Research Ethics Board for information regarding patient's rights in research studies although this person cannot provide any health-related information about the study.

CONSENT FORM

I have been informed about the nature of the study and the way it will be conducted.

1. I have read the consent form and I have been given a copy.
2. I have been able to ask questions pertaining to the study and they have been answered.
3. After thoughtful consideration, I agree that I/ my parent/guardian will participate in this research study.

Name of parent/guardian (Capital letters)	Parent's / legal guardian's consent (Signature)	Date
Name of child/youth (Capital letters)	Youth's consent (Signature)	Date

I have explained to the participant and/or his/her parent or legal guardian all aspects pertaining to this study and I have answered the questions they have asked me. I have indicated to them that participation in the study is free and voluntary and that their participation may be ceased at any time.

Name of the person who has obtained the consent (Capital letters)	Signature	Date

COMMITMENT FORM FOR THE RESEARCHER OR HIS/HER DELEGATE

The research project must be explained to the participant and/or his/her parent or legal guardian as well as the requirements for participation. A member of the research team must answer their questions and must specify that participation in the project is free and voluntary. The research team will respect the terms of the consent form.

Name of the researcher (Capital letters)	Signature	Date

Information and consent form for parents

Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

Letter of Information and Consent Form (for Parent/Guardian)

Effectiveness of Decision Coaching Using the Ottawa Family Decision Guide for Health Decision-Making in the Pediatric Context

Principal Investigator:
Bryan Feenstra, RN, MScN (Student)

Co-investigators:
Dawn Stacey, RN, MScN, PhD, Margaret Lawson, MD, MSc, FRCP, Denise Harrison, RN, MScN, PhD

You and your child/youth are being asked to take part in a study to test if decision coaching using the Ottawa Family Decision Guide (OFDG) helps you and your child/youth with health decisions. Please read this information to help you decide if you would like to take part in this study.

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When a health decision has more than one option, the right choice for each person is not always clear. A "decision coach" can guide people in the decision-making process and can prepare them to talk about the decision with their doctor or health care team. Decision coaches in this study are health professionals who have received extra training in decision coaching. Sometimes the decision coach will use a decision aid (i.e., a booklet that provides information on options and helps people clarify what is important to them). Decision coaching using decision aids has been shown to be helpful when used with adults, by helping to decrease conflicts about decisions. However this has not been tested with parents and children/youth. We are doing the study to see if decision coaching helps to reduce your conflict about your decision.

Who may take part in the study?

You can join this study if:

- □ You are making a decision with your child/youth who is of age 18 or younger.
- □ You and your child/ youth are currently working through a health-related decision that involves your child/youth.
- □ The decision involves choosing between two or more reasonable options (including the option of doing nothing).
- □ Your child/youth is capable of participating in the decision-making process. For example, he/she is *capable* if:
  - He/ she can read and speak English or French
  - He/ she can think about and ask questions related to the decision and communicate how he/she feels about the different options

- □ You and your child/youth live in the area served by the Children's Hospital of Eastern Ontario (CHEO)
- □ You and your child/youth sign this informed consent form.

You cannot join this study if:

- □ You want to make a decision for your child/youth without him/her.
- □ Your child/youth wants to make a decision without you.
- □ Your child/youth is not capable of contributing to the decision-making process.
- □ You and/or your child are unable to read and/or speak either English or French.

Even though the study will take place at CHEO, you don't need to be a CHEO patient to join the study. A total of 45 parents and youth will take part in this study.

What will I have to do in the study?

1. The decision coach will ask you a few questions by telephone or in person. This will take about 5 to 10 minutes.
2. At a time agreed upon by you and the decision coach (either immediately or later), you will meet with the decision coach at CHEO. During the session, you and your child/youth will be asked to sign this consent form and will discuss the decision to be made. You and your child/youth will be asked some questions that will help you think about the decision. At the end of the visit, you will be given a summary of the decision and this summary along with a progress note, will be sent to your doctor in preparation for discussing the decision at your next visit.
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Psychological

- When the decision coach asks you and your child/youth to think about the benefits and harms of each option, it is possible that you and your child/youth may feel more unsure about what to do and/or may feel worried.
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The findings from this study will help improve the way we use decision coaching and decision aids with other parents and children/youth.

If I chose, how would I withdraw from the study?

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All paper forms will be stored in a locked file and/or office. All electronic records will be stored in the CHEO server and secured by a user password known only by the researchers responsible for the study.

The results of this study may be published and presented at scientific meetings. However, you and your child/youth will not be known in any publication or presentation of this study. Members of the CHEO Research Ethics Board may have access to your and your child/youth's study forms to be able to make sure we followed the approved procedures.

Compensation

- You will be compensated $13.00/day for parking fees at the hospital

Other Information

We will inform you of any new information that might influence your and your child/youth's decision to continue to take part in this research project. At your request, you and your child/youth can receive a copy or a summary of the study results at the end of the study. A copy of the signed consent form will be given to you and your child/youth.

For more information concerning this study, please contact the researcher responsible for conducting it, Bryan Feenstra.

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Appendix I

Table Summarizing Evaluation Measures for Parents and Youth

Scale/ Item	Number of Items	Time (s)- (T1, T2, T3)				Psychometric Properties
		T1	OFDG	T2	T3	
Decision Conflict Scale	10 items, 3 response categories	✓			✓	• Reliability- 0.86 • Internal consistency- 0.78-0.92 (adult) • Effect size 0.4-1.2 for total scale in decision supporting interventions
Option preference	1 item, 15- point scale	✓	✓			• Test- retest coefficient greater than 0.90
Actual Choice	2 items				✓	• n/a
Dyadic OPTION Scale	12 items, 4 Response Categories			✓		• Interrater (ICC=0.77, Kappa=0.66) • Intrarater(ICC=0.82- rater1 and 0.65- rater 2)
Satisfaction with Coaching	6 items, 5 Response Categories				✓	• Adapted from Genetic Counseling Satisfaction Scale which has reliability- 0.80 to 0.90.
Strength of Values (on OFDG)	Maximum of 6 items, 6 response categories		✓			• Reliability from 0.79 to 0.91
Feeling of pressure(s) (on OFDG)	Maximum of 6 items, 4 response categories		✓			• n/a
Follow up with practitioner	1 Item				✓	• n/a

Appendix J

Demographic (child/youth)

1. What is your date of birth?

Month		Year			

2. What is your sex? [Tick one box]

☐ Female ☐ Male

3. ***What is your primary language [Tick one box]***

☐ French ☐ Other: _____

☐ English

4. ***What grade/level are you currently in (or if summer, about to enter)? [Tick one box]***

☐ Grade 2 ☐ Grade 3 ☐ Grade 4

☐ Grade 5 ☐ Grade 6 ☐ Grade 7

☐ Grade 8 ☐ Grade 9 ☐ Grade 10

☐ Grade 11 ☐ Grade 12 ☐ 1st Year University/ College

☐ Other:_____

5. ***How long have you had the medical condition that requires this decision to be made?***

☐ 1 week or less ☐ > 1 week to 4 weeks ☐ > 1 month to 6 months ☐ > 6 months to 1 year ☐ > 1 year to 5 years ☐ >5 years

Demographic (parent)

1. What is your year of birth?

1	**9**		

2. What is your sex? [Tick one box]

☐ Female ☐ Male

3. What is your marital Status? [Tick one box]

☐ Married/ Common-law ☐ Single

☐ Divorced/ separated ☐ Widowed

4. What is your primary language [Tick one box]

☐ French ☐ Other: _____

☐ English

5. What is your highest level of completed education?[Tick one box]

☐ Less than grade 9 ☐ Some high school ☐ University- undergraduate

☐ High school diploma ☐ Trade certificate/ diploma ☐ University- graduate studies

6. How long has your youth experienced her/ his medical condition that has required this decision to be made? [Tick one box]

☐ 1 week or less ☐ > 1 week to 4 weeks ☐ > 1 month to 6 months ☐ > 6 months to 1 year ☐ > 1 year to 5 years ☐ >5 years

T1- Baseline questionnaire (child/youth)

A. Preferred Option (child/youth)

We would like to know if you are leaning towards a certain option. If so, please fill in the options you are considering and show where you would be on the scale by placing a check in the box:

- If you definitely wish to use option #2, check the box in the far right
- If you definitely wish to use option #1, check the box in the far left
- If you are uncertain, check the centre box
- If there is a third option (#3), please rate your preference for this compared to #1 and #2 using the second and third rows

Insulin Pump Therapy														**Standard Insulin Therapy**
Option #1							**Uncertain**							**Option #2**
Standard Insulin Therapy														**Multiple Daily Injections**
Option #2							**Uncertain**							**Option #3**
Multiple Daily Injections														**Insulin Pump Therapy**
Option #3							**Uncertain**							**Option #1**

B. What decision do you face? _____

C. Decisional Conflict Scale

Considering the option you prefer, please answer the following questions:

	Yes [0]	**Unsure [2]**	**No [4]**
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?	☐	☐	☐
10. Do you feel sure about what to choose?	☐	☐	☐

T1- Baseline questionnaire (parent)

A. Preferred Option (parent)

We would like to know if you are leaning towards a certain option. If so, please fill in the options you are considering and show where you would be on the scale by placing a check in the box:

- If you definitely wish to use option #2, check the box in the far right
- If you definitely wish to use option #1, check the box in the far left
- If you are uncertain, check the centre box
- If there is a third option (#3), please rate your preference for this compared to #1 and #2 using the second and third rows

Insulin Pump Therapy														**Standard Insulin Therapy**
Option #1							**Uncertain**							**Option #2**
Standard Insulin Therapy														**Multiple Daily Injections**
Option #2							**Uncertain**							**Option #3**
Multiple Daily Injections														**Insulin Pump Therapy**
Option #3							**Uncertain**							**Option #1**

B. What decision do you face? _____

C. Decisional Conflict Scale

Considering the option you prefer, please answer the following questions:

	Yes [0]	**Unsure [2]**	**No [4]**
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?	☐	☐	☐
10. Do you feel sure about what to choose?	☐	☐	☐

T2- Post-decision coaching questionnaire (child/youth)

A. Dyadic OPTION scale

Most encounters about health problems lead to decisions of one sort or another. These questions ask about the idea of being or feeling involved in decisions, for example, having an opinion or deciding whether to take medication, and if so which one, or what to do next. Answer the questions from your point of view by putting a tick in one box for each question. Please answer every question.

What was the main problem you talked about? Please describe it in a few words…			
Check ☑ the best answer.	**Yes**	**Unsure**	**No**
1. A health problem/situation was identified.	☐	☐	☐
2. Different options (including the possibility of doing nothing) were discussed.	☐	☐	☐
3. If available, different sources of information (e.g. leaflets, websites, contact with other people) to help make the decision were discussed.	☐	☐	☐
4. The advantages, disadvantages and possible outcomes of options were discussed.	☐	☐	☐
5. Ideas or expectations about the options were discussed.	☐	☐	☐
6. Concerns or worries about the options were discussed.	☐	☐	☐
7. It was made sure that information had been understood.	☐	☐	☐
8. There were opportunities to ask questions.	☐	☐	☐
9. The preference to take part in the decision (or not) was respected.	☐	☐	☐
10. During the consultation, a preferred option was discussed/identified.	☐	☐	☐
11. The possibility of coming back to the decision coach was discussed.	☐	☐	☐
Check ☑ the best answer.	**Yes**	**Unsure**	**No**
12. Did this session prepare you for a follow up with your health care provider (family doctor, nurse practitioner, etc.)?	☐	☐	☐

T2- Post-Decision Coaching Questionnaire (parent)

A. Dyadic OPTION scale

Most encounters about health problems lead to decisions of one sort or another. These questions ask about the idea of being or feeling involved in decisions, for example, having an opinion or deciding whether to take medication, and if so which one, or what to do next. Answer the questions from your point of view by putting a tick in one box for each question. Please answer every question.

What was the main problem you talked about? Please describe it in a few words…			
Check ☑ the best answer.	**Yes**	**Unsure**	**No**
1. A health problem/situation was identified.	☐	☐	☐
2. Different options (including the possibility of doing nothing) were discussed.	☐	☐	☐
3. If available, different sources of information (e.g. leaflets, websites, contact with other people) to help make the decision were discussed.	☐	☐	☐
4. The advantages, disadvantages and possible outcomes of options were discussed.	☐	☐	☐
5. Ideas or expectations about the options were discussed.	☐	☐	☐
6. Concerns or worries about the options were discussed.	☐	☐	☐
7. It was made sure that information had been understood.	☐	☐	☐
8. There were opportunities to ask questions.	☐	☐	☐
9. The preference to take part in the decision (or not) was respected.	☐	☐	☐
10. During the consultation, a preferred option was discussed/identified.	☐	☐	☐
11. The possibility of coming back to the decision coach was discussed.	☐	☐	☐
Check ☑ the best answer.	**Yes**	**Unsure**	**No**
12. Did this session prepare you for a follow up with your health care provider (family doctor, nurse practitioner, etc.)?	☐	☐	☐

T2- Post-Decision Coaching Questionnaire (decision coach)

A. Dyadic OPTION scale

Most encounters about health problems lead to decisions of one sort or another. These questions ask about the idea of being or feeling involved in decisions, for example, having an opinion or deciding whether to take medication, and if so which one, or what to do next. Answer the questions from your point of view by putting a tick in one box for each question. Please answer every question.

What was the main problem you talked about? Please describe it in a few words…			
Check ☑ the best answer.	**Yes**	**Unsure**	**No**
1. A health problem/situation was identified.	☐	☐	☐
2. Different options (including the possibility of doing nothing) were discussed.	☐	☐	☐
3. If available, different sources of information (e.g. leaflets, websites, contact with other people) to help make the decision were discussed.	☐	☐	☐
4. The advantages, disadvantages and possible outcomes of options were discussed.	☐	☐	☐
5. Ideas or expectations about the options were discussed.	☐	☐	☐
6. Concerns or worries about the options were discussed.	☐	☐	☐
7. It was made sure that information had been understood.	☐	☐	☐
8. There were opportunities to ask questions.	☐	☐	☐
9. The preference to take part in the decision (or not) was respected.	☐	☐	☐
10. During the consultation, a preferred option was discussed/identified.	☐	☐	☐
11. The possibility of coming back to the decision coach was discussed.	☐	☐	☐
Check ☑ the best answer.	**Yes**	**Unsure**	**No**
12. Did this session prepare you for a follow up with your health care provider (family doctor, nurse practitioner, etc.)?	☐	☐	☐

T3- Post-decision coaching questionnaire- (child/youth)

(Please complete less Than Two Weeks Following Decision Coaching)

A. What decision do you face? _____

B. Decisional Conflict Scale

Considering the option you prefer, please answer the following questions:

	Yes [0]	**Unsure [2]**	**No [4]**
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?	☐	☐	☐
10. Do you feel sure about what to choose?	☐	☐	☐

Decision Conflict Scale © AM O'Connor, 1993, revised 2005

C. Follow up with Health Practitioner

1. Have you had (or scheduled) a follow up appointment with your health practitioner (e.g. family physician, CHEO physician, nurse practitioner)?

   ☐ Yes ☐ No

D. Actual Choice

1. If you have had a follow up appointment, did you make a decision?

   ☐ Yes ☐ No

2. If yes, what option did you choose?

   ☐ Option #1_____

   ☐ Option #2_____

   ☐ Option #3_____

E. Satisfaction with decision coaching (child/youth)

Please read each statement below very carefully, and tell us how much you agree or disagree with each statement by circling your response on the scale to the right.

Please check ☑ you answer in the box.	**Strongly Disagree**	**Disagree Somewhat**	**Uncertain**	**Agree Somewhat**	**Agree Strongly**
1. The decision coach seemed to understand the stresses I was facing.	☐	☐	☐	☐	☐
2. The decision coach helped me to identify what we needed to know to make decisions about what would happen to me.	☐	☐	☐	☐	☐
3. I felt better about my decision after meeting with the decision coach.	☐	☐	☐	☐	☐
4. The decision coaching session was about the right length of time.	☐	☐	☐	☐	☐
5. The decision coach was truly concerned about my well-being.	☐	☐	☐	☐	☐
6. The decision coaching session was valuable to me.	☐	☐	☐	☐	☐

7. Did the decision coach suggest or recommend a specific option to influence your decision?

   ☐ Yes

   ☐ No

8. How helpful was the decision coaching in helping you come to a preferred option?

   ☐ Very helpful

   ☐ Somewhat helpful

   ☐ A little helpful

   ☐ Not helpful

9. Would you recommend decision coaching to other people who are facing the same decision?

- ☐ I would definitely recommend it
- ☐ I would probably recommend it
- ☐ I would probably not recommend it
- ☐ I would definitely not recommend it

10. Any other comments about the decision coaching session?

Adapted from Barry et al. (1995)

T3- Post-Decision Coaching Questionnaire- (parent)

(Please complete less Than Two Weeks Following Decision Coaching)

A. What decision do you face? _____

B. Decisional Conflict Scale

Considering the option you prefer, please answer the following questions:

	Yes [0]	**Unsure [2]**	**No [4]**
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?	☐	☐	☐
10. Do you feel sure about what to choose?	☐	☐	☐

Decision Conflict Scale © AM O'Connor, 1993, revised 2005

C. Follow up with Health Practitioner

1. Have you had (or scheduled) a follow up appointment with your health practitioner (e.g. family physician, CHEO physician, nurse practitioner)?

   ☐ Yes ☐ No

D. Actual Choice

1. If you have had a follow up appointment, did you make a decision?

   ☐ Yes ☐ No

2. If yes, what option did you choose?

   ☐ Option #1_____

   ☐ Option #2_____

   ☐ Option #3_____

E. Satisfaction with decision coaching (parent)

Please read each statement below very carefully, and tell us how much you agree or disagree with each statement by circling your response on the scale to the right.

Please check ☑ you answer in the box.	**Strongly Disagree**	**Disagree Somewhat**	**Uncertain**	**Agree Somewhat**	**Agree Strongly**
1. The decision coach seemed to understand the stresses I and my (son/ daughter) were facing.	☐	☐	☐	☐	☐
2. The decision coach helped us to identify what we needed to know to make decisions about what would happen to my son/ daughter.	☐	☐	☐	☐	☐
3. I felt better about the decision my son/ daughter is facing after meeting with the decision coach.	☐	☐	☐	☐	☐
4. The decision coaching session was about the right length of time.	☐	☐	☐	☐	☐
5. The decision coach was truly concerned about our well-being.	☐	☐	☐	☐	☐
6. The decision coaching session was valuable to me.	☐	☐	☐	☐	☐

7. Did the decision coach suggest or recommend a specific option to influence your decision?

   ☐ Yes

   ☐ No

8. How helpful was the decision coaching in helping you come to a preferred option?

   ☐ Very helpful

   ☐ Somewhat helpful

   ☐ A little helpful

   ☐ Not helpful

9. Would you recommend decision coaching to other people who are facing the same decision?

- ☐ I would definitely recommend it
- ☐ I would probably recommend it
- ☐ I would probably not recommend it
- ☐ I would definitely not recommend it

10. Any other comments about the decision coaching session?

Adapted from Barry et al. (1995)

Appendix K

Record of recruitment invitations with reasons for lack of inclusion

Date	Invited?	Agreed to Participate?	Participated ?	Reason for Lack of Inclusion
January 11, 2012	Yes	Yes	No	-Family agreed to come but did not attend. We were unable to determine the reason why.
January 12, 2012	-	-	-	-Pump assessment rescheduled to January 17.
January 17, 2012	Yes	Yes	Yes	-**Included**
January 18, 2012	No	-	-	-Did not meet inclusion criteria due to age
January 19, 2012	No	-	-	-Did not meet inclusion criteria due to age
January 26, 2012	No	-	-	-Decision coach (LB) was unavailable
February 2, 2012	Yes	Yes	Yes	**-Included**
February 8, 2012	Yes	Yes	Yes	**-Included**
February 9, 2012	No	-	-	-Did not meet inclusion criteria due to age
February 15, 2012	No	-	-	-Family did not show up to pump assessment with endocrinologist. Family contacted by telephone by Diabetes Nurse Educator but with no response.
February 23, 2012	No	-	-	-Decision coach (MM) was not available on this date.
March 7, 2012	No	-	-	-Did not meet inclusion criteria due to age
March 8, 2012	Yes	Yes	No	-Family approached about study but could not attend due to scheduling conflict.
March 14, 2012	No	-	-	-Did not meet inclusion criteria due to age
March 15, 2012	No	-	-	-Did not meet inclusion criteria due to age
March 21, 2012	Yes	No	-	-Decision coach (AC) was unavailable. Decision coach indicated she would contact and reschedule an appointment. Awaiting response.
March 28, 2012	No	-	-	-Decision coach (AC) unavailable.
March 29, 2012	Yes	No	-	-Family contacted by Diabetes Nurse Educator, but declined to participate.
April 5, 2012	Yes	No	-	-Pump assessment was rescheduled earlier to April 2, 2012- unknown to researcher. Diabetes Nurse Educator invited family to participate and

				they indicated they would think about it.
April 12, 2012	Yes	Yes	Yes	-**Included**
April 18, 2012	No	-	-	-Did not meet inclusion criteria due to age
April 25, 2012	Yes	Yes	Yes	-**Included**
May 2, 2012	Yes	Yes	Yes	-**Included**
May 9, 2012	Yes	No	-	-Declined to participate
May 16, 2012	Yes	Yes	No	-Decision coach (AC) unavailable.
May 23, 2012	Yes	Yes	No	-Decision coach (AC) unavailable.
May 30, 2012	No	-	-	-Language barrier
June 6, 2012	Yes	Yes	No	-Decision coach (AC) unavailable.
June 28, 2012	Yes	Yes	Yes	-**Included**
	No	-	-	-Did not meet inclusion criteria due to age