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TITLE:

PREVALENCE OF CLINICALLY SIGNIFICANT DECISIONAL CONFLICT: A POOLED ANALYSIS OF FIVE STUDIES ON DECISION MAKING IN PRIMARY CARE

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Conceived and designed the analysis plan: FL, ML, PTL, ST. Analyzed the data: FL, ML, PTL, ST. Wrote the paper: FL, PTL. Critically reviewed the manuscript for important intellectual content: FL, PTL, ML, ST. Read and approved the final version: FL, PTL, ML, ST. Guarantors: FL, PTL

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ABBREVIATIONS:

CI: Confidence intervals

CSDC: Clinically Significant Decisional Conflict

DCS: Decisional Conflict Scale

FPTU: Family Practice Teaching Unit

OR: Odds ratio

PBRN: Practice-based Research Network

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No additional data are available.

ABSTRACT (**297**/300 WORDS)

Objectives: Unresolved clinically significant decisional conflict (CSDC) in patients following a consultation with a health professional is often the result of inadequate patient involvement in decision making and may result in poor outcomes. We sought to identify the prevalence of CSDC in studies on decision making in primary care contexts and to explore its risk factors.

Setting: We performed a secondary analysis of existing datasets from studies conducted in Primary Care Practice-Based Research Networks in Quebec and Ontario, Canada.

Participants: Eligible studies included a patient-reported measure on the 16-item Decisional Conflict Scale (DCS) following a decision made with a healthcare professional with no study design restriction.

Primary and secondary outcome measures: CSDC was defined as a score ≥ 25/100 on the DCS. The prevalence of CSDC was stratified by sex; and patient-level logistic regression analysis was performed to explore its potential risk factors. Datasets of studies were analyzed individually and qualitatively compared.

Results: Five projects conducted between 2003 and 2010 were included. They covered a range of decisions: prenatal genetic screening, antibiotics for acute respiratory infections and miscellaneous. They included a total of 1338 primary care patients (69% female;

range of age: 15 to 83). The prevalence of CSDC in patients varied across studies and ranged from 10.3% (95% confidence interval: 7.2% – 13.4%) to 31.1% (95% confidence interval: 26.6% – 35.6%). Across the five studies, risk factors of CSDC included being male, living alone, and being 45 or older.

Conclusions: Prevalence of CSDC in patients who had enrolled in studies conducted in primary care contexts was substantial and appeared to vary according to the type of decision as well as to patient characteristics such as sex, living arrangement and age. Patients presenting risk factors of CSDC should be offered decision aids to increase their involvement in decision making.

Strengths and limitations of this study

- This study included data on 1338 patients from five studies conducted in primary care contexts in two Canadian provinces, Quebec and Ontario.
- To the best of our knowledge, this is the first account of the prevalence of CSDC as reported in studies conducted exclusively in primary care and with this many unique clinical encounters. None of the earlier studies measuring CSDC in a primary care clinical context focused on a decision dealt with entirely at the primary care level.
- Our results 1) contradict a common belief that primary care only deals with mundane types of decision that involve no risk, loss, regret, or challenges to personal life values, and that primary care decisions therefore involve little personal uncertainty; 2) report a higher prevalence of CSDC in men than in women in all four datasets that included men and women; 3) show that people reporting living alone experienced a consistently higher prevalence of CSDC than people reporting living with at least one other person; and 4) reveal that older patients showed a higher prevalence of CSDC in all relevant datasets.
- The fact that measuring CSDC was not the primary objective of any of the selected studies could affect interpretation of the results.
- A meta-analysis was not possible given the heterogeneity of the data sets (type of decision, study design, available variables).

INTRODUCTION

When facing health-related decisions and presented with multiple options, patients are subject to uncertainty about what to choose. This uncertainty is known as decisional conflict. Decisional conflict is an intra-personal psychological construct that is felt by individuals when facing decisions that involve risk, loss, regret, or challenges to personal life values. [1 2] In lay terms, decisional conflict reflects the level of comfort that an individual faces in making a decision. In some patients it may translate into clinically significant decisional conflict (CSDC), at which point decisional conflict is positively associated with decisional delay, departure from active treatment, decision regret, nervousness and a higher intention to sue physicians in cases of harms from treatment.[3 4] Thus it is essential to identify patients experiencing CSDC, as there are several modifiable deficits that lead to CSDC, including 1) inadequate knowledge of options; 2) unclear values regarding harms and benefits of options; and 3) inadequate support or resources for decision making. These may all be addressed with effective decision support.[5]

In primary care CSDC may be particularly relevant. Primary care is defined as the level of the healthcare system that provides individuals with: 1) a gateway into the system for all their needs and problems; 2) care focused on the individual and their context (not disease-oriented); 3) care for all but very uncommon or unusual conditions; 4) continuity of care; and 5) the coordination or integration of the care provided by other levels of the system or by other professionals.[6] Primary care is also a context in which the available evidence is often equivocal, goals are often ill-defined, and decision making is subject to structural, organizational and time pressures.[7-9] While lack of information, unclear values and insufficient support can make decision making

more difficult, these difficulties can be addressed successfully with effective decision support.[5] For example, patient decision aids have proven to be effective in resolving CSDC following the decision-making process.[10 11] Analyzing and comparing the outcomes of studies on decision making among primary care patients could thus have a beneficial impact on the quality of care for a large number of individuals. We sought to identify the prevalence of CSDC in studies conducted in primary care contexts and to explore its risk factors.

METHODS

Source of data and participants

We carried out a secondary analysis of existing datasets from studies conducted within or in collaboration with the Laval University Primary Care Practice-Based Research Network (PBRN) in the Province of Quebec, Canada. This network comprises twelve family practice teaching units affiliated with Laval University and collaborates with other research networks nationally and internationally.[12] We screened the Laval University PBRN for potentially eligible studies and considered all patient data gathered from five eligible studies. Studies were included if 1) they were set entirely in primary care (defined as the patient's point of entry into the healthcare system, most often consulting a family physician[13]); 2) they assessed patient-reported decisional conflict using the French or English version of the 16-item Decisional Conflict Scale (DCS)[14]; and 3) DCS scores were collected from patients following a clinical encounter with a primary care provider. There was no study design restriction. Studies were excluded if data had been gathered in a specialized clinic, if participants were recruited from the public (through newspaper

ads, for instance), or if data collected with individuals did not relate to a clinical encounter with a primary care provider. For experimental studies, only patients from control or baseline groups were considered for analysis.

Data collected

All data collected with patients enrolled in the included studies had been collected using self-administered paper-based questionnaires. From the baseline data (i.e. before-and-after or randomized controlled trial studies) we extracted the following characteristics of each study: year of data collection, study type, main objective of original study, clinical setting and types of decision(s) made by patients. For each study, we assessed patient characteristics such as sex, age (<45 years old, ≥45 years old), professional status (full or part-time employment, no employment, retired), education (no postsecondary education, some postsecondary education), annual household income (<CAD $60,000, ≥$60,000), household size (living alone, living with at least one other person), marital status (married, single, separated/divorced, widowed), and whether the patient had a private drug insurance plan (yes, no). We also assessed clinical characteristics: whether this was the first encounter with that particular primary care provider (yes, no), whether the patient was accompanied during the encounter (yes, no), whether the decision was for a child (yes, no), patient preference for involvement in decision making (passive, active[15 16]), average annual frequency of consultations with any doctor (≤3, >3), self-reported health status[17] (excellent/very good/good, or fair/poor), whether the patient received a drug prescription (yes, no).

Data analysis

First, we computed CSDC as defined by a score of ≥25/100 on the DCS,[3 4 14 18] at which point decisional conflict is positively associated with decisional delay, departure from active treatment, decision regret, nervousness and a higher intention to sue physicians in cases of harms from treatment. [3 4] This is the threshold most commonly used to distinguish a harmless from a harmful level of decisional conflict. [3 19 20] The DCS consists of 16 items, each of which is measured on a 5-point Likert scale (1 = strongly agree to 5 = strongly disagree, treated as a 0-4 score). The mean score of all items is multiplied by 25 to give a score out of 100. Higher scores indicate higher levels of decisional conflict.[21] The DCS shows good psychometric properties (test-retest reliability coefficient: 0.81, Cronbach's alpha range: 0.78 – 0.92) and its French translation has been validated.[22-25] Second, we conducted complete-subject analyses of the prevalence and risk factors of CSDC individually for each dataset at the patient level. After deletion of missing data and removal of participants in experimental groups, patient characteristics were similar to those of the original study populations. In studies where clusters of patients were recruited under the same clinician and/or within the same clinic, we assessed the impact of a potential cluster effect at each level of analysis (clinician and/or clinic). For each dataset, we computed overall prevalence of CSDC and prevalence for each category of available variables stratified by sex. Logistic regression (backwards selection) was used to explore the independent association between CSDC and potential risk factors, including interaction terms with each variable and sex. All significant variables at $\alpha \leq 0.10$ were kept in the final model. We defined statistical significance at $\alpha \leq 0.10$ because this was an exploratory study. If we found a non-negligible cluster effect, we used a generalized estimation equation (PROC GENMOD) with binary logit outcome. Otherwise, logistic regression was used. We calculated the receiver operating

characteristic to estimate the models' performance. All analyses were conducted with SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Description of included studies

We estimated the prevalence of CSDC in the context of five different studies conducted in primary care. Each of these studies was designed to address different issues, and each collected quite different data. However, each study group had independently identified the need to measure decisional conflict using the DCS.[24] The following is a short description of included studies.

The first study was a before-and-after trial conducted in Ontario to assess the impact of implementing the Ottawa Decision Support Framework (ODSF) on correspondences between patients' and physicians' decisional conflict scores. Implementation of the framework consisted of an interactive workshop, feedback, and a reminder at the point of care. Secondary objectives were to evaluate the barriers and facilitators to implementation of the ODSF in primary care practices and examine changes in physicians' intention to adopt the DSC. [26]

The second study evaluated decisional conflict in the context of prenatal screening for Down syndrome (GENETIC). This cross-sectional survey conducted with patients from Quebec assessed the willingness of women and their family physicians to engage in shared decision-

making about prenatal Down-syndrome screening and factors that might influence this willingness. [27]

The third study evaluated the impact of a training program for physicians (DECISION+)[28]. This pilot randomized controlled trial conducted in Quebec integrated multiple educational/behavioral change components that aimed to promote shared decision making about treatment options and specifically about the use of antibiotics for acute respiratory infections. [28]

The goal of the fourth study was to assess the psychometric properties of dyadic measures for shared decision making research. The study used a shared decision-making model (EXACKTE2) to explore how patients and clinicians influence one another. This cross-sectional study conducted in 17 primary care clinics in Ontario and Quebec explored the mutual influence between patients and physicians during consultations. [29]

The last study used data gathered during a pilot study [28] to establish the feasibility of conducting the DECISION+ training program on a larger scale. The program was improved and renamed DECISION+2 [30] before the definitive trial. This randomized controlled trial conducted in Quebec assessed the impact of DECISION+2 on antibiotics use for acute respiratory infections.

Table 1 presents the characteristics of the included studies and their related datasets alongside the available independent variables.[26-30] All datasets were from projects conducted between 2003 and 2010. Three were conducted in the province of Quebec, one was conducted in Ontario and one was conducted jointly by teams from Ontario and Quebec.[29] Of the five datasets available,

two were clustered randomized trials (DECISION+[28], DECISION+2[30]), two were cross-sectional surveys (GENETIC[27], EXACKTE2[29]) and one was a before-and-after trial (iODSF[26]). Decisions were about undergoing a prenatal Down syndrome genetic screening test (GENETIC[27]), taking antibiotics to treat acute respiratory infections (DECISION+[28], DECISION+2[30]) and various other primary care decisions (iODSF[26], EXACKTE2[29]). Altogether, data from 1,338 primary care patients were analyzed. Patients were aged between 15 and 83 years old and 69% were female.

Table 1: Characteristics of datasets

Characteristics	Dataset				
	iODSF [26]	GENETIC [27]	DECISION+ [28]	EXACKTE2 [29]	DECISION+2 [30]
Year of data collection	2003	2007	2007	2009	2010
Study type	Before and after trial	Cross-sectional survey	Cluster randomized trial	Cross-sectional survey	Cluster randomized trial
Main objective of study	To assess the impact of implementing the Ottawa Decision Support Framework on correspondences between patients' and physicians' decisional conflict scores.	To assess the willingness of women and their family physicians to engage in shared decision making about prenatal Down-syndrome screening and the factors that might influence this willingness.	To develop, adapt and validate a shared decision making training program and estimate its impact on the decision of family physicians and their patients about whether to use antibiotics for ARIs.	To assess the psychometric properties of dyadic measures for shared decision making research.	To evaluate the effect of a shared decision making training program on decisions of family physicians and their patients about whether to use antibiotics for ARIs.
Clinical setting	5 FPTUs in the Quebec City area	3 FPTUs in the Quebec City area	4 family medicine groups in the Quebec City area	17 primary care clinics in the Quebec City area and in Ontario	9 FPTUs in the province of Quebec
Type of decision	Various other primary care decisions	To do a prenatal test or not	To take antibiotics or not for treating ARIs	Various other primary care decisions	To take antibiotics or not for treating ARIs
Total participants (N)	370	130	225	198	415
Women; n (%)	234 (63)	130 (100)	154 (68)	131 (66)	277 (67)
Aged ≥ 45 years old; n(%)	209 (56)	0 (0)	60 (27)	117 (59)	164 (40)
Living by themselves; n(%)	119 (32)	1 (1)	39 (17)	42 (21)	74 (18)
Professional status; n(%)					
- Employed full- or part-time	185 (50)	105 (81)	176 (78)	109 (55)	318 (77)
- Unemployed	69 (19)	25 (19)	36 (16)	30 (15)	65 (16)
- Retired	116 (31)	0 (0)	13 (6)	59 (30)	32 (8)
Household income ≥ $ 60,000; n (%)	97 (26)	62 (48)	87 (39)	24 (12)	194 (47)
Available variables	Age, sex, employment status, education, annual income, household size, first encounter with that doctor	Age, sex, employment status, education, annual income, household size	Age, sex, employment status, education, annual income, household size, first encounter with that doctor, patient preference for involvement in decision making, self-reported health status, whether making a decision for a child, whether patient receives a prescription, whether patient has a private drug insurance plan	Age, sex, employment status, education, annual income, household size, marital status, average annual frequency of physician visits, first encounter with that doctor, patient is alone or accompanied	Age, sex, employment status, education, annual income, household size, first encounter with that doctor, patient preference for involvement in decision making, self-reported health status, whether making a decision for a child, whether patient receives a prescription, whether patient has a private drug insurance plan

FPTU: Family practice teaching unit; ARIs: Acute respiratory infections

Prevalence of clinically significant decisional conflict

Table 2 shows the prevalence of CSDC across all five datasets stratified by sex for available variables, since sex was found to be a modifying factor for at least one variable in four datasets. Prevalence ranged between 10.3% (iODSF[26]) (95% confidence intervals [CI]: 7.2 – 13.4) and 31.1% (DECISION+2[30]) (95%CI: 26.6 – 35.6). CSDC was consistently more prevalent in males (4/4 studies), people aged 45 or older (4/4 studies), people living alone (4/5 studies), retirees (4/4 studies), people preferring active participation in decision making (2/2 studies), people reporting poor health status (2/2 studies), people making the decision for themselves as opposed to for their children (2/2 studies), and people who did not have a private drug insurance plan (2/2 studies).

Table 2: Prevalence* of clinically significant decisional conflict according to datasets and sex

	iODSF [26]			GENETIC [27]	DECISION+ [28]			EXACKTE2 [29]			DECISION+2 [30]		
	F	**M**	**All**	**All†**	**F**	**M**	**All**	**F**	**M**	**All**	**F**	**M**	**All**
Total participants (N)	234	136	370	130	154	71	225	131	67	198	277	138	415
Overall prevalence (95% confidence interval)	7.7 (4.3; 11.1)	14.7 (8.7; 20.7)	10.3 (7.2; 13.4)	16.9 (10.4; 23.5)	17.5 (11.5; 23.6)	31.0 (20.0; 42.0)	21.8 (16.3; 27.2)	15.3 (9.0; 21.5)	28.4 (17.3; 39.4)	19.7 (14.1; 25.3)	28.5 (23.2; 33.9)	36.2 (28.1; 44.4)	31.1 (26.6; 35.6)
Sociodemographic characteristics													
Age													
< 45 years old	6.1	13.0	8.1	16.9	11.5	27.0	16.4	10.9	17.7	12.4	26.0	29.2	26.9
≥ 45 years old	9.2	15.6	12.0	N/A	34.2	42.1	36.7	19.4	32.0	24.8	36.2	50.0	41.5
Professional status													
Full- or part-time employment	9.3	14.9	11.4	18.1	17.7	28.1	21.0	10.8	25.7	15.6	27.6	37.0	30.8
No employment	6.0	0.0	4.4	12.0	11.5	50.0	22.2	18.2	25.0	20.0	29.8	27.8	29.2
Retired	6.1	20.0	12.1	N/A	33.3	25.0	30.8	22.9	33.3	27.1	35.0	41.7	37.5
Education													
No postsecondary education	5.9	14.4	9.1	9.8	16.0	34.7	23.4	26.0	21.4	24.4	26.3	33.3	28.9
At least some postsecondary education	11.1	15.2	12.6	21.5	19.0	22.7	19.8	8.7	33.3	16.7	29.4	37.8	32.1
Annual household income													
< $60,000	5.1	13.3	8.1	17.7	14.1	41.3	23.2	15.0	24.1	17.8	32.3	30.3	31.7
≥ $60,000	15.3	18.4	16.5	16.1	22.6	12.0	19.5	18.2	46.1	33.3	23.8	41.7	30.4
Household size													
Living alone	9.2	23.3	14.3	0.0	31.8	47.1	38.5	25.0	36.4	31.0	42.9	40.0	41.9
Living with ≥ 1 other person	7.0	10.8	8.4	17.1	15.2	25.9	18.3	13.5	24.4	16.7	25.4	35.4	28.7
Marital status													
Married								9.3	25.0	13.9			
Single								25.0	27.8	26.2			
Separated /divorced								33.3	44.4	38.1			
Widowed								22.2	25.0	23.1			
Private drug insurance plan													
Yes					17.5	26.0	20.1				26.3	35.6	29.4
No					17.5	42.9	26.2				34.2	37.8	35.3

F = Female; M = Male; N/A = Not applicable; * Prevalence of Clinically Significant Decisional Conflict was defined as a score ≥ 25/100 on the Decisional Conflict Scale [14] ; †In the GENETIC study, all participants were female.

Table 2: Prevalence* of clinically significant decisional conflict according to datasets and sex (continuation)

Clinical characteristics	iODSF [26]			GENETIC [27]	DECISION+ [28]			EXACKTE2 [29]			DECISION+2 [30]		
	F	M	All	All†	F	M	All	F	M	All	F	M	All
First encounter with that particular doctor													
Yes	8.5	18.6	12.8		12.5	31.8	17.4	17.8	36.4	23.5	32.6	25.9	30.1
No	7.4	12.9	9.3		21.1	31.6	24.5	15.7	24.4	18.4	27.7	38.7	31.3
Patient accompanied during encounter													
Yes								11.1	33.3	18.5			
No								15.9	27.6	19.9			
Decision for a child													
Yes					10.0	31.2	15.2				22.9	30.0	25.0
No					21.2	30.9	24.5				30.4	38.0	33.0
Patient preference for involvement													
Passive					15.2	30.4	20.3				27.8	26.7	27.3
Active					21.0	32.0	24.1				28.6	37.4	31.4
Average annual frequency of physician visits													
≤ 3 average physician visits per year								9.9	39.4	19.2			
> 3 average physician visits per year								21.7	17.7	20.2			
Self-reported health status													
Excellent, very good, good					16.7	27.4	19.9				27.5	32.8	29.2
Fair, poor					30.0	55.6	42.1				40.9	69.2	51.4
Patient received a prescription													
Yes					16.4	32.8	21.7				29.5	34.6	31.1
No					23.1	20.0	22.2				24.5	42.9	30.9

F = Female; M = Male; N/A: Not applicable; * Prevalence of Clinically Significant Decisional Conflict was defined as a score ≥ 25/100 on the Decisional Conflict Scale [14] ; †In GENETIC study, all participants were female.

Risk factors of clinically significant decisional conflict

The impact of cluster effect at the clinician level was found to be negligible in all datasets. However, we found a cluster effect at the clinic level in three projects (iODSF[26], DECISION+[28], DECISION+2[30]). Table 3 presents the multivariable regression analysis of the association between CSDC and its potential independent risk factors. Sex was found to be a modifying factor for at least one variable in all datasets (except GENETIC[27], as all participants were women) and an independent risk factor in one (EXACKTE2[29]). Living alone was positively associated with CSDC in three out of four datasets (iODSF[26], DECISION+[28], DECISION+2[30]). Being aged 45 or older was also positively associated with CDSC in three out of four datasets (DECISION+[28], EXACKTE2[29], DECISION+2[30]) and there was a significant interaction with sex in one dataset (iODSF[26]). An annual income above or equal to CAD $60,000 was positively associated with CSDC in two of the five datasets (iODSF[26], EXACKTE2[29]) and we observed an interaction term with sex in one dataset (DECISION+[28]). Other study variables were not significantly associated with CSDC in more than one study.

Table 3: Association between clinically significant decisional conflict and potential risk factors according to dataset

Potential risk factors	Dataset									
	iODSF [26]		GENETIC [27]		DECISION+ [28]		EXACKTE2 [29]		DECISION+2 [30]	
	β ± SE	*p-value*	β ± SE	*p-value*	β ± SE	*p-value*	β ± SE	*p-value*	β ± SE	*p-value*
Sex (being male)	-0.54 ± 0.58	0.36	n = 0		-0.35 ± 0.56	0.54	1.45 ± 0.56	**0.01**	0.39 ± 0.25	0.11
Postsecondary education	-		0.93 ± 0.54	0.08	-		-0.79 ± 0.43	0.07	-	
Age (≥45)	0.66 ± 0.57	0.25	n = 0		1.02 ± 0.24	**< 0.0001**	0.57 ± 0.45	0.09	0.61 ± 0.18	**< 0.001**
Age (≥45) x sex	1.40 ± 0.39	**< 0.001**	N/A		-		-		-	
Living alone	1.01 ± 0.23	**< 0.0001**	n = 1		0.81 ± 0.25	**< 0.01**	-		0.40 ± 0.17	0.02
Making the decision for a child (vs. for self)	N/A		N/A		-0.73 ± 0.39	0.06	N/A		-	
Making the decision for a child (vs. for self) x sex	N/A		N/A		1.20 ± 0.19	**< 0.0001**	N/A		-	
Having received a prescription	N/A		N/A		-0.66 ± 0.25	**< 0.01**	N/A		-	
Having received a prescription x sex	N/A		N/A		1.93 ± 0.10	**< 0.0001**	N/A		-	
Annual family income ≥ $60K	1.16 ± 0.13	**< 0.0001**	-		1.19 ± 0.24	**< 0.0001**	1.11 ± 0.56	**0.05**	-	
Annual family income ≥ $60K x sex	-		N/A		-2.54 ± 0.69	**< 0.001**	-		-	
Being unemployed	-0.89 ± 0.31	**< 0.01**	-		-		-		0.15 ± 0.42	0.71
Being unemployed x sex	-		N/A		-		-		-0.98 ± 0.22	**< 0.0001**
Retirement	-0.86 ± 0.44	**0.05**	n = 0		-		-		-0.34 ± 0.49	0.49
Being retired x sex	1.83 ± 0.69	**< 0.01**	N/A		-		-		0.16 ± 0.76	0.83
Being single (vs. being married)	N/A		N/A		N/A		1.16 ± 0.54	**0.03**	N/A	
Being separated or divorced (vs. being married)	N/A		N/A		N/A		0.22 ± 0.74	0.76	N/A	
Self-reported health status "Excellent", "Very good" or "good"	N/A		N/A		-		N/A		-0.95 ± 0.28	**< 0.001**
Consulting a physician > 3 times a year	N/A		N/A		N/A		0.39 ±0.55	0.48	N/A	
Consulting a physician > 3 times a year x sex	N/A		N/A		N/A		-1.92 ±0.81	**0.02**	N/A	
ROC	**0.73**		**0.60**		**0.76**		**0.75**		**0.62**	

β = Regression coefficient; SE = Standard error; N/A = Not available; ROC = Receiver operating characteristic

DISCUSSION

Using data on 1338 patients from five studies conducted in primary care contexts in two Canadian provinces, Quebec and Ontario, we observed that the prevalence of CSDC in patients, defined as a score of ≥25/100 on the DCS, was substantial and varied across studies ranging from 10% to 31%. Populations at risk of CSDC included males, people living alone and people aged 45 years or older. To the best of our knowledge, this is the first account of the prevalence of CSDC as reported in studies conducted exclusively in primary care and with this many unique clinical encounters. None of the earlier studies measuring CSDC in a primary care clinical context focused on a decision dealt with entirely at the primary care level. [31-34] Our results lead us to make four main observations.

First, our results contradict a common belief that primary care only deals with mundane types of decision that involve no risk, loss, regret, or challenges to personal life values, and that primary care decisions therefore involve no personal uncertainty. Clearly, this is not how patients enrolled in these five studies saw it. Given the harmful downstream effects of unresolved CSDC, our results suggest that a significant number of primary care patients would benefit greatly from patient decision aids,[11] decision coaching[35] or from their healthcare providers being trained in shared decision making. These clinical approaches are known to be effective in resolving CSDC.[36]

Second, we observed a higher prevalence of CSDC in men than in women in all four datasets that included men and women. Moreover, sex was found to be an independent risk factor in one

dataset and significantly interacted with at least one variable in all datasets. This may be explained by the fact that more women than men consult primary care providers over their lifetime.[37] Women tend to consult healthcare providers more frequently due to their gynecological and obstetrical needs and also because they are often involved in health-related decision making for other family members.[37 38] Furthermore, physicians are known to discuss therapeutic and preventive interventions more often with women than with men.[39] Together, more visits to physicians and more discussion with them may contribute to a higher sense of self-efficacy among women about engaging in decision making.[40] This in turn could reduce CSDC in women.[40] As in earlier studies on the impact of sex on outcomes, our results highlight a significant effect of sex on CSDC and suggest that primary care providers should tailor their decision-making approach to the patient's sex.[41]

Third, people reporting living alone showed a consistently higher prevalence of CSDC than people reporting living with at least one other person. This is congruent with the theory underlying the DCS.[24] The higher prevalence of CSDC in people reporting living alone could be due to a lack of social support when they face health-related decisions, one of the key contributors to CDSC.[5] During the clinical encounter, primary care providers should explore the patient's social support systems, i.e. whether he/she can 1) check other people's opinions, 2) focus on those whose opinions matter most (physician, family, and friends) and 3) handle diverse sources of pressure.[42] Such support-clarification exercises help patients understand other perspectives and gather opinions about what other people would do if they were in the same situation. Our results suggest that lack of support for people living alone may aggravate CSDC in primary care patients. Although the contribution of family members is increasingly recognized as

an important source of social support for patients facing health decisions,[43] the literature has still not adequately addressed its full impact on decision making.[44] Primary care providers should pay closer attention to their patients living alone in their efforts to detect CSDC during the decision making process.

Lastly, patients aged 45 or older showed a higher prevalence of CSDC in all relevant datasets. As older adults tend to seek less information when making a decision, defer the decision more often, and are generally more risk avoidant than young adults, they may be more at risk of CSDC.[45] In addition, an enduring myth is that older and more vulnerable patients are less interested in participating in decision making with their healthcare providers than are less vulnerable patients.[46] Any and all of these reasons may contribute to the higher prevalence of CSDC observed in populations aged 45 years or older and should inform clinicians and researchers of the urgent need to foster the participation of older patients in decision making with the appropriate strategies.

Our study has some limitations. First, measuring CSDC was not the primary objective of any of the selected studies. Also, potentially relevant variables such as marital status or self-reported health status were missing in some datasets, and therefore we could not draw conclusions relating to these variables. Furthermore, a meta-analysis was not possible given the heterogeneity of the data sets (type of decision, study design, available variables). Nevertheless, the similar nature of the questionnaires in each study enabled us to compare associations in datasets independently from one another and thus assure external validity of the results.[47] Finally, we acknowledge that we cannot infer that our results are generalizable to the wider population as we

drew upon secondary analysis of existing datasets of studies conducted in specific primary care clinical contexts in two provinces in Canada. Further studies with appropriate survey methods and sampling frames could depict a more accurate portrait of CSDC in other primary care clinical contexts.

CONCLUSION

We observed that the prevalence of CSDC in studies on decision making conducted in primary care contexts in two Canadian provinces, Quebec and Ontario, ranged from 10% to 31%. This prevalence varied depending on the type of decision and was higher in males, in people living alone, and in people aged 45 or older. Although we cannot generalize our results to the wider population, they should alert primary care providers to patients who may be at higher risk of CSDC. Training health professionals to identify CDSC in patients and ensuring that effective decision support interventions such as patient decision aids are implemented at the point of care should be encouraged to resolve CDSC.[11 48]

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PRISMA Checklist

Prevalence of clinically significant decisional conflict: a pooled analysis of five studies on decision making in primary care

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Criteria		Page	Brief description of how the criteria were handled in the manuscript
TITLE			
1	Identify the report as a systematic review, meta-analysis, or both.	p. 1	"Prevalence of clinically significant decisional conflict: a pooled analysis of five studies on decision making in primary care".
ABSTRACT			
2	Provide a structured summary including, as applicable: Background (research question and main objectives); Methods (data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods); Results (number and type of studies and participants, main outcomes with CI); Discussion (strengths and	pp. 4-5	**"Objectives:** Unresolved clinically significant decisional conflict (CSDC) in patients following a consultation with a health professional is often the result of inadequate patient involvement in decision making and may result in poor outcomes. We sought to identify the prevalence of CSDC in studies on decision making in primary care contexts and to explore its risk factors. **Setting:** We performed a secondary analysis of existing datasets from studies conducted in Primary Care Practice-Based Research

	limitations of the evidence, general interpretation and important implications) Other (report primary funding source, registration number)		Networks in Quebec and Ontario, Canada. **Participants:** Eligible studies included a patient-reported measure on the 16-item Decisional Conflict Scale (DCS) following a decision made with a healthcare professional with no study design restriction. **Primary and secondary outcome measures:** CSDC was defined as a score ≥ 25/100 on the DCS. The prevalence of CSDC was stratified by sex; and patient-level logistic regression analysis was performed to explore its potential risk factors. Datasets of studies were analyzed individually and qualitatively compared. **Results:** Five projects conducted between 2003 and 2010 were included. They covered a range of decisions: prenatal genetic screening, antibiotics for acute respiratory infections and miscellaneous. They included a total of 1338 primary care patients (69% female; range of age: 15 to 83). The prevalence of CSDC in patients varied across studies and ranged from 10.3% (95% confidence interval: 7.2% – 13.4%) to 31.1% (95% confidence interval: 26.6% – 35.6%). Across the five studies, risk factors of CSDC included being male, living alone, and being 45 or older. **Conclusions:** Prevalence of CSDC in patients who had enrolled in studies conducted in primary care contexts was substantial and appeared to vary according to the type of decision as well as to patient characteristics such as sex, living arrangement and age. Patients presenting risk factors of CSDC should be offered decision aids to increase their involvement in decision making.”
INTRODUCTION			
3	*Rationale*: describe the rationale for the review in the context of what is already known.	p. 7	“When facing health-related decisions and presented with multiple options, patients are subject to uncertainty about what to choose. This uncertainty is known as decisional conflict. Decisional conflict is an intra-

			personal psychological construct that is felt by individuals when facing decisions that involve risk, loss, regret, or challenges to personal life values. 1 2 In lay terms, decisional conflict reflects the level of comfort that an individual faces in making a decision. In some patients it may translate into clinically significant decisional conflict (CSDC), at which point decisional conflict is positively associated with decisional delay, departure from active treatment, decision regret, nervousness and a higher intention to sue physicians in cases of harms from treatment.3 4 Thus it is essential to identify patients experiencing CSDC, as there are several modifiable deficits that lead to CSDC, including 1) inadequate knowledge of options; 2) unclear values regarding harms and benefits of options; and 3) inadequate support or resources for decision making. These may all be addressed with effective decision support."
4	*Objectives*: provide an explicit statement of questions being addressed with reference to participants, intervention, comparisons, outcomes, and study design (PICOS)	p. 8	"Analyzing (S) and comparing (C) the outcomes (O) of decision-making studies (I) among primary care patients (P) could thus have a beneficial impact on the quality of care for a large number of individuals. We sought to identify the prevalence of CSDC in studies conducted in primary care contexts and to explore its risk factors (*Objective)*."
METHODS			Data extracted from each of the studies were relevant to the population characteristics, study design, exposure, outcome, and possible effect modifiers of the association.
5	*Protocol and registration*	N/A	There was no registered protocol, but the first author performed a protocol for this study in his masters degree.
6	*Eligibility criteria* (studies characteristics, the rationale for criteria should be stated)	pp. 8-9	"Studies were included if 1) they were set entirely in primary care (defined as the patient's point of entry into the healthcare system, most often consulting a family physician13); 2) they assessed patient-reported decisional conflict using the French or English version of the 16-item Decisional Conflict Scale (DCS)14; and 3) DCS scores were collected from patients following a clinical encounter with a primary care

			provider. There was no study design restriction. Studies were excluded if data had been gathered in a specialized clinic, if participants were recruited from the public (through newspaper ads, for instance), or if data collected with individuals did not relate to a clinical encounter with a primary care provider. For experimental studies, only patients from control or baseline groups were considered for analysis."
7	*Information sources* (details of hand searching with dates)	p. 8	"We carried out a secondary analysis of existing datasets from studies conducted within or in collaboration with the Laval University Primary Care Practice-Based Research Network (PBRN) in the Province of Quebec, Canada. This network comprises twelve family practice teaching units affiliated with Laval University and collaborates with other research networks nationally and internationally."
8	*Search* (present the full electronic search strategy for at least one database)	N/A	Not applicable.
9	*Study selection:* State the process for determining which studies were eligible for inclusion (screening)	p. 8	"Studies were included if 1) they were set entirely in primary care (defined as the patient's point of entry into the healthcare system, most often consulting a family physician13); 2) they assessed patient-reported decisional conflict using the French or English version of the 16-item Decisional Conflict Scale (DCS)14; and 3) DCS scores were collected from patients following a clinical encounter with a primary care provider. There was no study design restriction."
10	*Data collection process* (extraction data independently in duplicate and any process for confirming these data with investigators)	p. 9	"From the baseline data (i.e. before-and-after or randomized controlled trial studies) we extracted the following characteristics of each study: year of data collection, study type, main objective of original study, clinical setting and types of decision(s) made by patients."
11	*Data items*: describe how the information and variables to be collected were chosen. List and define all study level and	p. 9	"All data collected with patients enrolled in the included studies had been collected using self-administered paper-based questionnaires. From the baseline data (i.e. before-and-after or

	participant level, including baseline and follow-up information. If applicable, describe methods of standardizing or translating variables within the datasets to ensure common scales or measurement across studies (list and define all variables for which data were sought)		randomized controlled trial studies) we extracted the following characteristics of each study: year of data collection, study type, main objective of original study, clinical setting and types of decision(s) made by patients. For each study, we assessed patient characteristics such as sex, age (<45 years old, ≥45 years old), professional status (full or part-time employment, no employment, retired), education (no postsecondary education, some postsecondary education), annual household income (<CAD $60,000, ≥$60,000), household size (living alone, living with at least one other person), marital status (married, single, separated/divorced, widowed), and whether the patient had a private drug insurance plan (yes, no). We also assessed clinical characteristics: whether this was the first encounter with that particular primary care provider (yes, no), whether the patient was accompanied during the encounter (yes, no), whether the decision was for a child (yes, no), patient preference for involvement in decision making (passive, active[15 16]), average annual frequency of consultations with any doctor (≤3, >3), self-reported health status[17] (excellent/very good/good, or fair/poor), whether the patient received a drug prescription (yes, no).”
12	*Risk of bias in individual studies*: Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), report if and how this information is to be used in any data synthesis.	N/A	Not applicable.
13	*Summary measures*: State all outcomes addressed and define them in detail, and whether they were primary or secondary outcomes. Give the principal measures of effect (e.g., risk ratio, difference in means) used for each outcome.	p. 10	“First, we computed CSDC as defined by a score of ≥25/100 on the DCS,[3 4 14 18] at which point decisional conflict is positively associated with decisional delay, departure from active treatment, decision regret, nervousness and a higher intention to sue physicians in cases of harms from treatment. [3 4] This is the threshold most commonly

			used to distinguish a harmless from a harmful level of decisional conflict. [3 19 20] The DCS consists of 16 items, each of which is measured on a 5-point Likert scale (1 = strongly agree to 5 = strongly disagree, treated as a 0-4 score). The mean score of all items is multiplied by 25 to give a score out of 100. Higher scores indicate higher levels of decisional conflict.[21] The DCS shows good psychometric properties (test-retest reliability coefficient: 0.81, Cronbach's alpha range: 0.78 – 0.92) and its French translation has been validated.[22-25]"
14	*Synthesis of results*: Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis. How effect estimates were generated separately within each study and combined across studies (where applicable). How missing data within studies were deal. Estimation of interactions. Potential effect modifiers.	p. 10	"Second, we conducted complete-subject analyses of the prevalence and risk factors of CSDC individually for each dataset at the patient level. After deletion of missing data and removal of participants in experimental groups, patient characteristics were similar to those of the original study populations. In studies where clusters of patients were recruited under the same clinician and/or within the same clinic, we assessed the impact of a potential cluster effect at each level of analysis (clinician and/or clinic). For each dataset, we computed overall prevalence of CSDC and prevalence for each category of available variables stratified by sex. Logistic regression (backwards selection) was used to explore the independent association between CSDC and potential risk factors, including interaction terms with each variable and sex. All significant variables at $\alpha \leq 0.10$ were kept in the final model. We defined statistical significance at $\alpha \leq 0.10$ because this was an exploratory study. If we found a non-negligible cluster effect, we used a generalized estimation equation (PROC GENMOD) with binary logit outcome. Otherwise, logistic regression was used. We calculated the receiver operating characteristic to estimate the models' performance. All analyses were conducted with SAS 9.3 (SAS Institute Inc., Cary, NC, USA)."
15	*Risk of bias across studies*: Specify any assessment of risk	N/A	Not applicable

	of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).		
16	*Additional analyses*: Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	p. 10	All methods have been described in point 13 and 14.
RESULTS			
17	*Study selection*: Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram	pp. 11-12	We included a before-and-after study, two cross-sectional studies, and two randomized studies.
18	*Study characteristics:* For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	pp12-13	"Table 1 presents the characteristics of the included studies and their related datasets alongside the available independent variables.[26-30] All datasets were from projects conducted between 2003 and 2010. Three were conducted in the province of Quebec, one was conducted in Ontario and one was conducted jointly by teams from Ontario and Quebec.[29] Of the five datasets available, two were clustered randomized trials (DECISION+[28], DECISION+2[30]), two were cross-sectional surveys (GENETIC[27], EXACKTE2[29]) and one was a before-and-after trial (iODSF[26]). Decisions were about undergoing a prenatal Down syndrome genetic screening test (GENETIC[27]), taking antibiotics to treat acute respiratory infections (DECISION+[28], DECISION+2[30]) and various other primary care decisions (iODSF[26], EXACKTE2[29]). Altogether, data from 1,338 primary care patients were analyzed. Patients were aged between 15 and 83 years old and 69% were female."
19	*Risk of bias within studies:* Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A	Not applicable.

20	*Results of individual studies:* For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	pp. 16-17	95% confidence intervals are presented with all individual estimates in Table 2: "Table 2 shows the prevalence of CSDC across all five datasets stratified by sex for available variables, since sex was found to be a modifying factor for at least one variable in four datasets. Prevalence ranged between 10.3% (iODSF[26]) (95% confidence intervals [CI]: 7.2 – 13.4) and 31.1% (DECISION+2[30]) (95%CI: 26.6 – 35.6). CSDC was consistently more prevalent in males (4/4 studies), people aged 45 or older (4/4 studies), people living alone (4/5 studies), retirees (4/4 studies), people preferring active participation in decision making (2/2 studies), people reporting poor health status (2/2 studies), people making the decision for themselves as opposed to for their children (2/2 studies), and people who did not have a private drug insurance plan (2/2 studies)."
21	*Synthesis of results:* Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A	Not applicable.
22	*Risk of bias across studies:* Present results of any assessment of risk of bias across studies (see Item 15).	N/A	Not applicable.
23	*Additional analysis:* Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	p. 19	Table 3 present results of association testing with p-values for each dataset: "The impact of cluster effect at the clinician level was found to be negligible in all datasets. However, we found a cluster effect at the clinic level in three projects (iODSF[26], DECISION+[28], DECISION+2[30]). Table 3 presents the multivariable regression analysis of the association between CSDC and its potential independent risk factors. Sex was found to be a modifying factor for at least one variable in all datasets (except GENETIC[27], as all participants were women) and an independent risk factor in one (EXACKTE2[29]). Living alone was positively associated with CSDC in three out of four datasets (iODSF[26],

			DECISION+[28], DECISION+2[30]). Being aged 45 or older was also positively associated with CDSC in three out of four datasets (DECISION+[28], EXACKTE2[29], DECISION+2[30]) and there was a significant interaction with sex in one dataset (iODSF[26]). An annual income above or equal to CAD $60,000 was positively associated with CSDC in two of the five datasets (iODSF[26], EXACKTE2[29]) and we observed an interaction term with sex in one dataset (DECISION+[28]). Other study variables were not significantly associated with CSDC in more than one study."
DISCUSSION			
24	*Summary of evidence*: Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	p. 20	"Using data on 1338 patients from five studies conducted in primary care contexts in two Canadian provinces, Quebec and Ontario, we observed that the prevalence of CSDC in patients, defined as a score of ≥25/100 on the DCS, was substantial and varied across studies ranging from 10% to 31%. Populations at risk of CSDC included males, people living alone and people aged 45 years or older. … Given the harmful downstream effects of unresolved CSDC, our results suggest that a significant number of primary care patients would benefit greatly from patient decision aids,[11] decision coaching[35] or from their healthcare providers being trained in shared decision making. These clinical approaches are known to be effective in resolving CSDC.[36]" We discussed the more consistent risk factors of CSDC one by one.
25	*Strengths and Limitations:* Discuss strengths and limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	p. 22	"Measuring CSDC was not the primary objective of any of the selected studies. Also, potentially relevant variables such as marital status or self-reported health status were missing in some datasets, and therefore we could not draw conclusions relating to these variables. Furthermore, a meta-analysis was not possible given the heterogeneity of the data sets (type of decision, study design, available variables). Nevertheless, the similar nature of the questionnaires in each study

			enabled us to compare associations in datasets independently from one another and thus assure external validity of the results.[47] Finally, we acknowledge that we cannot infer that our results are generalizable to the wider population as we drew upon secondary analysis of existing datasets of studies conducted in specific primary care clinical contexts in two provinces in Canada. Further studies with appropriate survey methods and sampling frames could depict a more accurate portrait of CSDC in other primary care clinical contexts."
26	*Conclusions*: Provide a general interpretation of the results in the context of other evidence, and implications for future research.	p. 23	"We observed that the prevalence of CSDC in studies on decision making conducted in primary care contexts in two Canadian provinces, Quebec and Ontario, ranged from 10% to 31%. This prevalence varied depending on the type of decision and was higher in males, in people living alone, and in people aged 45 or older. Although we cannot generalize our results to the wider population, they should alert primary care providers to patients who may be at higher risk of CSDC. Training health professionals to identify CDSC in patients and ensuring that effective decision support interventions such as patient decision aids are implemented at the point of care should be encouraged to resolve CDSC.[11 48]."
FUNDING			
27	*Funding*: Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	p. 2	"FL is Tier-2 Canada Research Chair in Implementation of Shared Decision Making in Primary Care."

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PREVALENCE OF CLINICALLY SIGNIFICANT DECISIONAL CONFLICT: AN ANALYSIS OF FIVE STUDIES ON DECISION MAKING IN PRIMARY CARE

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PREVALENCE OF CLINICALLY SIGNIFICANT DECISIONAL CONFLICT: AN ANALYSIS OF FIVE STUDIES ON DECISION MAKING IN PRIMARY CARE

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ABBREVIATIONS:

CI: Confidence intervals

CSDC: Clinically Significant Decisional Conflict

DCS: Decisional Conflict Scale

FPTU: Family Practice Teaching Unit

OR: Odds ratio

PBRN: Practice-based Research Network

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ABSTRACT (**300**/300 WORDS)

Objectives: Unresolved clinically significant decisional conflict (CSDC) in patients following a consultation with health professionals is often the result of inadequate patient involvement in decision-making and may result in poor outcomes. We sought to identify the prevalence of CSDC in studies on decision-making in primary care and to explore its risk factors.

Setting: We performed a secondary analysis of existing datasets from studies conducted in Primary Care Practice-Based Research Networks in Quebec and Ontario, Canada.

Participants: Eligible studies included a patient-reported measure on the 16-item Decisional Conflict Scale (DCS) following a decision made with a healthcare professional with no study design restriction.

Primary and secondary outcome measures: CSDC was defined as a score ≥ 25/100 on the DCS. The prevalence of CSDC was stratified by sex; and patient-level logistic regression analysis was performed to explore its potential risk factors. Datasets of studies were analyzed individually and qualitatively compared.

Results: Five projects conducted between 2003 and 2010 were included. They covered a range of decisions: prenatal genetic screening, antibiotics for acute respiratory infections and miscellaneous. Altogether, the five projects gathered data from encounters with a

total of 1,338 primary care patients (69% female; range of age: 15 to 83). The prevalence of CSDC in patients varied across studies and ranged from 10.3% (95% confidence interval: 7.2% – 13.4%) to 31.1% (95% confidence interval: 26.6% – 35.6%). Across the five studies, risk factors of CSDC included being male, living alone, and being 45 or older.

Conclusions: Prevalence of CSDC in patients who had enrolled in studies conducted in primary care contexts was substantial and appeared to vary according to the type of decision as well as to patient characteristics such as sex, living arrangement and age. Patients presenting risk factors of CSDC should be offered tools to increase their involvement in decision-making.

Strengths and limitations of this study

- This study included data on 1,338 patients from five studies conducted in primary care contexts in two Canadian provinces, Quebec and Ontario.
- To the best of our knowledge, this is the first account of the prevalence of CSDC as reported in studies conducted exclusively in primary care and with this many unique clinical encounters when combined.
- Our results contradict a common belief that primary care deals only with decisions involving no perception of risk, loss, or regret; our study also reports a higher prevalence of CSDC in men than women, in people living alone, and in older patients.
- The fact that measuring CSDC was not the primary objective of any of the selected studies could affect observed results.
- A meta-analysis was not possible given the heterogeneity of the data sets (type of decision, study design, available variables) and thus the difficulty associated with its interpretation.

INTRODUCTION

When facing health-related decisions and presented with multiple options, patients are subject to uncertainty about what to choose. This uncertainty is known as decisional conflict. Decisional conflict is an intra-personal psychological construct that is felt by individuals when facing decisions that involve risk, loss, regret, or challenges to personal life values.[1 2] In lay terms, decisional conflict reflects the level of comfort that an individual faces in making a decision. In some patients it may translate into clinically significant decisional conflict (CSDC), at which point decisional conflict is positively associated with decisional delay, departure from active treatment, decision regret, nervousness and a higher intention to sue physicians in cases of harms from treatment.[3 4] Thus it is essential to identify patients experiencing CSDC, as there are several modifiable deficits that lead to CSDC, including 1) inadequate knowledge of options; 2) unclear values regarding harms and benefits of options; and 3) inadequate support or resources for decision making. These may all be addressed with effective decision support.[5] In primary care, the gateway to the healthcare system, decisional conflict is particularly relevant. The majority of healthcare problems are treated in primary care, providing care focused on the individual and his or her context for all but very uncommon or unusual conditions. Primary care physicians provide continuity of care and coordinate or integrate the care provided by other levels of the system or by other professionals.[6] A greater emphasis on primary care is expected to lower the costs of care, improve health and reduce inequalities in the sphere of population's health. However, primary care is also the context in which costly and harmful overuse of treatment or screening options is most prevalent, and therefore an area where decision-making requires urgent improvement. It is also a context in which the available evidence is often equivocal, goals are

often ill-defined, and decision-making is subject to structural, organizational and time pressures.[7-9] These difficulties can be addressed successfully with effective decision support.[5] For example, patient decision aids have proven to be effective in reducing overuse of inappropriate treatments[10], and in resolving CSDC following the decision-making process.[11 12] Analyzing and comparing the outcomes of studies measuring decisional conflict among primary care patients could thus have a widespread impact on implementations to support optimal healthcare decisions and lead to improvement in quality of care for a large number of individuals. We therefore explored the magnitude of this phenomenon by determining the prevalence of CSDC in studies conducted in primary care contexts and their risk factors.

METHODS

Source of data and participants

We carried out a secondary analysis of existing datasets from studies conducted within or in collaboration with the Laval University Primary Care Practice-Based Research Network (PBRN) in the Province of Quebec, Canada. This network comprises twelve family practice teaching units affiliated with Laval University and collaborates with other research networks nationally and internationally.[13] We screened the Laval University PBRN for potentially eligible studies and considered all patient data gathered from five eligible studies. Studies were included if 1) they were set entirely in primary care (defined as the patient's point of entry into the healthcare system, most often consulting a family physician[14]); 2) they assessed patient-reported decisional conflict using the French or English version of the 16-item Decisional Conflict Scale (DCS) (i.e.

studies conducted after the development of the DCS in 1993);[15] and 3) DCS scores were collected from patients following a clinical encounter with a primary care provider. There was no study design restriction. Studies were excluded if data had been gathered in a specialized clinic, if participants were recruited from the public (through newspaper ads, for instance), or if data collected with individuals did not relate to a clinical encounter with a primary care provider. For experimental studies, only patients from control or baseline groups were considered for analysis. "Each of the projects from which data were extracted had been granted ethical approval by its respective institution. For this secondary analysis, all nominal data were redacted and none of the variables could be associated with individuals. Therefore further ethics approval was not required."

Data collected

All data collected with patients enrolled in the included studies had been collected using self-administered paper-based questionnaires. The Decisional Conflict Scale (DCS) is a generic 16-item scale developed to provide an instrument to evaluate or adapt decision aids and other decision support interventions to patient needs.[16] When administered in the context of the included studies, a preamble described the specific decision-type addressed, and patients were asked to indicate clearly in their own words the decision they were assessing. Therefore, the DCS items were generic and the same in every case, and participants were thus expected to respond in light of this one specific decision. From the baseline data (i.e. before-and-after or randomized controlled trial studies) we extracted the following characteristics of each study: year of data collection, study type, main objective of original study, clinical setting and types of decision(s) made by patients. For each study, we assessed patient characteristics such as sex, age

(<45 years old, ≥45 years old), professional status (full or part-time employment, no employment, retired), education (no postsecondary education, some postsecondary education), annual household income (<CAD $60,000, ≥$60,000), household size (living alone, living with at least one other person), marital status (married, single, separated/divorced, widowed), and whether the patient had a private drug insurance plan (yes, no). We also assessed clinical characteristics: whether this was the first encounter with that particular primary care provider (yes, no), whether the patient was accompanied during the encounter (yes, no), whether the decision was for a child (yes, no), patient preference for involvement in decision-making (passive, active[10 17]), average annual frequency of consultations with any doctor (≤3, >3), self-reported health status[18] (excellent/very good/good, or fair/poor), whether the patient received a drug prescription (yes, no).

Data analysis

First, we computed CSDC as defined by a score of ≥25/100 on the DCS,[3 4 15 19] at which point decisional conflict is positively associated with decisional delay, departure from active treatment, decision regret, nervousness and a higher intention to sue physicians in cases of harms from treatment.[3 4] This is the threshold most commonly used to distinguish a harmless from a harmful level of decisional conflict.[3 19 20] The DCS consists of 16 items, each of which is measured on a 5-point Likert scale (1 = strongly agree to 5 = strongly disagree, treated as a 0-4 score). The mean score of all items is multiplied by 25 to give a score out of 100. Higher scores indicate higher levels of decisional conflict.[21] The DCS shows good psychometric properties (test-retest reliability coefficient: 0.81, Cronbach's alpha range: 0.78 – 0.92) and its French translation has been validated.[16 22-24] Second, we conducted complete-subject analyses of the prevalence and risk

factors of CSDC individually for each dataset at the patient level. After deletion of missing data and removal of participants in experimental groups, patient characteristics were similar to those of the original study populations.[25 26 27 28 29] In studies where clusters of patients were recruited under the same clinician and/or within the same clinic, we assessed the impact of a potential cluster effect at each level of analysis (clinician and/or clinic). For each dataset, we computed overall prevalence of CSDC and prevalence for each category of available variables stratified by sex. All results pertaining to prevalence are reported as percentages of patients with CSDC. Logistic regression (backwards selection) was used to explore the independent association between CSDC and potential risk factors, including interaction terms with each variable and sex. All significant variables at $\alpha \leq 0.10$ were kept in the final model. We defined statistical significance at $\alpha \leq 0.10$ because this was an exploratory study. If we found a non-negligible cluster effect, we used a generalized estimation equation (PROC GENMOD) with binary logit outcome. Otherwise, logistic regression was used. We calculated the receiver operating characteristic to estimate the models' performance. All analyses were conducted with SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Description of included studies

We estimated the prevalence of CSDC in the context of five different studies conducted in primary care. Each of these studies was designed to address different issues, and each collected quite different data. However, each study group had independently identified the need to

measure decisional conflict using the DCS.[16] The following is a short description of included studies.

The first study was a before-and-after trial conducted in Ontario to assess the impact of implementing the Ottawa Decision Support Framework (ODSF) on correspondences between patients' and physicians' decisional conflict scores. Implementation of the framework consisted of an interactive workshop, feedback, and a reminder at the point of care. Secondary objectives were to evaluate the barriers and facilitators to implementation of the ODSF in primary care practices and examine changes in physicians' intention to adopt the DSC.[26]

The second study evaluated decisional conflict in the context of prenatal screening for Down syndrome (GENETIC). This cross-sectional survey conducted with patients from Quebec assessed the willingness of women and their family physicians to engage in shared decision-making about prenatal Down-syndrome screening and factors that might influence this willingness.[27]

The third study evaluated the impact of a training program for physicians (DECISION+).[25] This pilot randomized controlled trial conducted in Quebec integrated multiple educational/behavioral change components that aimed to promote shared decision-making about treatment options and specifically about the use of antibiotics for acute respiratory infections.[25]

The goal of the fourth study was to assess the psychometric properties of dyadic measures for shared decision-making research. The study used a shared decision-making model (EXACKTE2)

to explore how patients and clinicians influence one another. This cross-sectional study conducted in 17 primary care clinics in Ontario and Quebec explored the mutual influence between patients and physicians during consultations.[28]

The last study used data gathered during a pilot study [25] to establish the feasibility of conducting the DECISION+ training program on a larger scale. The program was improved and renamed DECISION+2 [29] before the definitive trial. This randomized controlled trial conducted in Quebec assessed the impact of DECISION+2 on antibiotics use for acute respiratory infections.

Table 1 presents the characteristics of the included studies and their related datasets alongside the available independent variables.[25-29] All datasets were from projects conducted between 2003 and 2010. Three were conducted in the province of Quebec, one was conducted in Ontario and one was conducted jointly by teams from Ontario and Quebec.[28] Of the five datasets available, two were clustered randomized trials (DECISION+[25], DECISION+2[29]), two were cross-sectional surveys (GENETIC[27], EXACKTE2 [28]) and one was a before-and-after trial (iODSF[26]). Decisions were about undergoing a prenatal Down syndrome genetic screening test (GENETIC[27]), taking antibiotics to treat acute respiratory infections (DECISION+[25], DECISION+2[29]) and various other primary care decisions (iODSF[26], EXACKTE2 [28]). Altogether, data from 1,338 primary care patients were analyzed. Patients were aged between 15 and 83 years old and 69% were female.

Table 1: Characteristics of datasets

Characteristics	Dataset				
	iODSF [26]	GENETIC [27]	DECISION+ [25]	EXACKTE2 [28]	DECISION+2 [29]
Year of data collection	2003	2007	2007	2009	2010
Study type	Before and after trial	Cross-sectional survey	Cluster randomized trial	Cross-sectional survey	Cluster randomized trial
Main objective of study	To assess the impact of implementing the Ottawa Decision Support Framework on correspondences between patients' and physicians' decisional conflict scores.	To assess the willingness of women and their family physicians to engage in shared decision making about prenatal Down-syndrome screening and the factors that might influence this willingness.	To develop, adapt and validate a shared decision-making training program and estimate its impact on the decision of family physicians and their patients about whether to use antibiotics for ARIs.	To assess the psychometric properties of dyadic measures for shared decision-making research.	To evaluate the effect of a shared decision-making training program on decisions of family physicians and their patients about whether to use antibiotics for ARIs.
Clinical setting	5 FPTUs in the Quebec City area	3 FPTUs in the Quebec City area	4 family medicine groups in the Quebec City area	17 primary care clinics in the Quebec City area and in Ontario	9 FPTUs in the province of Quebec
Type of decision	Various other primary care decisions	To do a prenatal test or not	To take antibiotics or not for treating ARIs	Various other primary care decisions	To take antibiotics or not for treating ARIs
Total participants (N)	370	130	225	198	415
Women; n (%)	234 (63)	130 (100)	154 (68)	131 (66)	277 (67)
Aged ≥ 45 years old; n(%)	209 (56)	0 (0)	60 (27)	117 (59)	164 (40)
Living by themselves; n(%)	119 (32)	1 (1)	39 (17)	42 (21)	74 (18)
Professional status; n(%)					
- Employed full- or part-time	185 (50)	105 (81)	176 (78)	109 (55)	318 (77)
- Unemployed	69 (19)	25 (19)	36 (16)	30 (15)	65 (16)
- Retired	116 (31)	0 (0)	13 (6)	59 (30)	32 (8)
Household income ≥ $ 60,000; n (%)	97 (26)	62 (48)	87 (39)	24 (12)	194 (47)
Available variables	Age, sex, employment status, education, annual income, household size, first encounter with that doctor	Age, sex, employment status, education, annual income, household size	Age, sex, employment status, education, annual income, household size, first encounter with that doctor, patient preference for involvement in decision-making, self-reported health status, whether making a decision for a child, whether patient receives a prescription, whether patient has a private drug insurance plan	Age, sex, employment status, education, annual income, household size, marital status, average annual frequency of physician visits, first encounter with that doctor, patient is alone or accompanied	Age, sex, employment status, education, annual income, household size, first encounter with that doctor, patient preference for involvement in decision making, self-reported health status, whether making a decision for a child, whether patient receives a prescription, whether patient has a private drug insurance plan

FPTU: Family practice teaching unit; ARIs: Acute respiratory infections

Prevalence of clinically significant decisional conflict

Table 2 shows the prevalence as a percentage of included participants with CSDC across all five datasets stratified by sex for available variables, since gender was found to be a modifying factor for at least one variable in all four datasets that included men. Prevalence was between 10.3% (iODSF[26]) (95% confidence intervals [CI]: 7.2 – 13.4) and 31.1% (DECISION+2[29]) (95%CI: 26.6 – 35.6). CSDC was consistently more prevalent in males (4/4 studies), people aged 45 or older (4/4 studies), people living alone (4/5 studies), retirees (4/4 studies), people preferring active participation in decision making (2/2 studies), people reporting poor health status (2/2 studies), people making the decision for themselves as opposed to for their children (2/2 studies), and people who did not have a private drug insurance plan (2/2 studies).

Table 2: Prevalence* of clinically significant decisional conflict according to datasets and sex

	iODSF [26]			GENETIC [27]	DECISION+ [25]			EXACKTE2 [28]			DECISION+2 [29]		
	F	M	All	All†	F	M	All	F	M	All	F	M	All
Total participants (N)	234	136	370	130	154	71	225	131	67	198	277	138	415
Overall prevalence (95% confidence interval)	7.7 (4.3; 11.1)	14.7 (8.7; 20.7)	10.3 (7.2; 13.4)	16.9 (10.4; 23.5)	17.5 (11.5; 23.6)	31.0 (20.0; 42.0)	21.8 (16.3; 27.2)	15.3 (9.0; 21.5)	28.4 (17.3; 39.4)	19.7 (14.1; 25.3)	28.5 (23.2; 33.9)	36.2 (28.1; 44.4)	31.1 (26.6; 35.6)
Adjusted Chronbach Alpha rates (DCS)		0.85		0.93		0.91			0.95			0.93	
Sociodemographic characteristics													
Age													
< 45 years old	6.1	13.0	8.1	16.9	11.5	27.0	16.4	10.9	17.7	12.4	26.0	29.2	26.9
≥ 45 years old	9.2	15.6	12.0	N/A	34.2	42.1	36.7	19.4	32.0	24.8	36.2	50.0	41.5
Professional status													
Full- or part-time employment	9.3	14.9	11.4	18.1	17.7	28.1	21.0	10.8	25.7	15.6	27.6	37.0	30.8
No employment	6.0	0.0	4.4	12.0	11.5	50.0	22.2	18.2	25.0	20.0	29.8	27.8	29.2
Retired	6.1	20.0	12.1	N/A	33.3	25.0	30.8	22.9	33.3	27.1	35.0	41.7	37.5
Education													
No postsecondary education	5.9	14.4	9.1	9.8	16.0	34.7	23.4	26.0	21.4	24.4	26.3	33.3	28.9
At least some postsecondary education	11.1	15.2	12.6	21.5	19.0	22.7	19.8	8.7	33.3	16.7	29.4	37.8	32.1
Annual household income													
< $60,000	5.1	13.3	8.1	17.7	14.1	41.3	23.2	15.0	24.1	17.8	32.3	30.3	31.7
≥ $60,000	15.3	18.4	16.5	16.1	22.6	12.0	19.5	18.2	46.1	33.3	23.8	41.7	30.4
Household size													
Living alone	9.2	23.3	14.3	0.0	31.8	47.1	38.5	25.0	36.4	31.0	42.9	40.0	41.9
Living with ≥ 1 other person	7.0	10.8	8.4	17.1	15.2	25.9	18.3	13.5	24.4	16.7	25.4	35.4	28.7
Marital status													
Married								9.3	25.0	13.9			
Single								25.0	27.8	26.2			
Separated /divorced								33.3	44.4	38.1			
Widowed								22.2	25.0	23.1			
Private drug insurance plan													
Yes					17.5	26.0	20.1				26.3	35.6	29.4
No					17.5	42.9	26.2				34.2	37.8	35.3

F = Female; M = Male; N/A = Not applicable; * Prevalence of Clinically Significant Decisional Conflict was defined as a score ≥ 25/100 on the Decisional Conflict Scale (DCS) [15] ; †In the GENETIC study, all participants were female.

Table 2: Prevalence* of clinically significant decisional conflict according to datasets and sex (continuation)

Clinical characteristics	iODSF [26]			GENETIC [27]	DECISION+ [25]			EXACKTE2 [28]			DECISION+2 [29]		
	F	M	All	All†	F	M	All	F	M	All	F	M	All
First encounter with that particular doctor													
Yes	8.5	18.6	12.8		12.5	31.8	17.4	17.8	36.4	23.5	32.6	25.9	30.1
No	7.4	12.9	9.3		21.1	31.6	24.5	15.7	24.4	18.4	27.7	38.7	31.3
Patient accompanied during encounter													
Yes								11.1	33.3	18.5			
No								15.9	27.6	19.9			
Decision for a child													
Yes					10.0	31.2	15.2				22.9	30.0	25.0
No					21.2	30.9	24.5				30.4	38.0	33.0
Patient preference for involvement													
Passive					15.2	30.4	20.3				27.8	26.7	27.3
Active					21.0	32.0	24.1				28.6	37.4	31.4
Average annual frequency of physician visits													
≤ 3 average physician visits per year								9.9	39.4	19.2			
> 3 average physician visits per year								21.7	17.7	20.2			
Self-reported health status													
Excellent, very good, good					16.7	27.4	19.9				27.5	32.8	29.2
Fair, poor					30.0	55.6	42.1				40.9	69.2	51.4
Patient received a prescription													
Yes					16.4	32.8	21.7				29.5	34.6	31.1
No					23.1	20.0	22.2				24.5	42.9	30.9

F = Female; M = Male; N/A: Not applicable; * Prevalence of Clinically Significant Decisional Conflict was defined as a score ≥ 25/100 on the Decisional Conflict Scale [15] ; †In GENETIC study, all participants were female.

Risk factors of clinically significant decisional conflict

The impact of cluster effect at the clinician level was found to be negligible in all datasets. However, we found a cluster effect at the clinic level in three projects (iODSF[26], DECISION+[25], DECISION+2[29]). Table 3 presents the multivariable regression analysis of the association between CSDC and its potential independent risk factors. Sex was found to be a modifying factor for at least one variable in all datasets (except GENETIC[27], as all participants were women) and an independent risk factor in one (EXACKTE2[28]). We tested the interaction between the patient's gender and the first visit with a physician but found that it was not significant (data not shown). Living alone was positively associated with CSDC in three out of four datasets (iODSF[26], DECISION+[25], DECISION+2[29]). Being aged 45 or older was also positively associated with CDSC in three out of four datasets (DECISION+[25], EXACKTE2 [28], DECISION+2[29]) and there was a significant interaction with sex in one dataset (iODSF[26]). An annual income above or equal to CAD $60,000 was positively associated with CSDC in two of the five datasets (iODSF[26], EXACKTE2[28]) and we observed an interaction term with sex in one dataset (DECISION+[25]). Other study variables were not significantly associated with CSDC in more than one study.

Table 3: Association between clinically significant decisional conflict and potential risk factors according to dataset

Potential risk factors	Dataset									
	iODSF [26]		GENETIC [27]		DECISION+ [25]		EXACKTE2 [28]		DECISION+2 [29]	
	β ± SE	*p-value*	β ± SE	*p-value*	β ± SE	*p-value*	β ± SE	*p-value*	β ± SE	*p-value*
Sex (being male)	-0.54 ± 0.58	0.36	n = 0		-0.35 ± 0.56	0.54	1.45 ± 0.56	**0.01**	0.39 ± 0.25	0.11
Postsecondary education	-		0.93 ± 0.54	0.08	-		-0.79 ± 0.43	0.07	-	
Age (≥45)	0.66 ± 0.57	0.25	n = 0		1.02 ± 0.24	**< 0.0001**	0.57 ± 0.45	0.09	0.61 ± 0.18	**< 0.001**
Age (≥45) x sex	1.40 ± 0.39	**< 0.001**	N/A		-		-		-	
Living alone	1.01 ± 0.23	**< 0.0001**	n = 1		0.81 ± 0.25	**< 0.01**	-		0.40 ± 0.17	0.02
Making the decision for a child (vs. for self)	N/A		N/A		-0.73 ± 0.39	0.06	N/A		-	
Making the decision for a child (vs. for self) x sex	N/A		N/A		1.20 ± 0.19	**< 0.0001**	N/A		-	
Having received a prescription	N/A		N/A		-0.66 ± 0.25	**< 0.01**	N/A		-	
Having received a prescription x sex	N/A		N/A		1.93 ± 0.10	**< 0.0001**	N/A		-	
Annual family income ≥ $60K	1.16 ± 0.13	**< 0.0001**	-		1.19 ± 0.24	**< 0.0001**	1.11 ± 0.56	**0.05**	-	
Annual family income ≥ $60K x sex	-		N/A		-2.54 ± 0.69	**< 0.001**	-		-	
Being unemployed	-0.89 ± 0.31	**< 0.01**	-		-		-		0.15 ± 0.42	0.71
Being unemployed x sex	-		N/A		-		-		-0.98 ± 0.22	**< 0.0001**
Retirement	-0.86 ± 0.44	**0.05**	n = 0		-		-		-0.34 ± 0.49	0.49
Being retired x sex	1.83 ± 0.69	**< 0.01**	N/A		-		-		0.16 ± 0.76	0.83
Being single (vs. being married)	N/A		N/A		N/A		1.16 ± 0.54	**0.03**	N/A	
Being separated or divorced (vs. being married)	N/A		N/A		N/A		0.22 ± 0.74	0.76	N/A	
Self-reported health status "Excellent", "Very good" or "good"	N/A		N/A		-		N/A		-0.95 ± 0.28	**< 0.001**
Consulting a physician > 3 times a year	N/A		N/A		N/A		0.39 ±0.55	0.48	N/A	
Consulting a physician > 3 times a year x sex	N/A		N/A		N/A		-1.92 ±0.81	**0.02**	N/A	
ROC	**0.73**		**0.60**		**0.76**		**0.75**		**0.62**	

β = Regression coefficient; SE = Standard error; N/A = Not available; ROC = Receiver operating characteristic

DISCUSSION

Using data on a total of 1,338 patients from combination of five studies conducted in primary care contexts in two Canadian provinces, Quebec and Ontario, we observed that the prevalence of CSDC in patients, defined as a score of ≥25/100 on the DCS, was substantial and varied between 10% and 31%. Populations at risk of CSDC included males, people living alone and people aged 45 years or older. To the best of our knowledge, this is the first account of the prevalence of CSDC as reported in studies conducted exclusively in primary care and with this many unique clinical encounters. None of the earlier studies measuring CSDC in a primary care clinical context focused on a decision dealt with entirely at the primary care level.[30-33] Our results lead us to make four main observations.

First, our results contradict a common belief that primary care only deals with mundane types of decisions that involve no perception of risk, loss, regret, or challenges to personal life values, and that primary care decisions therefore involve no personal uncertainty. Clearly, this is not how some patients enrolled in these five studies saw the issues they were confronting. Given the harmful downstream effects of unresolved CSDC, our results suggest that a significant number of primary care patients would benefit greatly from patient decision aids,[12] decision coaching[34] or from their healthcare providers being trained in shared decision-making. These clinical approaches are known to be effective in resolving CSDC.[35]

Second, we observed a higher prevalence of CSDC in men than in women in all four datasets that included men and women. Moreover, sex was found to be an independent risk factor in one

dataset and significantly interacted with at least one variable in all datasets. This may be explained by the fact that more women than men report having a regular family doctor [36] and consulting primary care providers over their lifetime.[37] Women tend to consult healthcare providers more frequently due to their gynecological and obstetrical needs and also because they are often involved in health-related decision making for other family members.[37 38] Furthermore, physicians are known to discuss therapeutic and preventive interventions more often with women than with men.[39] Together, more visits to physicians and more discussion with them may contribute to a higher sense of self-efficacy among women about engaging in decision-making.[40] This in turn could reduce CSDC in women.[40] Since sex was not an independent risk factor across all studies, it would be erroneous to conclude that men are systematically more at risk of CSDC than women. As in earlier studies on the impact of sex on outcomes, our results highlight a significant effect of sex on CSDC and suggest that primary care providers should tailor their decision-making approach to the patient's sex.[41]

Third, people reporting living alone showed a consistently higher prevalence of CSDC than people reporting living with at least one other person. This is congruent with the theory underlying the DCS.[16] The higher prevalence of CSDC in people reporting living alone could be due to a lack of social support when they face health-related decisions, one of the key contributors to CDSC.[5] During the clinical encounter, primary care providers should explore the patient's social support systems, i.e. whether he/she can 1) check other people's opinions, 2) focus on those whose opinions matter most (physician, family, and friends) and 3) handle diverse sources of pressure.[42] Such support-clarification exercises help patients understand other perspectives and gather opinions about what other people would do if they were in the same

situation. Our results suggest that lack of support for people living alone may aggravate CSDC in primary care patients. Although the contribution of family members is increasingly recognized as an important source of social support for patients facing health decisions,[43] the literature has still not adequately addressed its full impact on decision-making.[44] Primary care providers should pay closer attention to their patients living alone in their efforts to detect CSDC during the decision-making process.

Lastly, patients aged 45 or older showed a higher prevalence of CSDC in all relevant datasets. As older adults tend to seek less information when making a decision, defer the decision more often, and are generally more risk avoidant than young adults, they may be more at risk of CSDC.[45] In addition, an enduring myth is that older and more vulnerable patients are less interested in participating in decision-making with their healthcare providers than are less vulnerable patients.[46] Any and all of these reasons may contribute to the higher prevalence of CSDC observed in populations aged 45 years or older and should inform clinicians and researchers of the urgent need to foster the participation of older patients in decision-making with the appropriate strategies.

Our study has some limitations. First, measuring CSDC was not the primary objective of any of the selected studies. Also, potentially relevant variables such as marital status and self-reported health status were missing in some datasets, and therefore we could not draw conclusions relating to these variables. Furthermore, all studies were weighted equally, as a meta-analysis was not judged appropriate given the heterogeneity of the data sets (type of decision, study design, available variables). Nevertheless, the similar nature of the questionnaires in each study

enabled us to compare associations in datasets independently from one another and thus assure external validity of the results.[47] We also acknowledge that there might be a selection bias in the included studies and thus our results will need to be reproduced in future studies. Also, there might be bias within the studies resulting from patients who willingly participated in the study and regarding the study design. However, we performed multivariate analyses to adjust for confounding factors. Finally, we acknowledge that we cannot infer that our results are generalizable to the wider population as we drew upon secondary analysis of existing datasets of studies conducted in specific primary care clinical contexts in two provinces in Canada. Further studies with appropriate survey methods and sampling frames could depict a more accurate portrait of CSDC in other primary care clinical contexts, and explore how much the prevalence varies according to decision-type.

CONCLUSION

We observed that the prevalence of CSDC in studies on decision-making conducted in primary care contexts in two Canadian provinces, Quebec and Ontario, ranged from 10% to 31%. This prevalence varied depending on the type of decision and was higher in males, in people living alone, and in people aged 45 or older. Although we cannot generalize our results to the wider population, they should alert primary care providers to patients who may be at higher risk of CSDC. Training health professionals to identify CDSC in patients and ensuring that effective decision support interventions such as patient decision aids are implemented at the point of care should be encouraged to resolve CDSC.[12 48]

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PRISMA Checklist

PREVALENCE OF CLINICALLY SIGNIFICANT DECISIONAL CONFLICT: AN ANALYSIS OF FIVE STUDIES ON DECISION MAKING IN PRIMARY CARE

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Criteria		Page	Brief description of how the criteria were handled in the manuscript
TITLE			
1	Identify the report as a systematic review, meta-analysis, or both.	p. 1	PREVALENCE OF CLINICALLY SIGNIFICANT DECISIONAL CONFLICT: AN ANALYSIS OF FIVE STUDIES ON DECISION MAKING IN PRIMARY CARE
ABSTRACT			
2	Provide a structured summary including, as applicable: Background (research question and main objectives); Methods (data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods); Results (number and type of studies and participants, main	pp. 4-5	**Objectives:** Unresolved clinically significant decisional conflict (CSDC) in patients following a consultation with health professionals is often the result of inadequate patient involvement in decision-making and may result in poor outcomes. We sought to identify the prevalence of CSDC in studies on decision-making in primary care and to explore its risk factors.

	outcomes with CI); Discussion (strengths and limitations of the evidence, general interpretation and important implications) Other (report primary funding source, registration number)		**Setting:** We performed a secondary analysis of existing datasets from studies conducted in Primary Care Practice-Based Research Networks in Quebec and Ontario, Canada. **Participants:** Eligible studies included a patient-reported measure on the 16-item Decisional Conflict Scale (DCS) following a decision made with a healthcare professional with no study design restriction. **Primary and secondary outcome measures:** CSDC was defined as a score ≥ 25/100 on the DCS. The prevalence of CSDC was stratified by sex; and patient-level logistic regression analysis was performed to explore its potential risk factors. Datasets of studies were analyzed individually and qualitatively compared. **Results:** Five projects conducted between 2003 and 2010 were included. They covered a range of decisions: prenatal genetic screening, antibiotics for acute respiratory infections and miscellaneous. Altogether, the five projects gathered data from encounters with a total of 1,338 primary care patients (69% female; range of age: 15 to 83). The prevalence of CSDC in patients varied across studies and ranged from 10.3% (95% confidence interval: 7.2% – 13.4%) to 31.1% (95% confidence interval: 26.6% – 35.6%). Across the five studies, risk factors of CSDC included being male, living alone, and being 45 or older. **Conclusions:** Prevalence of CSDC in patients who had enrolled in studies conducted in primary care contexts was substantial and appeared to vary according to the type of decision as well as to patient characteristics such as sex, living arrangement and age. Patients presenting risk factors of CSDC should be offered tools to increase their involvement in decision-making.
INTRODUCTION			

3	*Rationale*: describe the rationale for the review in the context of what is already known.	p. 7	When facing health-related decisions and presented with multiple options, patients are subject to uncertainty about what to choose. This uncertainty is known as decisional conflict. Decisional conflict is an intra-personal psychological construct that is felt by individuals when facing decisions that involve risk, loss, regret, or challenges to personal life values.1 2 In lay terms, decisional conflict reflects the level of comfort that an individual faces in making a decision. In some patients it may translate into clinically significant decisional conflict (CSDC), at which point decisional conflict is positively associated with decisional delay, departure from active treatment, decision regret, nervousness and a higher intention to sue physicians in cases of harms from treatment.3 4 Thus it is essential to identify patients experiencing CSDC, as there are several modifiable deficits that lead to CSDC, including 1) inadequate knowledge of options; 2) unclear values regarding harms and benefits of options; and 3) inadequate support or resources for decision making. These may all be addressed with effective decision support.5
4	*Objectives*: provide an explicit statement of questions being addressed with reference to participants, intervention, comparisons, outcomes, and study design (PICOS)	p. 8	"Analyzing (S) and comparing (C) the outcomes (O) of decision-making studies (I) among primary care patients (P) could thus have a beneficial impact on the quality of care for a large number of individuals. We sought to identify the prevalence of CSDC in studies conducted in primary care contexts and to explore its risk factors (*Objective)*."
METHODS			Data extracted from each of the studies were relevant to the population characteristics, study design, exposure, outcome, and possible effect modifiers of the association.
5	*Protocol and registration*	N/A	There was no registered protocol, but the first author performed a protocol for this study in his masters degree.
6	*Eligibility criteria* (studies characteristics, the rationale for criteria should be stated)	pp. 8-9	Studies were included if 1) they were set entirely in primary care (defined as the patient's point of entry into the healthcare system, most often consulting a family physician14); 2) they assessed patient-

			reported decisional conflict using the French or English version of the 16-item Decisional Conflict Scale (DCS) (i.e. studies conducted after the development of the DCS in 1993);15 and 3) DCS scores were collected from patients following a clinical encounter with a primary care provider. There was no study design restriction. Studies were excluded if data had been gathered in a specialized clinic, if participants were recruited from the public (through newspaper ads, for instance), or if data collected with individuals did not relate to a clinical encounter with a primary care provider. For experimental studies, only patients from control or baseline groups were considered for analysis.
7	*Information sources* (details of hand searching with dates)	p. 8	We carried out a secondary analysis of existing datasets from studies conducted within or in collaboration with the Laval University Primary Care Practice-Based Research Network (PBRN) in the Province of Quebec, Canada. This network comprises twelve family practice teaching units affiliated with Laval University and collaborates with other research networks nationally and internationally.13
8	*Search* (present the full electronic search strategy for at least one database)	N/A	Not applicable.
9	*Study selection:* State the process for determining which studies were eligible for inclusion (screening)	p. 8	Studies were included if 1) they were set entirely in primary care (defined as the patient's point of entry into the healthcare system, most often consulting a family physician14); 2) they assessed patient-reported decisional conflict using the French or English version of the 16-item Decisional Conflict Scale (DCS) (i.e. studies conducted after the development of the DCS in 1993);15 and 3) DCS scores were collected from patients following a clinical encounter with a primary care provider. There was no study design restriction.
10	*Data collection process* (extraction data independently in duplicate and any process for confirming these data with	p. 9	From the baseline data (i.e. before-and-after or randomized controlled trial studies) we extracted the following characteristics of each study: year of data collection, study type,

	investigators)		main objective of original study, clinical setting and types of decision(s) made by patients.
11	*Data items*: describe how the information and variables to be collected were chosen. List and define all study level and participant level, including baseline and follow-up information. If applicable, describe methods of standardizing or translating variables within the datasets to ensure common scales or measurement across studies (list and define all variables for which data were sought)	p. 9	All data collected with patients enrolled in the included studies had been collected using self-administered paper-based questionnaires. The Decisional Conflict Scale (DCS) is a generic 16-item scale developed to provide an instrument to evaluate or adapt decision aids and other decision support interventions to patient needs.16 When administered in the context of the included studies, a preamble described the specific decision-type addressed, and patients were asked to indicate clearly in their own words the decision they were assessing. Therefore, the DCS items were generic and the same in every case, and participants were thus expected to respond in light of this one specific decision. From the baseline data (i.e. before-and-after or randomized controlled trial studies) we extracted the following characteristics of each study: year of data collection, study type, main objective of original study, clinical setting and types of decision(s) made by patients. For each study, we assessed patient characteristics such as sex, age (<45 years old, ≥45 years old), professional status (full or part-time employment, no employment, retired), education (no postsecondary education, some postsecondary education), annual household income (<CAD $60,000, ≥$60,000), household size (living alone, living with at least one other person), marital status (married, single, separated/divorced, widowed), and whether the patient had a private drug insurance plan (yes, no). We also assessed clinical characteristics: whether this was the first encounter with that particular primary care provider (yes, no), whether the patient was accompanied during the encounter (yes, no), whether the decision was for a child (yes, no), patient preference for involvement in decision-making (passive, active10 17), average annual frequency of consultations with any doctor (≤3, >3), self-reported health

			status18 (excellent/very good/good, or fair/poor), whether the patient received a drug prescription (yes, no).
12	*Risk of bias in individual studies*: Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), report if and how this information is to be used in any data synthesis.	N/A	Not applicable.
13	*Summary measures*: State all outcomes addressed and define them in detail, and whether they were primary or secondary outcomes. Give the principal measures of effect (e.g., risk ratio, difference in means) used for each outcome.	p. 10	First, we computed CSDC as defined by a score of ≥25/100 on the DCS,3 4 15 19 at which point decisional conflict is positively associated with decisional delay, departure from active treatment, decision regret, nervousness and a higher intention to sue physicians in cases of harms from treatment.3 4 This is the threshold most commonly used to distinguish a harmless from a harmful level of decisional conflict.3 19 20 The DCS consists of 16 items, each of which is measured on a 5-point Likert scale (1 = strongly agree to 5 = strongly disagree, treated as a 0-4 score). The mean score of all items is multiplied by 25 to give a score out of 100. Higher scores indicate higher levels of decisional conflict.21 The DCS shows good psychometric properties (test-retest reliability coefficient: 0.81, Cronbach's alpha range: 0.78 – 0.92) and its French translation has been validated.16 22-24
14	*Synthesis of results*: Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis. How effect estimates were generated separately within each study and combined across studies (where applicable). How missing data within studies were deal.	p. 10	Second, we conducted complete-subject analyses of the prevalence and risk factors of CSDC individually for each dataset at the patient level. After deletion of missing data and removal of participants in experimental groups, patient characteristics were similar to those of the original study populations.25 26 27 28 29 In studies where clusters of patients were recruited under the same clinician and/or within the same clinic, we assessed the impact of a potential cluster effect at each level of analysis (clinician and/or clinic). For each dataset, we computed overall prevalence of

	Estimation of interactions. Potential effect modifiers.		CSDC and prevalence for each category of available variables stratified by sex. All results pertaining to prevalence are reported as percentages of patients with CSDC. Logistic regression (backwards selection) was used to explore the independent association between CSDC and potential risk factors, including interaction terms with each variable and sex. All significant variables at $\alpha \leq 0.10$ were kept in the final model. We defined statistical significance at $\alpha \leq 0.10$ because this was an exploratory study. If we found a non-negligible cluster effect, we used a generalized estimation equation (PROC GENMOD) with binary logit outcome. Otherwise, logistic regression was used. We calculated the receiver operating characteristic to estimate the models' performance. All analyses were conducted with SAS 9.3 (SAS Institute Inc., Cary, NC, USA).
15	*Risk of bias across studies*: Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A	Not applicable
16	*Additional analyses*: Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	p. 10	All methods have been described in point 13 and 14.
RESULTS			
17	*Study selection*: Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram	pp. 11-12	We included a before-and-after study, two cross-sectional studies, and two randomized studies.
18	*Study characteristics:* For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	pp12-13	Table 1 presents the characteristics of the included studies and their related datasets alongside the available independent variables.25-29 All datasets were from projects conducted between 2003 and 2010. Three were conducted in the province of Quebec, one was conducted in Ontario and

			one was conducted jointly by teams from Ontario and Quebec.28 Of the five datasets available, two were clustered randomized trials (DECISION+25, DECISION+229), two were cross-sectional surveys (GENETIC27, EXACKTE2 28) and one was a before-and-after trial (iODSF26). Decisions were about undergoing a prenatal Down syndrome genetic screening test (GENETIC27), taking antibiotics to treat acute respiratory infections (DECISION+25, DECISION+229) and various other primary care decisions (iODSF26, EXACKTE2 28). Altogether, data from 1,338 primary care patients were analyzed. Patients were aged between 15 and 83 years old and 69% were female.
19	*Risk of bias within studies:* Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A	Not applicable.
20	*Results of individual studies:* For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	pp. 16-17	95% confidence intervals are presented with all individual estimates in Table 2: Table 2 shows the prevalence as a percentage of included participants with CSDC across all five datasets stratified by sex for available variables, since gender was found to be a modifying factor for at least one variable in all four datasets that included men. Prevalence was between 10.3% (iODSF26) (95% confidence intervals [CI]: 7.2 – 13.4) and 31.1% (DECISION+229) (95%CI: 26.6 – 35.6). CSDC was consistently more prevalent in males (4/4 studies), people aged 45 or older (4/4 studies), people living alone (4/5 studies), retirees (4/4 studies), people preferring active participation in decision making (2/2 studies), people reporting poor health status (2/2 studies), people making the decision for themselves as opposed to for their children (2/2 studies), and people who did not have a private drug insurance plan (2/2 studies).
21	*Synthesis of results:* Present results of each meta-analysis done, including confidence intervals and measures of	N/A	Not applicable.

	consistency.		
22	*Risk of bias across studies:* Present results of any assessment of risk of bias across studies (see Item 15).	N/A	Not applicable.
23	*Additional analysis:* Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	p. 19	Table 3 present results of association testing with p-values for each dataset: The impact of cluster effect at the clinician level was found to be negligible in all datasets. However, we found a cluster effect at the clinic level in three projects (iODSF26, DECISION+25, DECISION+229). Table 3 presents the multivariable regression analysis of the association between CSDC and its potential independent risk factors. Sex was found to be a modifying factor for at least one variable in all datasets (except GENETIC27, as all participants were women) and an independent risk factor in one (EXACKTE228). We tested the interaction between the patient's gender and the first visit with a physician but found that it was not significant (data not shown). Living alone was positively associated with CSDC in three out of four datasets (iODSF26, DECISION+25, DECISION+229). Being aged 45 or older was also positively associated with CDSC in three out of four datasets (DECISION+25, EXACKTE2 28, DECISION+229) and there was a significant interaction with sex in one dataset (iODSF26). An annual income above or equal to CAD $60,000 was positively associated with CSDC in two of the five datasets (iODSF26, EXACKTE228) and we observed an interaction term with sex in one dataset (DECISION+25). Other study variables were not significantly associated with CSDC in more than one study.
DISCUSSION			
24	*Summary of evidence*: Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and	p. 20	Using data on a total of 1,338 patients from combination of five studies conducted in primary care contexts in two Canadian provinces, Quebec and Ontario, we observed that the prevalence of CSDC in patients, defined as a score of ≥25/100 on the DCS,

	policy makers).		was substantial and varied between 10% and 31%. Populations at risk of CSDC included males, people living alone and people aged 45 years or older. … Given the harmful downstream effects of unresolved CSDC, our results suggest that a significant number of primary care patients would benefit greatly from patient decision aids,[11] decision coaching[35] or from their healthcare providers being trained in shared decision making. These clinical approaches are known to be effective in resolving CSDC.[36] We discussed the more consistent risk factors of CSDC one by one.
25	*Strengths and Limitations:* Discuss strengths and limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	p. 22	First, measuring CSDC was not the primary objective of any of the selected studies. Also, potentially relevant variables such as marital status and self-reported health status were missing in some datasets, and therefore we could not draw conclusions relating to these variables. Furthermore, all studies were weighted equally, as a meta-analysis was not judged appropriate given the heterogeneity of the data sets (type of decision, study design, available variables). Nevertheless, the similar nature of the questionnaires in each study enabled us to compare associations in datasets independently from one another and thus assure external validity of the results.47 We also acknowledge that there might be a selection bias in the included studies and thus our results will need to be reproduced in future studies. Also, there might be bias within the studies resulting from patients who willingly participated in the study and regarding the study design. However, we performed multivariate analyses to adjust for confounding factors. Finally, we acknowledge that we cannot infer that our results are generalizable to the wider population as we drew upon secondary analysis of existing datasets of studies conducted in specific primary care clinical contexts in two provinces in Canada. Further studies with appropriate survey methods and sampling frames could depict a more accurate portrait

			of CSDC in other primary care clinical contexts, and explore how much the prevalence varies according to decision-type.
26	*Conclusions*: Provide a general interpretation of the results in the context of other evidence, and implications for future research.	p. 23	We observed that the prevalence of CSDC in studies on decision-making conducted in primary care contexts in two Canadian provinces, Quebec and Ontario, ranged from 10% to 31%. This prevalence varied depending on the type of decision and was higher in males, in people living alone, and in people aged 45 or older. Although we cannot generalize our results to the wider population, they should alert primary care providers to patients who may be at higher risk of CSDC. Training health professionals to identify CDSC in patients and ensuring that effective decision support interventions such as patient decision aids are implemented at the point of care should be encouraged to resolve CDSC.12 48
FUNDING			
27	*Funding*: Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	p. 2	"FL is Tier-2 Canada Research Chair in Implementation of Shared Decision Making in Primary Care."