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Decisional needs assessment for patient-centred pain care in Canada: the DECIDE-PAIN study protocol

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ABSTRACT

Introduction The 2021 Action Plan for Pain from the Canadian Pain Task Force advocates for patient-centred pain care at all levels of healthcare across provinces. Shared decision-making is the crux of patient-centred care. Implementing the action plan will require innovative shared decision-making interventions, specifically following the disruption of chronic pain care during the COVID-19 pandemic. The first step in this endeavour is to assess current decisional needs (ie, decisions most important to them) of Canadians with chronic pain across their care pathways.

Methods and analysis Design Grounded in patient-oriented research approaches, we will perform an online population-based survey across the ten Canadian provinces. We will report methods and data following the CROSS reporting guidelines.

Sampling The Léger Marketing company will administer the online population-based survey to its representative panel of 500,000 Canadians to recruit 1646 adults (age ≥18 years old) with chronic pain according to the definition by the International Association for the Study of Pain (eg, pain ≥12 weeks).

Content Based on the Ottawa Decision Support Framework, the self-administered survey has been codesigned with patients and contain six core domains: (1) healthcare services, consultation and postpandemic needs, (2) difficult decisions experienced, (3) decisional conflict, (4) decisional regret, (5) decisional needs and (6) sociodemographic characteristics. We will use several strategies such as random sampling to improve survey quality.

Analysis We will perform descriptive statistical analysis. We will identify factors associated with clinically significant decisional conflict and decision regret using multivariable analyses.

Ethics and dissemination Ethics was approved by the Research Ethics Board at the Research Centre of the Centre Hospitalier Universitaire de Sherbrooke (project #2022-4645). We will codevelop knowledge mobilisation products with research patient partners (eg, graphical summaries and videos). Results will be disseminated via peer-reviewed journals and national and international conferences to inform the development of innovative shared decision-making interventions for Canadians with chronic pain.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study is grounded in patient-oriented methods including active engagement of patient research partners living with chronic pain.
⇒ This study is informed by the Ottawa Decision Support Framework and will provide a comprehensive understanding of decisional needs, decisional conflict and decision regret.
⇒ The survey will collect multiple difficult decisions across care pathways for chronic pain.
⇒ Data collection will occur in the ten Canadian provinces. The three Canadian territories are not included in Leger Marketing panel. Since Canadian territories include important indigenous communities, culturally adapted methods will be required to assess decisional needs in these populations.
⇒ The survey administration will require internet access which may limit the recruitment of certain vulnerable populations.

INTRODUCTION

In May 2021, the Canadian Pain Task Force published the Action Plan for Pain to ‘provide advice and information to guide Health Canada towards an improved approach to the prevention and management of chronic pain in Canada’. This action plan is the result of a consultation with nearly 2000 Canadians with chronic pain who shared their experiences within the healthcare system before the COVID-19 pandemic. The disruption of chronic pain management during the pandemic led to the recommendation of six priorities to transform how clinicians and decision-makers understand and treat pain. Among these six priorities, the Action Plan advocates that ‘people have equitable and consistent access to a continuum of timely, evidence-informed, and patient-centred pain care and supports across jurisdictions.’

The Institute of Medicine defines patient centredness as ‘providing care that is
responsible of and responsive to patient preferences, needs and values and ensuring that patient values guide all clinical decisions. Despite this concept in multiple clinical guidelines, patient-centred care is poorly implemented. Shared decision-making (SDM) is considered the key to operationalise patient-centred care. SDM is a process by which clinicians collaborate with patients to provide high-quality care based on best evidence and the patient’s needs, values and preferences.

Implementing SDM in clinical practice is a top priority for patient partners with chronic musculoskeletal (MSK) pain (ie, the most prevalent category of chronic pain conditions). A systematic review of SDM interventions for chronic MSK pain reports disappointing results on decision-related and patient outcomes compared with other conditions. The methodological quality of the design and development processes of these interventions was not assessed. Several publications highlight the low quality of these processes for many current SDM interventions leading to potentially biased results. High-quality SDM interventions must determine their effects on the attributes related to the decision-making process in populations with chronic pain.

International standards exist to develop high-quality SDM interventions. According to the DEVELOP-Tools, the first step to develop high-quality SDM interventions is to understand potential users (ie, Canadians with chronic pain) and their needs. To achieve this understanding, high-quality decisional needs assessments based on the Ottawa Decision Support Framework (ODSF) are required. To our knowledge, no study assessed decisional needs of Canadians with chronic pain.

The COVID-19 pandemic has laid bare the vulnerability of people with chronic pain. The pressure on the healthcare system to respond to the pandemic has led to negative impacts and disruption of care pathways and management options for Canadians with chronic pain. To achieve the implementation of patient-centred care in Canada using SDM, it is timely to survey Canadians living with chronic pain to understand their decisional needs.

2. Assess the decisional needs (ie, decisional conflict and decisional regret) of Canadians with chronic pain related to diagnostic and management options.

3. Determine the prevalence and factors associated with clinically significant decision conflict.

4. Determine the prevalence and factors associated with decisional regret.

Conceptual underpinnings

To develop high-quality SDM interventions, we rely on the International Patient Decision Aids Standards. A recent update resulted in a conceptual proposal for a development process based on iterative cycles consisting of three elements: (1) understanding the needs and context of users, (2) developing and refining the protocol and (3) observing users interact with the prototype. The DECIDE-PAIN study is the first element of this development process, hereby assessing decisional needs for Canadians with chronic pain.

To guide our data collection to develop high-quality SDM interventions, it is important to rely on a robust conceptual framework. Our decision needs assessment relies on the ODSF. The ODSF is a theory-based framework developed to guide researchers in assessing patients’ decisional needs. This framework proposes that some factors or components of the decision (ie, decisional needs) can adversely affect the quality of the decision. This can negatively influence the patients’ behaviours (eg, adherence to the chosen option is reduced) or can lead to negative emotions (eg, regret, blame). Finally, these consequences can influence healthcare utilisation (overuse, underuse or misuse). To determine if decisional needs are met, researchers evaluate decisional conflict. An update of the ODSF refined its content and resulted in eight decisional needs core components with multiple manifestations: (1) difficult decisional type and timing, (2) unreceptive decisional stage, (3) decisional conflict, (4) inadequate knowledge, (5) unrealistic expectations, (6) unclear values, (7) inadequate support and resources to make and implement the decision and (8) personal and clinical needs.

METHODS AND ANALYSIS

Aims

This study is embedded within a larger research programme with the overarching goal to implement patient-centred care and SDM for chronic pain in Canada. The DECIDE-PAIN study aims to assess the decisional needs of Canadians with chronic pain to inform the development of SDM interventions for this population.

The specific objectives of the study are to:

1. Identify the most difficult decisions faced by patients with chronic pain related to their diagnostic and management options (ie, diagnostic tests, pharmacological treatments, non-pharmacological and rehabilitation approaches).

2. Assess the decisional needs (ie, decisional conflict and decisional regret) of Canadians with chronic pain related to diagnostic and management options.

3. Determine the prevalence and factors associated with clinically significant decision conflict.

4. Determine the prevalence and factors associated with decisional regret.

Patient and public involvement statement

Our objectives are aligned with the Strategy for Patient-Oriented Research (SPOR) by enhancing patient’s healthcare experience and improving health outcomes, and engaging patients as partners in the project. Patient needs, experiences and perspectives are incorporated in the study design, analysis, interpretation and dissemination. We will report two measures of patient engagement. We will use the Patient-Oriented Research Level of Engagement Tool to measure the extent to which our survey meets the definition of patient-oriented research. We will use the short version of the Patient Engagement In Research Scale to measure the patients’ perspective of the quality if their engagement. The GRIPP2-short form reporting checklist will guide our reporting of patient contributions in the future publications.
Two patient-partners living with chronic pain are part of the steering committee having developed this protocol and are listed as coauthors. One patient partner is also a rehabilitation professional. The patient partners have more than 5 years of experience in health research and have received training by SPOR SUPPORT units in Canada. The patient partners identified the tasks which were most meaningful for them. We discussed and decided appropriate compensation for their time. We will validate the results of the survey with a panel of patients with chronic pain. This panel will include people with no experience with research to have a diversity of perspectives.

Study design and setting
We will conduct an online population-based cross-sectional survey using a pan-Canadian Web panel (Léger Marketing). We will collect self-reported data from Canadians with chronic pain living in Alberta, British Columbia, Manitoba, Newfoundland and Labrador, New Brunswick, Nova Scotia, Ontario, Prince Edward Island, Quebec and Saskatchewan. We will use the STrengthening the Reporting of OBServational studies in Epidemiology (STROBE) combined with the Checklist for Reporting Of Survey Studies (CRES) to report the results.

Participants and recruitment
We will recruit community-dwelling Canadians with chronic non-cancer pain from the largest Canadian-owned market research and analytics company, Léger Marketing (https://leger360.com/). This company maintains a panel of 500,000 active members of Canadian society from the 10 provinces with access to the internet. Participants will include a randomly selected sample of citizens, permanent residents or refugees living in Canada, aged ≥18 years old, with primary chronic pain (eg, low back pain, fibromyalgia, migraine) or secondary pain (eg, postsurgical pain, pain due to structural changes, pain associated with a disease of the nervous system). We follow the definitions of chronic primary and secondary pain from the International Association for the Study of Pain. Participants will need to be able to read, write and understand French or English. We will exclude participants with chronic cancer pain or chronic postcancer treatment pain, which requires specific care pathways and management options. We will use a stratified proportional random sampling based on the population and chronic pain prevalence of each province (see table 1). Léger Marketing will solicit weekly random samples for voluntary participation in our survey until 65,000 invitations sent or until the sample size is reached for each province. Léger Marketing profiled their panelists by characteristics, which allow to efficiently direct-recruit respondents based on our eligibility criteria. Stratified randomisation method was used for this study. Using proprietary panel management software, random sampling is ensured by the following steps: (A) a query is entered into the panel management software based on the eligibility criteria to locate all eligible respondents on our panel and (B) using random sampling software, a random sample is then generated from all eligible respondents and invited to participate in the study. After each solicitation, the next random sample is generated considering the characteristics of the previous participants (ie, province, sex, age and education level) to target future solicitations on profiles to achieve a more representative sampling. Léger Marketing updates the sociodemographic characteristics of the sample frame monthly.

Data collection method and variables
The survey includes a question on language preference (English or French), three sections including the characteristics of participants. The full questionnaire will contain 50 questions and will take an average time for completion of 30 min (online supplemental appendix 1). No standardised questionnaire is available to assess the decisional needs for people with chronic primary and secondary pain. We developed a questionnaire with six domains. Three ODSF core domains (ie, difficult decisional type and timing, unceptive decisional stage and unrealistic expectations) were not included in the questionnaire because the survey method was not an optimal way to collect these data. We also expanded the questionnaire with additional decisional needs from the literature in the field. The list of the variables and measures included in our survey is available in online supplemental material 1. The summary of the validated measurement tools used in our survey is available in table 2. The six domains of the questionnaire and their content are graphically represented in figure 1. Our decisional needs assessment is designed according to the objectives of this study and is composed of the six following domains (figure 1).

Domain 1 covers the difficult decisions that Canadians with chronic pain experienced during medical consultation (eg, obtain a second opinion), regarding the diagnosis (eg, medical imaging), regarding the treatment (eg, adoption of new lifestyle habits and behaviours) and regarding daily life (eg, reduce or stop working) and the

<table>
<thead>
<tr>
<th>Province</th>
<th>Population*</th>
<th>Chronic pain prevalence†</th>
<th>No of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta</td>
<td>4262635</td>
<td>20.6</td>
<td>~216</td>
</tr>
<tr>
<td>Atlantic</td>
<td>2409874</td>
<td>21.9</td>
<td>~130</td>
</tr>
<tr>
<td>British Columbia</td>
<td>5000879</td>
<td>21.8</td>
<td>~269</td>
</tr>
<tr>
<td>Quebec</td>
<td>8501833</td>
<td>15.7</td>
<td>~329</td>
</tr>
<tr>
<td>Ontario</td>
<td>14223942</td>
<td>16.6</td>
<td>~582</td>
</tr>
<tr>
<td>Prairie</td>
<td>2474658</td>
<td>19.6</td>
<td>~120</td>
</tr>
</tbody>
</table>

*From Statistics Canada 2022; †From Schopflocher 2011.
most difficult one and the professional with whom they made the most difficult decision (eg, primary care professional). It is composed of six questions (online supplemental appendix 1).

Domain 2 covers the healthcare needs (eg, access to a family physician, treatment course guidance, better reimbursement of treatment), health consultation needs (eg, more information on rehabilitation options, feel empathy from my healthcare provider, more involved in the decision-making process) and post-pandemic needs (eg, new needs that appeared during the COVID-19 pandemic). It is composed of three questions (online supplemental appendix 1).

Domain 3 covers decisional conflict. It is composed of 17 questions divided into 1 contextual question for recall accuracy and the 16 items of the Decisional Conflict Scale (DCS) (online supplemental appendix 1). The DCS is a standard tool to conduct decisional needs assessment within the ODSF framework. The DCS consists of items designed to elicit information on the five dimensions of decision-making: feeling uncertain, feeling uninformed, feeling unclear about values, feeling unsupported and ineffective decision-making. Each item is rated on a five-level Likert scale (1=strongly agree and 5=strongly disagree).

A continuous decisional conflict score is obtained (between 0=absence of decisional conflict and 100=maximum decisional conflict). A score >25 is related to decisional conflict that reflects ‘a state of uncertainty about the course of action to take’. A

Table 2: Summary of the validated measurement tools used in our survey

<table>
<thead>
<tr>
<th>Measurement tool</th>
<th>Content</th>
<th>Measurement properties</th>
<th>Scoring and interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decisional conflict domain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decisional Conflict Scale</td>
<td>16 items</td>
<td>Reliability: Average Cronbach’s alpha between 0.71 and 0.88 Validity: 0.71 and 0.92 Cross-cultural validation: French, Dutch, Spanish, German, Thai, Japanese, Italian, Portuguese, Chinese, Mandarin/Cantonese, Korean</td>
<td>Each item is rated on a five-level Likert scale. After transformation, global score between 0 and 100. Score &gt;25: presence of decisional conflict. Score ≥37.5: presence of clinically significant decisional conflict.</td>
</tr>
<tr>
<td><strong>Decision regret domain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision Regret Scale</td>
<td>5 items</td>
<td>Reliability: Cronbach’s alpha between 0.81 and 0.92 Validity: 0.81 and 0.92 Cross-cultural validation: Chinese, Japanese</td>
<td>Each item is rated on a five-level Likert scale. After transformation, global score between 0 and 100.</td>
</tr>
<tr>
<td><strong>Decisional needs domain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Preferences Scale</td>
<td>1 item</td>
<td>Validity: 0.73 Cross-cultural validation: Japanese, Spanish</td>
<td>The item is rated on a five-level Likert scale.</td>
</tr>
</tbody>
</table>

Figure 1: Content of the six domains of the questionnaire.

Unmet needs

Domain #2 Health care needs

Domain #3 Conflict

Domain #4 Regret

Domain #5 Decisional needs

Domain #6 Characteristics

Unmet needs

Domain #1 Decisions

Domain #4 Regret

Domain #3 Conflict

Domain #5 Decisional needs

Domain #6 Characteristics

Quality of life
Satisfaction with current health state
Health literacy
Sociodemographic characteristics
Painful body region(s)
Diagnosis
Pain duration

Options
Knowledge
Decision self-efficacy
Anxiety during the decision making process
Other(s) involvement
Role in the decision making process
Elements considered
Valuable outcomes
Treatment and Family burdens

Domain #2 Health care needs

Healthcare utilization needs
Health consultation needs
Post-pandemic needs

Domain #1 Decisions

Most difficult decision
Professional involved in the most difficult decision

Difficult decisions

Figure 1: Content of the six domains of the questionnaire.
score $\geq 37.5$ is related to clinically significant decisional conflict that is positively associated with decisional delay, departure from active treatment, decision regret and nervousness.

The DCS was validated, and its measurement properties were satisfactory in multiple settings such as primary care, specialty care and mental health (eg, average Cronbach’s alpha=0.88). The scale also has cross-cultural validity in French. The DCS is freely available and was translated in twelve languages including French (https://decisionaid.ohri.ca/eval_dcs.html) (table 2).

Domain 4 covers decision regret. It is composed of the five items of the Decision Regret Scale (DRS) (online supplemental appendix 1). The DRS is the standard tool to assess decision regret according to the update of the ODSF. Each item is rated on a five-level Likert scale (1=strongly agree, 5=strongly disagree).

A continuous score of decision regret is obtained (between 0=absence of decision regret and 100=maximum decision regret). This scale shows satisfactory measurement properties in different populations (Cronbach’s alpha between 0.81 and 0.92). This scale has no cross-cultural validation in French. We use the version translated into French for the EXACKTE project. The DRS is freely available in eight languages (not all validated) in https://decisionaid.ohri.ca/eval_regret.html (table 2).

Domain 5 covers decisional needs. It is composed of 17 questions (online supplemental appendix 1). We built two questions with the Control Preferences Scale (CPS), a five-level Likert scale representing the degrees of control (roles) an individual wants to assume when making a health decision: (A) I made the decision (active role), (B) I made the decision after seriously considering my providers’ opinion (active role), (C) my providers and I shared the responsibility for making the decision (collaborative role), (D) my providers made the decision after seriously considering my opinion (passive role) and (E) My providers made the decision (passive role).

This scale shows satisfactory measurement properties (table 2). We use the version translated into French for the IPSDM-SW study.

The other questions include information on knowledge about the options, cognitive-emotional variables, other(s)’s involvement, elements considered during the decision-making, valuable outcomes, treatment and family burden, information needs and format, quality of life, satisfaction with current health state.

Domain 6 covers the characteristics of participants. It is composed of 21 questions (online supplemental appendix 1). Baseline characteristic required by the ODSF includes age, gender, education, marital status, ethnicity, socioeconomic status, occupation, diagnosis and duration of condition, health status, and religion/spirituality. We expanded the domain with supplementary information such as comorbidity, sex at birth, first characters of the postal code, number of people living at home and income.

**Pretesting**

We performed a pretesting on the questionnaire content and its readability with a panel of seven international experts in decisional needs assessment and two patient partners to assess its face validity. We performed a pilot test in October 2022 with a sample of 50 random participants (~3% of the sample) who meet the inclusion criteria. We collected the time to complete the questionnaire during this pilot test and we determined the average time.

**Survey administration and confidentiality**

Léger Marketing will send an email invitation to the random samples of eligible participants including a cover letter describing the aim of the survey. Interested participants will log to their panel membership account to consent and begin the questionnaire. Léger Marketing will transform each panel membership account into a unique code to ensure confidentiality and minimise nonresponse. Participants will have access to the questionnaire for 3 weeks. A reminder will be sent weekly to solicited participants. All participants will complete the questionnaire once. The participation will be free and voluntary but, participants will receive a standardised compensation from Léger Marketing as compensation for the time required to complete the survey. This compensation consists of 1200 LEO points from Léger Marketing which can be redeemed for gift cards or prepaid VISA/Mastercard or donated to charity.

To minimise missing data, participants will have to respond to all questions to validate and send back the questionnaire. The participants will be able to respond ‘I don’t know’ or ‘prefer not to answer’ for ethical considerations. Participants will not be able to go backward to review or change their answers.

**Survey quality**

**Respondent selection issues**

We will use a stratified proportional random sampling to minimise the sampling error. In 2020, 94% of the Canadian population had a household internet access. The Léger Marketing panel is representative of the Canadians with access to the internet and is updated monthly to control the quality of the panel and limit the coverage error.

**Response accuracy issues**

Because of the length of our survey, measurement error due to respondents will be the main risk of poor accuracy. Measurement error due to respondents covers several aspects such as lack of participant motivation, unclear questions, biased question wording, demanding more detailed information than respondents can be expected to know or remember as well as order effects (question order effects or response order effects), and fatigue effects. We will set up several strategies to obtain the most valuable data.
Development process and pretesting
We will use rigorous question development procedures to limit question wording effects. We will label each category of ordinal scales to make the meaning of each category clearer. We will use 5–7 scale level for bipolar ordinal scales and 4–5 level for unipolar ordinal scales. We will use strategies such as building the important points in the question to improve the comprehension and increase response rate. The pretesting and pilot test will identify variables likely to have missing data (ie, ‘I don’t know’ or ‘I prefer not to answer’).

Questionnaire completion
We will randomise the order of certain questions within domains to limit question effects. We will randomise the order of the response options when we propose a list of alternatives to limit response order effects. Participants will be able to stop and save the questionnaire at any time and resume later to limit the loss of accuracy due to fatigue or due to pain increasing because of the cognitive activity or prolonged seated posture.

Data cleaning
We will remove the questionnaires with a time to complete less than ten minutes to limit the loss of accuracy due to questionnaire length. To identify and remove poor responses, we will also include quality control questions throughout the survey. These questions will ask participants to select a particular response option to make sure they are carefully reading the question and response options. For example, ‘to make sure we are capturing your responses correctly, please select ‘I don’t know’.’ We will ask the participants ‘How accurately do you remember this consultation?’ rating on a 0–10 Visual Analogue Scale to grasp the recall bias.

Survey administration issues
Each participant will have to log into their membership account to obtain a unique code. This strategy and the use of computerised format will limit multiple response and postsurvey error.

Statistical analysis
The statistical analysis sequence is presented in figure 2. We followed best practices for our plan analyses using the STRengthening Analytical Thinking for Observational Studies initiative recommendations.

Initial data analyses
Metadata
An Excel file will contain metadata to understand the context related to data collection in order to interpret it appropriately. We will report variable names, possible response options, missing data coding, measure unit, measure method and known associations with other variable(s).

Data cleaning and screening
We will verify collected data for outliers and assess the normality of continuous variables with the Shapiro-Wilk test and data visualisation (Quantile-Quantile plot).

Handling of missing data
We will handle missing data for the decisional needs (domain #5) and the characteristics of participants (domain #6). To make the process reproducible and transparent, we will use the treatment and reporting of missing data in observational studies framework. We will determine missing data pattern with Rubin’s rules (if a single incomplete variable) or causal diagrams (if multiple incomplete variables). We will use fraction of

Statistical analyses sequence
1. Weightings depending on the missing data pattern, nonresponse characteristics, and differences between participants and target population characteristics
2. Missing data: method selection depending on the missing data pattern
3. Objective 1: Descriptive analysis
4. Objective 2: Descriptive analyses
5. Objective 3: Descriptive (domain #3) and multivariable (domains #3, 5, and 6) analyses
6. Objective 4: Descriptive (domain #4) and multivariable (domains #4, 5, and 6) analyses
7. Sensitivity analysis

Figure 2 Statistical analysis sequence.
missing information to determine whether a multiple imputation method could reduce bias and/or increase the result precision comparing to a complete-case analysis.\textsuperscript{66} We will finally determine the best multiple imputation approach to apply.\textsuperscript{61}

**Data generalisability**

Depending on the missing data pattern, non-response characteristics, and differences between participants and target population characteristics, we could apply weightings on the six domains.\textsuperscript{62} In this case, we will keep the weighted dataset for our analyses.

**Statistical analyses**

**Characteristics of our sample**

We will use the variables of the domain #6 (characteristics of the participants) to describe our sample. For the continuous variables, we will report means±SD for normally distributed variables and medians and IQRs for non-normally distributed variables. Five open-ended questions will collect information on age, diagnosis, the first three numbers of postal code, number of people in the household, and symptom duration. We will use the same descriptive analyses to address these variables.

**Objective 1: descriptive analysis**

We will report the difficult decisions according to the four categories of domain #1: (A) regarding medical consultation, (B) regarding the diagnosis, (C) regarding the treatment and (D) regarding daily living. All these variables will be categorical. We will use percentages and absolute numbers of cases to describe these difficult decisions.

We will also report percentages and absolute numbers of cases of the most difficult decisions expressed by participants. We will categorise them according to the four categories described above and report the average DCS score for each category as well as the proportion of participants with a clinically significant decisional conflict (DCS score ≥37.5) for each category.

**Objective 2: descriptive analyses**

We will describe the variables from domains #2, 3, 4 and 5. For domain #2 (healthcare needs), we will report percentages and absolute numbers of cases because all variables will be categorical. For domain #3 (decisional conflict), we will report the appropriate descriptive analyses according to the normality of this continuous variable. These descriptive analyses will include the total DCS score as well as the score for each DCS dimension. For domain #4 (decision regret), we will report the appropriate descriptive analysis according to the normality of this continuous variable. This analysis will focus on the total DRS score. For domain #5 (decisional needs), we will report the proportions of participants based on their assumed and preferred role according to the CPS. From these data, we will process them to determine the proportions of participants with congruence between their preferred and assumed role. We will report the appropriate descriptive analyses for the remaining variables.

**Objective 3: descriptive analysis**

To determine the prevalence of clinically significant decision conflict, we will present the proportion of participants with a DCS score ≥37.5.

**Multivariable analysis**

From the DCS score ranged between 0 and 100, there is a validated threshold of clinically significant decisional conflict (DCS score ≥37.5).\textsuperscript{36} We will dichotomise the decisional conflict variable in presence or absence of clinically significant decisional conflict. To identify predictors of clinically significant decisional conflict, we will perform a binary logistic regression analysis. Another DCS threshold exists to detect decisional conflict (DCS score >25). We will dichotomise the decisional conflict variable in presence or absence of decisional conflict. To identify predictors of decisional conflict, we will perform a binary logistic regression analysis. The dichotomisation of a variable implies a loss of information.\textsuperscript{63} To ensure a good description of the decisional conflict, we will also process this variable as continuous and perform a multiple linear regression analysis.

**Objective 4: descriptive analysis**

To determine the prevalence of decision regret, we will present the proportion of participants with a DRS score ≥1. Depending on the DRS scores distribution, we will present the proportion of participants with a DRS score ≥1 (dichotomisation between no regret and any level of regret) or the proportion of participants with no regret (DRS score=0), mild regret (DRS score between 1 and 25) and moderate to high regret (DRS score >25).\textsuperscript{64}

**Multivariable analysis**

There is no validated threshold to interpret DRS score. Because this score is a continuous variable, we will identify predictors of decision regret with a multiple linear regression analysis.

**Sensitivity analysis**

We will report 95\% CI for all results. We will perform the statistical analyses on R. If we apply a multiple imputation of missing data, we will perform a sensitivity analysis based on a complete case analysis.\textsuperscript{58} This approach will allow us to test the robustness of our approach and understand why the results between the two approaches are different if they are different.\textsuperscript{65}

**Sample size**

We calculated the required sample size to respond to the third objective (ie, binary logistic regression). The common rules of thumb of 10, 15 or 20 events per variable showed limitations that required the development of context-specific sample size calculation.\textsuperscript{66–68} To overcome these limitations, Riley \textit{et al} proposed a method.\textsuperscript{69} We fixed the following context-specific information: prevalence of the outcome=0.10 (ie, prevalence of clinically significant decisional conflict in primary care),\textsuperscript{70} Nagelkerke’s R\textsuperscript{2}=0.15\textsuperscript{69} and number of predictors=30.\textsuperscript{69} We used
the pmsampsize package for R developed by Riley et al and obtain a sample size of 1646 participants.

Anticipated impact
The four objectives of this survey will add new, unique and relevant information contributing to the implementation of the Action Plan for Pain in Canada. We will identify the decisions that require SDM interventions and the key healthcare professionals to empower and train to deliver patient-centred care. We will determine unmet decisional needs that explain decision conflict and/or decision regret. These needs will be ideal targets for developing SDM interventions. With its national scope, our decisional needs will lead to cross-jurisdiction collaboration to adapt the future intervention with a quality improvement perspective.

Limitations and strengths
Our survey presents some limitations. Our survey assesses the decisional needs of Canadians from the 10 Canadian provinces but limits the generalisability to the three Canadian territories. However, 96% of the Canadian population lives in the 10 provinces. The territories have specific issues regarding access to care and require cultural adjustment for SDM interventions.1 Our survey requires access to the Internet which may result in selection bias. Vulnerable individuals such as homeless, people living with lower income may be under-represented. However, in 2020, 94% of the Canadian population has a household internet access.49

Our survey presents some strengths. Our survey is grounded in patient-oriented methods with the use of two measures of patient engagement and the use of a reporting checklist for future publications on the survey results. Our survey is informed by a theory-based framework (ie, the ODSF) to collect relevant and high-quality data. Our survey will collect multiple difficult decisions across the care pathways (ie, primary care, secondary care, tertiary care, rehabilitation care or complementary and complementary medicine care).

ETHICS AND DISSEMINATION

Ethics
We obtained the ethics approval from the Research Ethics Board of the Research Centre at the Centre Hospitalier Universitaire de Sherbrooke (project #2022-4645). We will conduct the survey following the Canadian Personal Information Protection and Electronic Documents Act and the Marketing Research and Intelligence Association’s Charter of Respondent Rights. Participants will consent to participate in the study. All participants will have to give their consent before their participation and may request to be removed from the study at any time. Participants will also have to consent to Léger Marketing’s terms of use and privacy policy.

Knowledge mobilisation and capacity-building
We will disseminate the study findings through several mechanisms to reach different target audiences. We will disseminate the results to the scientific community through publications in peer-reviewed journals and presentations at provincial, national and international conferences in the fields of SDM and chronic pain. We will disseminate the results to patient communities through the development of graphical summaries and presentations for patient organisations. We will disseminate the results to a broader audience through social media posts and through an online public forum coanimated by the patient partners. Quebec SPOR unit (ie, Unité Soutien SSA) will support our team in organising this forum.

The project represents an opportunity for capacity-building. Supported by the SPOR units, we will propose to students to complete the three modules of the patient partnership curriculum (ie, basis of patient partnership, patient partnership in research and consolidate the patient partnership), one module on co-construction research curriculum and one module on patient engagement evaluation curriculum. The patient partners will also complete these modules.

CONCLUSION
This pan-Canadian survey will assess the decisional needs of Canadians with chronic pain regarding the diagnosis and management of their condition. This information is fundamental to developing innovative SDM interventions. This decisional need assessment will also contribute to the implementation of a national strategy for patient-centred pain care.

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REFERENCES
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52 Wolf C, Joyce D, Smith T, et al. The SAGE handbook of survey methodology. 1 Oliver’s Yard, 55 City Road London EC1Y 1SP.


67 Ogundimu EO, Altman DG, Collins GS. Adequate sample size for developing prediction models is not simply related to events per variable. J Clin Epidemiol 2016;76:175–82.


