# DEVELOPMENT AND CONTENT VALIDATION OF CLINICAL VIGNETTES TO MEASURE DECISION-MAKING PREFERENCES ALONG THE CANCER CONTINUUM IN ADULT PATIENTS

## (ADAPTATION OF THE AUTONOMY PREFERENCES INDEX)

# DEVELOPMENT AND CONTENT VALIDATION OF CLINICAL VIGNETTES TO MEASURE DECISION-MAKING PREFERENCES ALONG THE CANCER CONTINUUM IN ADULT PATIENTS (ADAPTATION OF THE AUTONOMY PREFERENCES INDEX)

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TITLE: Development and Content Validation of Clinical Vignettes to Measure Decision-Making Preferences Along the Cancer Continuum in Adult Patients (Adaptation of the Autonomy Preferences Index)

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## Lay Abstract

We developed and tested clinical vignettes to better understand how involved adult patients with cancer want to be when making decisions about their care. These vignettes cover different stages of cancer care, from prevention to end-of-life, addressing gaps in existing instruments that mainly focus on acute conditions and short-term decisions.

Using both quantitative and qualitative methods, we asked ten experts, including healthcare providers and patients, to assess the relevance and clarity of the vignettes. Based on their feedback, we revised the vignettes to ensure they accurately represent real-life cancer care decisions.

The final set of vignettes demonstrated strong content validity, meaning they effectively capture patient decision-making preferences throughout the cancer journey.

This instrument can help healthcare providers engage in shared decision-making, ensuring care aligns with patients' values and preferences. Next step is to pilot the instrument in clinical settings to test its effectiveness in improving cancer care.

## Abstract

**Background**: We developed and validated clinical vignettes to assess decision-making preferences (DMP) among adults with cancer across the cancer care continuum. We aimed to adapt the Autonomy Preferences Index (API) to better reflect the complexities of cancer care, incorporating scenarios that span from prevention to end-of-life care. Existing tools often focus on acute conditions and short-term decisions, leaving a gap in addressing long-term cancer-related decision-making. **Methods**: Using a mixed-methods approach and following COSMIN methodology, we designed clinical vignettes around the cancer care continuum (CV-Ca) to represent real-life cancer care decisions. We then evaluated their content validity by having ten experts rate their relevance and clarity to obtain a Content Validity Index (CVI). Additionally, we conducted semi-structured interviews to gather qualitative insights. Based on this expert feedback, we revised the CV-Ca to ensure they aligned with current clinical practice and effectively captured the complexities of cancer decision-making. **Results**: The final CV-Ca demonstrated strong content validity, with improved CVI ratings after revisions. By using both quantitative and qualitative methods, we comprehensively assessed the vignettes and ensured their relevance and clarity. This study is the first to create vignettes that measure DMP across the entire cancer continuum, addressing a significant gap in existing tools. **Conclusions**: The validated CV-Ca can potentially provide healthcare providers with a reliable instrument to assess DMP in patients with cancer throughout their care journey. This tool supports shared decision-making, helping clinicians ensure that care aligns with patients' values and preferences. It has significant implications for improving patient-centered care in oncology, potentially enhancing treatment adherence, satisfaction, and outcomes. Future steps will involve piloting the tool in clinical settings and further assessing its reliability and construct validity.

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## List of Abbreviations

SDM: Shared Decision-Making

DMP: Decision-Making Preferences

DM: Decision-Making

API: Autonomy Preference Index

ISP: Information-Seeking Preferences

CV-Ca: Clinical Vignettes around Cancer Care Continuum

CVI: Content Validity Index

I-CVI: Item Level-Content Validity Index

S-CVI/Ave: Scale Level-Content Validity Index average method

Q#: Question #

CV#: Clinical Vignette #

HiREB: Hamilton Integrated Research Ethics Board

## Declaration of Academic Achievement

The following declaration confirms that Yetiani Roldan, Dr. Maura Marcucci, Dr. Julie Nguyen, Dr. Laura Duncan, Moizza Zia UI Haq, and Jill Dumaresq contributed to the elaboration of the study protocol, as well as revising, editing, and writing the document. Yetiani Roldan coordinated the study, recruited participants, collected data, conducted data analysis, and drafted the first version of this manuscript. Moizza Zia UI Haq assisted with the qualitative component of the study and contributed to the qualitative analysis.

*Development and Content Validation of Clinical Vignettes to Measure Decision-Making Preferences Along the Cancer Continuum in Adult Patients*

*(Adaptation of the Autonomy Preferences Index)*

## Chapter 1. Background and Rationale

Shared decision-making (SDM) is a process that requires healthcare providers and patients or a proxy decision-maker to interact and mutually engage and participate in making healthcare choices based on clinical evidence that balances risks and expected outcomes with patient preferences and values. [1,2] Unlike physician-led or patient-led decision-making, SDM promotes a collaborative approach between patients and physicians,[3] leading to improved treatment adherence and patient satisfaction, resulting in better health outcomes. [1,4–7] SDM represents a key component of patient-centered health care. However, the literature has shown that patient preferences for involvement in decision-making (DM) vary and are influenced by demographic variables (age, education, sex), experience, severity and knowledge of the disease; diagnosis, health and physical status, current quality of life, and previous experiences with health care practitioners.[4,8,9]

While research has shown SDM to be associated with positive outcomes, in parallel, other studies have found that the level of involvement in the DM process is associated with a sense of regret and self-blame if the chosen treatment does not lead to the desired outcome. [10–12] This can make SDM a sensitive and challenging process, when treatment decisions can have life-altering consequences, particularly in oncology. SDM across the cancer care continuum (prevention, detection, diagnosis, treatment, recurrence surveillance, and end-of-life care) [13] requires, at each stage, complete understanding of the benefits, harms, and uncertainty of the consequences among alternative courses of action, as well as acknowledgement and support of the patients' values and preferences (e.g., prioritizing quality of life or longevity). [12,14]

Although SDM has the goal to deliver patient-centered care, even when it comes to decision regarding cancer, patients might have different preferences and perspectives regarding the DM

process. A recent systematic review revealed a substantial difference between the role patients with cancer wished to assume in the DM process and their actual experiences. In cases where patients desired SDM, nearly half (median of 47% across studies) did not engage in this process despite their preference. [15] This finding underscores the challenge of aligning patients' desired level of involvement in DM with their actual experiences within clinical practice. It emphasizes the need for healthcare providers to understand the patients' expectations regarding their involvement in this process beforehand. [2] Moreover, patient's preferences for involvement and seeking information are influenced by sociodemographic (e.g., age, living situation, employment) and health factors (e.g., physical and health status, quality of life) which may change along the cancer care continuum. Therefore, it is crucial to dynamically elicit patients' expectations about the DM process throughout their cancer journey. [12]

Through a targeted literature search we identified a systematic review published in 2011 that reported and evaluated 32 instruments measuring DM-related aspects, including processes and outcomes. [16] Among these, eight instruments were classified as measuring decision antecedents, i.e., preferences for DM, with the Autonomy Preference Index (API) [17] being one of them. The API is a self-administered 23-item instrument consisting of two subscales: decision-making preferences (DMP) and information-seeking preferences (ISP). The DMP subscale includes general questions/items and three clinical vignettes (CV) illustrating clinical scenarios of acute illness presentations with increasing severity (refer to Appendix 1 for a detailed API description).[17] Although initially developed for patients in a primary care setting, the API has been used and validated in several specific settings and populations, including patients with mental illness, asthma, and chronic pain, showing good psychometric properties.[1,18–23] In some of these studies, the API has been partially adapted by modifying the clinical scenarios in the vignettes to better match the condition of their target population.[1,19] Indeed the flexibility of vignettes makes the API adaptable to specific clinical contexts, enhancing its relevance.

Vignette-based instruments (also known as factorial surveys) have been shown to be effective in eliciting patients' preferences and values. Factorial vignette methodology, studied across various disciplines, allows for a comprehensive examination of the intricacies involved in the decision-making process. [24–28] These instruments employ vignette narratives with a practical manipulation of case characteristics by introducing variables to explore decisions, beliefs, and attitudes of the participants. [29–32] The effectiveness of this approach lies in its capacity to simulate real-world scenarios, mirroring those real-life healthcare decisions that patients face while considering the trade-offs involved. [33] Compared to traditional surveys, factorial surveys employ structural elements that target the respondent's context, focusing their attention to content variations between vignettes and removing variability resulting from changing the approach to questioning. [29]

While the general DMP and ISP scales within the API encompass factors commonly encountered in diverse clinical settings, the clinical scenarios depicted in the original vignettes predominantly focus on acute conditions and decisions with mostly short-term implications. This raises concerns regarding the suitability of these scenarios for assessing DMP in medical decisions associated with cancer, which often entail long-term implications and life-altering consequences throughout the cancer care continuum, potentially evoking distinct emotional responses and behaviours.

## Study Objectives

The objectives of this study were to develop clinical vignettes that measure DMP around the cancer care continuum (CV-Ca) and to evaluate their content validity following recommended methodological standards.

# Chapter 2. Methods

We followed COSMIN Study Design checklist for Patient-reported outcome measurement instruments and COSMIN Methodology for Evaluating the Content Validity of Patient-Reported Outcome Measures. [34] [35]

We submitted and received approval from the Hamilton Integrated Research Ethics Board (HiREB), project approval number is 17124.

## Study Design and Framework

Our proposal involved developing alternative vignettes to the API, specifically tailored to assess individuals' DMP regarding medical choices related to cancer care, encompassing a wide range of clinical scenarios spanning the entire spectrum of the cancer care continuum. It also involved assessing the content validity of the developed CV-Ca.

Content validity refers to the extent to which the sampled items of an instrument adequately represent the construct to be measured. Content validation is essential in the development and testing process of any newly developed instrument and represents a foundational step that must be fulfilled before evaluating other types of validity, such as construct and criterion validity. [36–38]

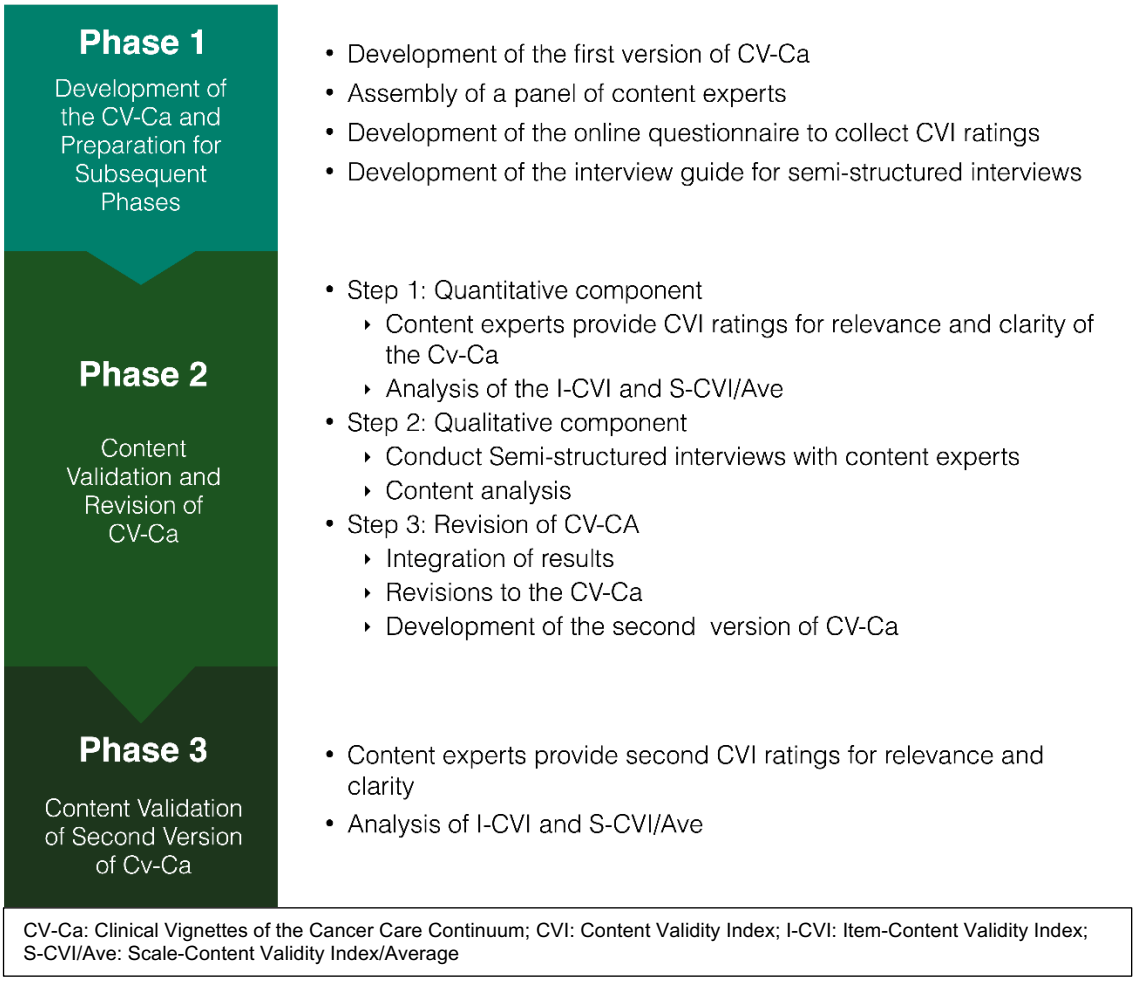
In developing vignettes and evaluating content validity of the CV-Ca, we adopted a multi-phased approach which includes an explanatory sequential mixed methods design, [39,40] following a process similar to that used by St. Marie et al., 2021. [41] To quantitatively assess content validity we adopted the Content Validity Index (CVI), which quantifies the extent to which a measurement instrument adequately covers the intended domain or content. It relies on ratings from content experts regarding the relevance and clarity of the instrument. [37,42] The qualitative component consisted of conducting semi-structured interviews with the content experts. These interviews provided insights into the rationale behind the experts' ratings for the CVI items.

[43]During the interviews, the experts evaluated the comprehensiveness (the extent to which the instrument covers relevant content that applies to the target population) and comprehensibility (level of understanding and interpretability of the content, instructions, or questions) of the CV-Ca.

We employed a multi-step, three-phased approach to comprehensively address the research objectives (Figure 1). [41,44] In Phase I, the research team developed the first version of CV-Ca and prepared for the subsequent phases. Phase II unfolded in three sequential steps: Step 1 involved rating and computing the CVI, in Step 2 we conducted semi-structured interviews with the content experts, and in Step 3 the research team created a revised second version of the CV-Ca. Phase III encompassed a second round of ratings by the experts to reassess the CVI of the revised CV-Ca.

For the development of the first version of the CV-Ca we relied on the research teams' collective experience and expertise. Our team consists of six members: two clinicians with ample clinical and health research experience–one specialized in gynecologic oncology and the other in perioperative medicine, both with experience providing care for patients with cancer; a measurement expert with extensive experience in the development and validation of instruments; a qualitative researcher and skilled interviewer; a patient partner with a strong background in human resource and communication; and a pediatrician by training with experience in health research methodology.

**Figure 1. Study flowchart**




CV-Ca: Clinical Vignettes of the Cancer Care Continuum; CVI: Content Validity Index; I-CVI: Item-Content Validity Index; S-CVI/Ave: Scale-Content Validity Index/Average

## Phase I. Development of CV-Ca and Preparation for Subsequent Phases

To ensure validity, a vignette-based instrument should possess two defining features.[29,33] The first one, *vignette equivalence*, consists of the inclusion of up to three structural elements within the context of the research study: 1) experimental aspects (specific components within the vignettes that are intentionally modified to assess their impact on the variables being studied), 2) controlled aspects (components that remain consistent and unchanged across all vignettes to remove unnecessary variability), and 3) contextual aspects (minor changes in vignettes to enhance their realism without influencing the variables being studied). The second feature

pertains to *response consistency*, which means that both the items and response options are standardized for all participants across all vignettes. [29,33]

We created the first version of the CV-Ca using a reflective model within the framework of classical test theory, which is a statistical approach employed to examine the relationship between the latent constructs and their observed indicators. In this model, the indicators (observable variables) are reflective of the latent construct, so changes in the latent construct are expected to cause changes in the measured indicators. Consequently, the indicators that share a common cause or latent variable, which represents the construct being measured, are expected to be highly correlated. [45,46]

The research team applied their content and methodological expertise, clinical experience, and best-practice guidelines around the cancer care continuum to develop the clinical vignettes. We followed guidelines from healthcare organizations or societies such as the World Health Organization,[47] Canadian Cancer Society, [48] Cancer Care Ontario, [49] the American Society of Clinical Oncology, [50] the National Cancer Institute, [51] and the National Institute for Health and Care Excellence (NICE) [52] to ensure coverage of key stages, from prevention to end-of-life care, including detection, diagnosis, treatment, recurrence surveillance, and palliative care. We chose the case scenarios based on the latest global cancer incidence statistics. [53,54] This approach ensured that the clinical vignettes (CV), along with their associated questions (Q), accurately mirror current practice and the real-life decisions patients may most frequently encounter along the cancer care continuum.

The original API included three vignettes, each tied to three questions. In contrast, when developing the CV-Ca we did not follow any restriction on the number of CVs, or the questions linked to them. Having additional items or questions at a development stage, even if some may appear redundant, ensures comprehensive coverage of the construct being measured, reducing

the risk of overlooking important domains. Additionally, it provides a buffer against potential item elimination during subsequent psychometric analysis.[55,56] We developed six CVs representing decisional moments covering the full spectrum of the cancer care continuum, and three questions associated with each vignette. Appendix 2 contains the first version of the CV-Ca.

As part of Phase I, we identified and invited 10 experts who met eligibility criteria to be members of the panel of content experts (see Participants section). In parallel, we developed the questionnaire form that was used to collect data on demographic characteristics of the content experts, and CVI ratings on the newly developed CV-Ca.

Additionally, we developed the interview guide that we used for the semi-structured interviews. These interviews aimed to understand the rationale behind the experts' CVI ratings and to gain insights into the comprehensiveness and comprehensibility of the instrument. We also crafted questions to assess how well the experts understood the CV-Ca content, the questions linked to each vignette, and the instructions to answer the questionnaire. Appendix 3 contains the interview guide.

## Phase II. Content Validation and Revision of CV-Ca

During Phase II, we followed a three-step sequential explanatory approach to assess the content validity of the first version of the CV-Ca. [57,58]

### Step 1. Quantitative Component

We sent an online questionnaire to the content experts, who answered it independently. In this questionnaire, we asked them to provide ratings on relevance and clarity for each of the questions using a 4-point scale, with 1 indicating 'not relevant' or 'not clear' and 4 indicating 'extremely relevant' or 'extremely clear'. We used these ratings to compute the CVI to assess content validity of the CV-Ca at both item and scale levels.

The Item-level CVI (I-CVI), represents the CVI at the question level, while the Scale-level CVI/Average method (S-CVI/Ave) is calculated as the average of the I-CVI scores for all items, both by vignette and across all vignettes. [37] This is approach is commonly used in the assessment of content validity at the item- and scale-level, particularly in survey-form instruments,[37,38] and more recently, in studies assessing content validity within vignette-based instruments. [41]

To calculate the I-CVI, we summed the number of experts who rated the questions ≥ 3 divided by the total number of experts, providing the proportion of agreement regarding content validity. We obtained the S-CVI/Ave by summing the I-CVI scores divided by the number of items (questions), calculating this average for each vignette and across all vignettes. [37,42,56] Following recommendations by Polit et al 2007, [37] we considered content validity scores as excellent when they were ≥ 0.78 for I-CVI and ≥ 0.90 for S-CVI/Ave. We revised questions and vignettes with scores below these thresholds. [37,38,59]

It is important to note that we did not assess CVI for the clinical scenarios. Instead, we considered that the ratings for relevance and clarity for each question would inform of any inconsistencies or potential missing information, as the questions are directly related to the scenarios. To complement this approach, the qualitative component in the next step was crucial for assessing the content validity of the clinical scenarios.

### Step 2. Qualitative Component

After the experts completed the online questionnaire with the CVI ratings, we conducted online semi-structured interviews via Zoom, using the interview guide previously developed, to elicit the content experts' opinions concerning potential gaps or redundancies in the case scenarios. Additionally, the experts had the opportunity to elaborate on the rationale behind their CVI ratings. With these questions, we aimed to explore aspects such as the potential for confusion

or misunderstanding of the vignettes, the alignment of scenarios with real-life patient experiences across the cancer care continuum, and the comprehensive representation of all stages within the continuum.

#### Step 3. Revision of the CV-Ca

Following the integration of the quantitative and qualitative results, we synthesized the findings of the content validation process into a comprehensive interpretation. This synthesis enabled us to identify and implement necessary adjustments intended to enhance the content validity of the CV-Ca, developing the second version of the CV-Ca

## Phase III. Content Validation of Second Version of CV-Ca

The content experts completed a second online questionnaire providing ratings for relevance and clarity for the second version of the CV-C and assessed content validity using the CVI, as previously described. If necessary, we made additional modifications to the CVs. We considered the results of this second assessment as final, with the CV-Ca obtained from these last revisions being primed for inclusion in an adapted API (replacing the original vignettes) to undergo further validation as a whole instrument.

## Participant Recruitment

We assembled a panel of content experts using a purposeful sampling method. To be considered experts and be eligible for the study, potential participants had to meet one of the following criteria: adult individuals who based on age or other criteria have been or could potentially be invited to participate in cancer screening; adult individuals with a history of cancer, whether active (‘patients’) or with a history; adult individuals who have cared for a friend or family member with a history of cancer (‘caregivers’); or providers of cancer care (e.g., patient navigators, primary care physicians, physicians of relevant specialties including but not limited

to oncologists and hematologists, allied healthcare professionals, nurses). All participants were required to understand and speak English language and have access to a computer or tablet with internet connection. Allowing for remote participation, we had no geographical restrictions, allowing participants to be local, national, or internationally based. We aimed to include experts whose participation in the content validation process would ensure that the CV-Ca accurately reflects real-life clinical scenarios, covering the full spectrum of the cancer care continuum, while also promoting diversity and independence of opinions. We identified potential participants primarily through existing connections and word-of-mouth. Healthcare providers on the primary research team, as well as participants, assisted in identifying patient participants.

We reached out to potential participants in person and via email, providing them with an informative letter that outlined the study's description, objectives, and overview of the procedures. Once they agreed to participate and become part of the panel of content experts, participants signed the consent form either by pen or digitally and returned the signed informed consent form in person or via email.

## Data Collection

We collected quantitative data through questionnaire forms utilizing the LimeSurvey platform. The questionnaire had two sections. The initial section gathered data on the demographic characteristics of the content experts (i.e., practice degree, years in clinical practice, time from cancer diagnosis, sex, gender, and age). The second section focused on collecting ratings for the CVI assessment of the CV-Ca.

We collected qualitative data through semi-structured interviews conducted via Zoom, through the McMaster campus-wide license. We asked participants to consent to record the interviews in video and audio format and an audio transcript was generated. We stored the data in a

secure server with password-protected access that will remain for ten years before being destroyed.

## Confidentiality

All information we collected was stored on a secure server and kept strictly confidential. We can only access the database with password-protected access systems and only the research team has access to it. Any data we generated because of the study, was available for inspection on request by the participating researchers, Hamilton Integrated Research Ethics Board (HiREB), and regulatory authorities.

## Analysis

### Quantitative Analysis

We summarized demographic characteristics data and CVI scores using descriptive statistics, with mean (SD) for continuous variables and frequencies (%) for categorical variables. We rated and scored the I-CVI for all questions with the following formula: number of experts rating an item ≥3 / the total number of experts. And the S-CVI/Ave for each vignette and across vignettes with the following formula: sum of I-CVI scores/number of items; as previously described in Step 1 and Step 2 of Phase II, and then descriptively compared the results. We expected the second version to have higher CVI scores. Analysis was done with SPSS software.

### Qualitative Analysis

Two reviewers independently followed a structured process for content and thematic analysis. [60] We chose to combine the two methods to ensure coverage of predefined elements or criteria within the instrument. [61]

Through content analysis, we focused on experts' opinions regarding the extent of coverage of DM across the cancer care continuum, the comprehensiveness and comprehensibility of the

instrument. Using thematic analysis, we explored and understood the nuances, emerging themes, or implicit meanings within the interview data that helped explain the CVI ratings.

Two reviewers, independently, read and re-read the interview transcripts and annotated relevant phrases or words with codes. Subsequently, they organized these codes into spreadsheets to categorize the data into themes. Next, they refined the themes to ensure they were coherent and representative of the data, and finally, we defined and interpreted the themes. Throughout this process, the reviewers compared their results and resolved any discrepancies through discussion or involving a third reviewer, when necessary. We made revisions only when we reached a consensus.

### Integration of Quantitative and Qualitative Results

We compared quantitative and qualitative findings to identify similarities, discrepancies, or convergence of the results. Through triangulation of the data, we ensured convergence and identified where both methods' results align and where they provide distinct insights. [58] Next, we comprehensively synthesized the integrated results in a report intended to guide the revisions of the CV-Ca to increase its content validity.

### Ethical Considerations

This study was conducted in compliance with the protocol, and principles established in the Declaration of Helsinki, Good Clinical Practice (GCP), as defined by the International Conference on Harmonisation (ICH), and all applicable laws and regulations. After ethics approval, each of the content experts signed a consent for participation in each phase of the study. We anonymized quantitative and qualitative data collected during the study before any report. Personal identifiers of the study participants are being stored in password-encrypted files saved on OneDrive.

# Chapter 3. Results

## Participants

We recruited participants from April 2024 to June 2024. Of 19 eligible participants, 10 were included as content experts and completed the study. Reasons for exclusion were not returning the signed informed consent (n = 8) and not answering the online questionnaire (n = 1) after three attempts to contact them by email. Included content experts had a mean (SD) age of 59.9 (10.97) years, 80% (n = 8) were living in Canada and, and 80% (n = 8) were female identifying as women. All experts had a college or higher educational degree. Half of them were healthcare providers, with a mean (SD) of 27 (17.29) years of clinical practice. 60% (n = 6) reported being caregivers for a friend or family member with cancer at some point in their lives. All participants had undergone at least one cancer screening test in their life, the most common was breast cancer screening. Half of them (n = 5) have been diagnosed with cancer after the age of 18 years, with 60% (n = 3) currently receiving treatment and forty percent (n = 2) being cancer-free and having received their last treatment more than 5 years before. See **Error! Reference source not found.** for more details on the content experts' characteristics.

### Table 1. Demographic characteristics

| Characteristic | N (%) (N=10) |
|---|---|
| **Country** | |
| Canada | 8 (80) |
| Mexico | 1 (10) |
| United Kingdom | 1 (10) |
| **Age, years** | |
| Mean (SD) | 59.4 (10.97) |
| Range | 34 - 74 |
| **Sex** | |
| Female | 8 (80) |
| Male | 2 (20) |
| **Gender** | |

| **Characteristic** | **N (%) (N=10)** |
|---|---|
| Woman | 8 (80) |
| Man | 2 (20) |
| Transgender | 0 |
| Non-binary | 0 |
| **Highest educational degree** | |
| No certificate, diploma, or degree | 0 |
| High (secondary) school diploma or equivalency certificate | 0 |
| Apprenticeship or trades certificate or diploma | 0 |
| College or other non-university certificate or diploma | 2 (20) |
| University certificate or diploma below bachelor level | 0 |
| Bachelor's degree | 3 (30) |
| University certificate or diploma above bachelor level | 1 (10) |
| Degree in medicine, dentistry | 3 (30) |
| Master's degree or postgraduate degree | 0 |
| Doctoral degree (PhD) | 1 (10) |
| **Health care provider** | |
| Yes | 5 (50) |
| No | 5 (50) |
| *Type of healthcare provider (N=5)* | |
| Primary care physician | 1 (20) |
| Medical specialist (Hematology-Oncology) | 1 (20) |
| Nurse (community specialist practitioner/district nurse/care coordinator) | 1 (20) |
| Dentistry (dentist, registered restorative dental hygienist) | 2 (40) |
| *Years of clinical practice (N=5)* | |
| Mean (SD) | 27 (17.29) |
| Range | 7,44 |
| **Caregiver for a friend or family member** | |
| Yes | 6 (60) |
| No | 4 (40) |
| **History of cancer** | |
| *Undergone a screening test for* | |
| Breast cancer | 5 (50) |
| Colon cancer | 3 (30) |
| Cervical cancer | 3 (30) |
| Ovarian cancer | 3 (30) |
| Prostate cancer | 1 (10) |
| *Cancer diagnosis* | |
| Yes | 5 (50) |

| Characteristic | N (%) (N=10) |
|---|---|
| No | 5 (50) |
| *Cancer diagnosis before the age of 18 years (N=5)* | |
| Yes | 0 |
| No | 5 (100) |
| *Currently being treated for cancer (N=5)* | |
| Yes | 3 (60) |
| No | 2 (40) |
| *First time receiving treatment for any type of cancer (N=3)* | |
| Yes | 2 (66.667) |
| No | 1 (33.33) |
| *Cancer free to the best of their knowledge (N=2)* | |
| Yes | 2 (100) |
| No | 0 |
| *Last cancer treatment (N=2)* | |
| 5 years ago, to less than 10 years ago | 1 (50) |
| 10 years ago, to less than 20 years ago | 1 (50) |

* Total N (included participants) is 10, unless otherwise specified.

## Phase II. Content Validation and Revision of CV-Ca

### Step 1. Quantitative component, CVI

The CVI ratings for relevance and clarity of the first version of the CV-Ca are summarized in **Error! Reference source not found.**.

For each of the six vignettes, the I-CVI scores for relevance and clarity across all questions in all vignettes ranged from 0.50 to 1 and 0.70 to 1, respectively. The S-CVI/Ave scores for relevance and clarity, calculated for each vignette separately, ranged from 0.73 to 1 and 0.80 to 1, respectively. The S-CVI/Ave for relevance and clarity across the six vignettes was 0.87 and 0.94, respectively. Three questions, for three different vignettes, had an I-CVI of 0.50 for relevance: Q2-CV2, Q3-CV3, and Q3-CV5. The lowest I-CVI for clarity among questions was 0.70 for one question (Q2-CV2).

## Table 2. I-CVI and S-CVI/Ave of first version of CV-Ca (N=10)

| **Clinical Vignette** | | **Relevance** | | | **Clarity** | | |
|---|---|---|---|---|---|---|---|
| Item | | Ne | I-CVI | S-CVI/Ave | Ne | I-CVI | S-CVI/Ave |
| CV1 Screening | | | | | | | |
| | Q1 | 10 | 1 | 0.90 | 9 | 0.90 | 0.93 |
| | Q2 | 9 | 0.90 | | 10 | 1 | |
| | Q3 | 8 | 0.80 | | 9 | 0.90 | |
| CV2 Detection | | | | | | | |
| | Q1 | 9 | 0.90 | 0.77 | 8 | 0.80 | 0.80 |
| | Q2 | 5 | 0.50 | | 7 | 0.70 | |
| | Q3 | 9 | 0.90 | | 9 | 0.90 | |
| CV3 Diagnosis | | | | | | | |
| | Q1 | 10 | 1 | 0.83 | 9 | 0.90 | 0.97 |
| | Q2 | 10 | 1 | | 10 | 1 | |
| | Q3 | 5 | 0.50 | | 10 | 1 | |
| CV4 Treatment | | | | | | | |
| | Q1 | 10 | 1 | 1 | 10 | 1 | 1 |
| | Q2 | 10 | 1 | | 10 | 1 | |
| | Q3 | 10 | 1 | | 10 | 1 | |
| CV5 Recurrence | | | | | | | |
| | Q1 | 8 | 0.80 | 0.73 | 10 | 1 | 0.97 |
| | Q2 | 9 | 0.90 | | 9 | 0.90 | |
| | Q3 | 5 | 0.50 | | 10 | 1 | |
| CV6 End-of-life | | | | | | | |
| | Q1 | 10 | 1 | 0.97 | 10 | 1 | 0.97 |
| | Q2 | 10 | 1 | | 10 | 1 | |
| | Q3 | 9 | 0.9 | | 9 | 0.90 | |
| CV-Ca total | | | | 0.87 | | | 0.94 |

I-CVI: item level-content validity index, S-CVI/Ave: scale level-content validity index/average method, CV-Ca: clinical vignettes-cancer continuum, N: total number of content experts, Ne: number of content experts rating ≥3 on the relevance and clarity scales, CV: clinical vignette, Q: question.
I-CVI formula: number of experts rating an item ≥3 / the total number of experts. (Polit et al 2007)
S-CVI/Ave formula: sum of I-CVI scores / number of items. (Polit et al 2007)

Content validity scores are excellent when they are ≥0.78 for I-CVI and ≥0.90 for S-CVI/Ave (Polit et al 2007)

### Step 2. Qualitative Component, semi-structured interviews

We conducted semi-structured interviews with 10 content experts after they provided CVI ratings for relevance and clarity of the first version of the CV-Ca. All interviews were completed without rescheduling or interruption, with an average duration of 45 minutes. None of the experts displayed any sign of disinterest, discomfort, or resistance during the interviews. All experts had experience with the cancer care continuum through family members or friends, and fifty percent (n = 2) had their own lived experience at different stages, from screening to end-of-life (palliative chemotherapy). Twenty percent (n = 2) of the experts had professional experience in cancer care: one family physician, involved mostly in screening, diagnosis, and in some cases, surveillance; and one oncologist-hematologist, experienced in hematological malignancies across all stages of the cancer care continuum. Ten percent (n = 1) of the experts also had professional experience in clinical research, including research in the development of scales and decision aids for patients.

After content analysis of the interviews, we found 8 main themes: 1) Structure and format of the online survey and the CV-Ca, 2) Factors influencing DMP in cancer care, 3) Information seeking preferences for DM regarding cancer care, 4) Impact of cancer experience on the perception of clinical vignettes, 5) Comprehensiveness of the instrument, 6) Comprehensibility of the instrument, 7) Alignment of Clinical Scenarios with Current Practice, 8) Relevance of clinical vignettes and questions. We summarized the qualitative findings in Table 3

**Table 3. Themes and subthemes.**

| Theme | Subthemes |
|---|---|
| Structure and Format of Online Questionnaire | Overall impressions<br>• Positive perceptions. |

| Theme | Subthemes |
|---|---|
| | • Clinical scenarios feel realistic.<br>• Questions relate to clinical scenarios.<br>• Adequate length.<br>Difficulty understanding instructions<br>• How to assess relevance and clarity.<br>Increase of severity of the clinical vignettes<br>• Answering the questionnaire in the order presented. |
| Factors Influencing DMP in Cancer Care | Personal and family dynamics<br>• DMP varies between patients.<br>Changes across the cancer continuum<br>• Patients' DMP can shift over time.<br>• Being at different stages of cancer may affect DMP.<br>Knowledge and understanding of the condition<br>• Education about their type of cancer, testing, and treatments.<br>• As knowledge increases, patients may want to be more in control. |
| Information-Seeking Preferences for DM Regarding Cancer Care | Desire for comprehensive information<br>• Detailed information about their condition, diagnosis, and treatment.<br>Requirements for DM<br>• Know relevant facts.<br>• Understanding of the risk and benefits of the options presented to them.<br>• Awareness of what to expect after treatment.<br>Family involvement in information gathering<br>• Family/caregivers may want information about treatments and their consequences. |
| Impact of Cancer Experience on Perception of CV-Ca | Diverse cancer experience<br>• Personal diagnosis.<br>• Relatives/friends with cancer.<br>• Healthcare provider.<br>Relatability to clinical vignettes<br>• Personal experience enhances relatability.<br>• Familiarity with cancer care influences. perception of the clinical scenario authenticity.<br>Empathy and relatability in sex-specific clinical scenarios<br>• Breast cancer screening.<br>• Prostate cancer recurrence. |
| Comprehensiveness of the CV-Ca | Coverage of the cancer care continuum<br>• Suggestions for additional CVs (routine screening, survivorship)<br>• Include other types of cancer (ovarian cancer)<br>Enhancing existing clinical vignettes<br>• Include mental health interventions in end-of-life CV |
| Comprehensibility of the CV-Ca | Overall clarity<br>Factors influencing comprehensibility<br>• Individual differences (personality, education, experience with cancer, mood, attitudes towards questions).<br>• Treatments affecting cognition.<br>Language considerations<br>• Plain language is preferred.<br>• Explanations for medical terms in brackets.<br>• Avoid words with negative connotations.<br>Suggestions for Information adequacy |

| Theme | Subthemes |
|---|---|
| | • Add information to explain medical terminology and procedures.<br>• Elaborate on cancer care process<br>• Balance information and simplicity |
| Alignment of Clinical Scenarios with Current Practice | Ensure clinical scenarios and options presented in the questions are medically appropriate and reflect current practice.<br>• Follow clinical practice guidelines<br>Three CVs require significant revisions<br>• CV2. Colon cancer detection<br>• CV3. AML diagnosis<br>• CV5. Prostate cancer recurrence |
| Relevance of Clinical Vignettes | Factors affecting relevance of the clinical scenarios and questions<br>• Health system limitations (lack of resources, availability, long waitlist, insurance coverage, financial limitations).<br>• Specific factors related to individual questions with I-CVI scores for relevance of 0.50 (Q2-CV2, Q3-CV3, Q3-CV5). |
| DMP: Decision-Making Preferences; DM: Decision-Making; CV-Ca: Clinical Vignettes around Cancer Care Continuum, CV: Clinical Vignette; Q #: Question number; CV #: Clinical Vignette number | |

**Structure and Format of the Online Questionnaire and the CV-Ca.** Overall, the instrument received positive feedback. Sixty percent (n = 6) of the experts expressed that the clinical scenarios felt realistic, and the questions were clear and relevant to each case scenario. Forty percent (n = 4) of the experts found the instrument to be good but noted that the instructions on how to answer the questionnaire were unclear and some questions contained technical terms that were difficult to understand. Most experts considered the length of the online questionnaire to be appropriate, although one expert felt it was somewhat long.

Some experts reported difficulty in understanding the instructions of the online questionnaire. Forty percent (n = 4) mentioned that they struggled to comprehend how to assess relevance and clarity. One expert said, *"I think, where I struggled with the clarity was some reference in the start of it (the survey instructions) …I just struggle to understand whether that was, what? Where that fitted into the overall questions."* Another expert added, *"I think it was like, the clarity issue. If the question was posed as 'Who should make the decision?' it makes more sense, like*

*asking who should be involved in the decision-making process. I guess I didn't really understand the clarity, part that much."*

During the interview, once we clarified what relevance and clarity measure and how to use the scales to rate them, forty percent (n = 4) of the experts changed their relevance ratings for five questions. Initially, they had rated these questions as not or somewhat relevant, but they adjusted their ratings to very or extremely relevant. One expert reflected, *"Yeah, see how I said it wouldn't be relevant…so like, yeah, I just misinterpreted. I would change that to 4, it's very relevant."*

Following the format of the API, we structured the clinical vignettes in sequence, with an increase in severity. We asked the experts if they noticed this pattern, and fifty percent (n = 5) acknowledged it, with all of them remarking that they answered the questionnaire in the order presented. Forty percent (n = 4) reported that they did not perceive any increase in severity, and of these, fifty percent (n = 2) observed that they did not answer the questionnaire in the order presented.

**Factors Influencing DMP in Cancer Care.** Sixty percent (n = 6) of the experts mentioned that DMP in the cancer care continuum vary among patients, noting that many of these decisions are personal (e.g., informing family members, deciding on palliative care) as noted by one expert who is a nurse: *"Oh, the overarching thing I would say is, how different they all (patients with cancer) are!"* Experts also mentioned that family dynamics can influence the DM process. One expert commented on genetic testing decisions: *"I think that's a good discussion. Because some people may not want to know that they do have the mutation and that's their choice. And also, some, maybe their children, want them to have it done to see if they've got a gene mutation."* Another expert noted, *"So when you're considering what you're going to do and how much control you need, there are…because you're not the one who's taking you to the hospital,*

*or maybe you have no one to take you to the hospital like everybody's situation is that bit different. So, there's a lot of variables within the question (of how much control the patient wants to have over the DM process).”*

Thirty percent (n = 3) of the experts mentioned that DMP across the cancer care continuum can shift over time, as noted by one expert, *“This sort of involvement on decision making can fluctuate so much along a patient's journey, depending on the basic knowledge, on how they feel and their age, and how much they want to be involved. And I think it, having looked after patients, I think that really does fluctuate.”*

Twenty percent (n = 2) of them expressed that when they were initially diagnosed, they chose to leave all or most of the DM to the physician. However, as they progressed in the cancer continuum, they began to take more control over decisions related to their care. Another expert noted that being in a later stage of the cancer care continuum can also influence DMP. For example, a patient in the end-of-life stage may want to have full control of their medical decision up until their condition worsens, at which point they might prefer the doctor to take control of all decisions about their care.

Thirty percent (n = 3) experts also highlighted how patient’s knowledge and understanding of their condition can influence DMP. As one expert remarked, *“I think the farther you're in, you start doing some research yourself and seeing what's best for you as well. But for myself, I've just been really doing what the doctor has been telling me to do… and then I go by kind of how I feel. But if I didn't feel like I'm getting any better, then I would probably like to pursue it more…I'd have more (control in) decision-making to see what would be best.”*

**Information-Seeking Preferences for DM Regarding Cancer Care.** Sixty percent (n = 6) of the experts expressed a preference for having comprehensive cancer-related information, either

from their own experience with cancer or that of a loved one. They stated that they seek detailed information about their condition, diagnostic tests, and treatment options. As one expert noted, *"My wife was fighting to have every single piece of information for every single decision she was going to make. She had to have the best information available. So, I took care of that."* Another expert added, *"I think I'm coming from a personal point of view–the more information I have, the better."* Additionally, twenty percent (n = 2) of the experts acknowledged that not all patients would want to "know everything", one of them speaking from a healthcare provider experience.

The experts reported that to make an informed decision about their cancer care, it is crucial to know all relevant facts, understand the risks and benefits of options presented to them, and be aware of what to expect afterward. As one expert said, *"You're just learning and becoming introduced to something you hope never to have become introduced to. And so, you want to know like, okay, so why are we even talking about this? Is it going to be quality of life or quantity of life, or is there going to be a reduction in the size of a tumor? So, we can do surgery, or what's the purpose here? And so that's why I say that there has to be a big picture plan here, and I would want to personally be involved in the entire conversation."*

Twenty percent (n = 2) of the experts also commented that family members, particularly caregivers, may also want to be informed and often seek information about treatments and their consequences. They want to know what to expect so they can prepare and take care of their loved ones. One expert remarked: *"Husband was just saying that, from his perspective and from my surgery, it would (have) benefited him to have like, the opportunity to have like a little course to know everything that had happened to me as a family member, so that he would know what I was coming out with. So that he wasn't…I wasn't coming out to shocked faces, and he'd be able to like prepare people… That type of thing and be able to help."*

**Impact of Cancer Experience on Perception of Clinical Vignettes.** All experts (100%, n = 10) reported a range of cancer-related experiences, with all of them having at least gone through the screening stage. Fifty percent (n = 5) of the experts have personally experienced a cancer diagnosis and have gone through treatment, surveillance, and/or recurrence stages. Ninety percent (n = 9) reported having cancer-related experiences through family members and/or friends, while thirty percent (n = 3) have provided care to patients with cancer. These experiences spanned across all stages of the cancer care continuum.

Due to these experiences, the experts were able to relate to the clinical vignettes of the instrument, with eighty percent (n = 8) mentioning that the clinical scenarios felt realistic or "like real life". Personal experience and familiarity with cancer care enhanced the relatability of the clinical scenario. One expert noted: *"I have like, experience because I had a screening for colon cancer, I had a screening for breast cancer. So, it was relevant, the questions, because I haven't had that diagnosis from cancer, but I still have the screen (test)."* Another expert added. *"So, I've had multiple encounters. First with a family physician. So, the screening, identification, and then the treatment and then, because there was a recurrence of the same skin cancer, I went to a skin cancer specialist…So, when I was looking at this (the instrument) I was looking at it from a patient perspective."* For twenty percent (n = 2) of the experts, having experience in cancer care brought up feelings of frustration and fear when rating the questions related to certain clinical vignettes. One observed*: "That (the question) could be upsetting to some people. It was upsetting to me to think that. Yes, I should get a second opinion, but I can't even get a 1st opinion from a surgeon. It was…Yeah, it was upsetting…because of the system."*

The CV-Ca includes two vignettes that focus on sex-specific cancer scenarios: one regarding breast cancer and the other regarding prostate cancer. When we asked the experts if they had any difficulty relating to these clinical vignettes, we found that the ability to empathize varied

among individuals, but most were able to draw from their personal experience with cancer to understand and rate the questions in these specific clinical scenarios, also regardless of the plausibility that that could happen to them. Seven of eight female experts were able to relate to the prostate cancer clinical vignette, and the two male experts had no difficulty rating the questions related to the breast cancer clinical vignette.

We also asked the experts how they interpreted 'cancer treatment' to understand their conceptualization in responses to questions Q1-CV4 and Q1-CV6. Our analysis showed that 70% (n = 7) interpret it as a treatment to cure or reduce cancer, including chemotherapy, radiation, and surgery; as observed by one expert*, "I think of anything for cancer. It might, but it would depend on it, could be surgery. It could be chemo. It could be radiation."* Twenty percent (n = 2) of the experts interpret 'cancer treatment' as referring to 'anything', whether it is a treatment to reduce or cure cancer or pain and symptom management. And Ten percent (n = 1) specifically interpret "cancer treatment' as referring to chemotherapy only.

**Comprehensiveness of the CV-Ca.** 90% (n = 9) of the experts agreed that the CV-Ca adequately covers all stages of the cancer care continuum. However, thirty percent (n = 3) provided suggestions for additional clinical vignettes. One expert suggested adding a survivorship clinical vignette to capture the risk of secondary malignancies from cancer treatments like chemotherapy and radiation. Another expert noted that a clinical scenario involving routine screening in a patient with no cancer risk factors would be helpful: *"I think they're all covered. I think, though, that there is a lot of screening that is done…there are the mammograms and the colon cancer screening that everybody does as part of the normal over-50 work that the province does, that isn't perhaps covered. This (the CV-Ca) covers all of the people who have cancer in their family, but it doesn't do anything for the mail-in and the go-in and check every year or every 4 years."* A third expert expressed that a clinical scenario

involving ovarian cancer would be important due to the difficulty in its diagnosis: *"I wish that ovarian cancer had been a scenario because it is a cancer that the diagnostics have not changed for over 50 years. There's no test for it. No reliable test. There's a Ca 125. It's not accurate. So, it's a cancer that needs to be talked about more. And once you have it, you have it. I'm in remission, they say: "You're not cured." … It's an important cancer because for so many, it's silent. The symptoms are so vague, very vague."*

To enhance the comprehensiveness of the existing CV-Ca, thirty percent (n = 3) of the experts recommended including mental health interventions in the end-of-life clinical vignette, and being explicit in what palliative care entails (i.e., pain and symptom management, emotional and spiritual support, focus on quality of life*): "…in the palliative care, I think there should be some mental healthcare in there…I think that mental health counseling is very important."* And *"If I say palliative care to the patient who's not in end-of-life, I tell them it's the team that supports them with their symptoms, whether it's pain or nausea or fatigue, depression, mood, and mood disorders…I have to tell them. They don't think that that's automatically part of the (palliative) care."*

**Comprehensibility of the CV-Ca.** Seventy percent (n=7) of the experts found the CV-Ca clear and easy to understand, while thirty percent (n =3) reported having difficulty with certain words, particularly medical terms. The experts noted that several factors can influence the comprehensibility of the instrument, such as receiving treatment that affects cognition, the time of the day when the questionnaire is completed (e.g., after work hours), the respondents' education and research literacy, their knowledge of the disease, their personality, and their general attitude to questions. One expert remarked, *"But I felt like it was worded properly this time…I remember doing it the 1st time, and for some reason, not being able to understand the questions fully. But that might have been…I might have done it after a time of chemo…"* Another

expert shared, *"…because honestly, first time I started the survey it was at 9 pm when I was just getting home from work and I feel tired, I just stopped. I say I'm just going to continue tomorrow."* A third expert added, *"Just think about your audience, of who you send it out to. Some people might wonder a bit and try to figure, try to puzzle through what you're trying to get as an answer, as opposed to just answering the questions."*

Our analysis also showed that fifty percent (n = 5) of participants appreciated the use of plain language and the explanations provided for medical terms in brackets (e.g., explaining 'bone marrow biopsy' in Q1-CV3), and two of them offered suggestions to replace some words with more familiar terms (e.g., 'smoking cessation program' to 'program to stop smoking', and 'bowel' instead of 'colon'). Additionally, thirty percent (n = 3) of the experts suggested changing words with negative connotations, such as replacing 'genetic mutations' with 'genetic variations that predispose'. Ten percent (n = 1) of the experts suggested using active voice consistently throughout the clinical vignettes and ensuring that the language used mirrors what is common in hospitals.

Lastly, the experts emphasized the importance of having enough information in the CV-Ca to improve comprehensibility. All experts offered suggestions for enhancing the clarity of certain questions, such as providing more context or simplifying overly technical or medical jargon. included: 1) offering additional explanations about medical procedures and what they entail. As one expert suggested*, "I think probably, rather certainly use the word lumbar puncture, because that actually is the medical term over here for it. But in your brackets I think I would put something really simple, like 'getting a sample of spinal fluid' or 'fluid from your spine', so that for everybody, it's a really clear picture about what the procedure involves…"*; 2) clarifying the purpose of a test and providing some context for interpreting results, as one expert noted regarding PSA testing for prostate cancer*,"… because you see, in this case, in this question*

*(Q1-CV5), for sure is going to be a yes, for me. Right? So maybe…for example, the PSA. To explain about this (test), and that this could change very quickly, there could be differences in one month (for example).”*; 3) expanding on the cancer care process, such as explaining the implications of stopping cancer treatment. One expert mentioned: *“You're not stopping any (all) treatments. You're just changing the care plan. Yes, the treatments aren't stopping. They're just changing…You're just no longer going to continue with chemotherapy. You're going to instead provide a pain management program and an end-of-life plan…”* Additionally, thirty percent (n = 3) of the experts recommended using ‘simple’ and ‘not too complex’ language throughout the CV-Ca to further support understanding

**Alignment of Clinical Scenarios with Current Practice.** Forty percent (n = 4) of the experts emphasized the importance of ensuring that the clinical scenarios reflect current practice for the questions to be meaningful and relevant. Our analysis showed that three clinical vignettes had inaccurate or incomplete information in the case scenario: CV2 (colon cancer detection), CV3 (AML diagnosis), and CV5 (prostate cancer recurrence).

Related to CV2, two experts noted the following key missing information: 1) Family risk assessment, which would guide the need for earlier screening and/or genetic testing. 2) Initial colonoscopy results, which would determine the frequency of the follow-up colonoscopies and the patients’ risk group. 3) Symptom appropriateness, the symptoms mentioned in the case scenario would not typically prompt a colonoscopy but rather lead to a screening fecal test. One expert reported: *“There are very few genetic colon cancers that they will test for here. if you've got a family history of colon cancer, you're gonna get your regular colonoscopies. But if… you don't unless you've got some funky familial thing, which, you know, is rare…”,* and further elaborated: *“I said, well. Recommendations here. So, because here it's determined by the guy who did the scope so like, if you have an adenomatous polyp, then you're gonna get rescoped*

*in one to 3 years, depending, so, one or three depending on availability. Depends on family history…they're gonna see you, kind of every three years, until you've got two clear scopes, and then it'll be every five (years). So, the recommendations are very patient-specific, I find, you know, and intervention-specific."* Another expert commented: *"I wouldn't with those symptoms, I probably wouldn't suggest a colonoscopy. Like stomach pain and constipation, I wouldn't go straight to a colonoscopy. But if you had like, iron deficiency, anemia, or bleeding bright red blood from the rectum, or something like that, that would prompt it right away."*

Regarding CV3, two experts highlighted the following discrepancies between the clinical scenario and the questions: 1) Symptom severity. The clinical scenario states that the patient has been symptomatic for two months, which would likely result in a referral to the emergency department rather than an outpatient clinic to see a hematologist. 2) Lumbar puncture. A lumbar puncture would not typically be indicated. Patients with this rare type of AML present with cognitive changes, which are not reported in the clinical scenario. 3) Diagnostic tests. At a diagnostic stage, the most commonly performed tests include bone marrow biopsy, HLA testing, and cytogenetic testing to identify the type of leukemia and risk group.

Concerning CV5, two experts noted that the clinical scenario was missing crucial information: 1) Treatment administered post-diagnosis. Usually, surgical resection of the prostate is the first line of treatment; therefore, the question about the biopsy of the prostate seems incorrect. 2) PSA values. There is no mention in the clinical scenario of the reference values of the PSA to understand what "slowly rise" implies. 3) Other tests to assess the recurrence of cancer. In clinical practice, imaging tests will often be done if there is a suspicion of recurrence, like a bone scan. One expert noted*: "It says, and you receive treatment. So, the question is, what treatment did you receive five years ago? Because if it was radiation, well… if it was surgery, there's nothing to biopsy. If it was radiation, you still wouldn't biopsy. You wouldn't need to biopsy the*

*prostate."* And further added, *"So, it's been 5 years and PSA is going up. So that would be very specific to the individual case. If the PSA has jumped like, you know if it's gone from 0 to point 3, they're gonna probably repeat it possibly in 3 months. If it's gone from 0 to 6, then not gonna repeat it. Well, they will repeat it at some future date. But they're not gonna wait to do further testing. They're gonna do bone scans or CT scans."* Another expert noted, *"Because this is only…just at the indexes because I understood the index is high. I don't know. It was like, I have to do that procedure, has to be right away. Why no, instead of a biopsy, a CT scan?*"

**Relevance of Clinical Vignettes.** After analysis, we found two main factors affecting the relevance of the clinical vignettes and questions: 1) factors related to health system limitations, and 2) specific factors related to individual questions within the instrument.

Thirty percent (n = 3) of the experts noted that some of the tests and treatment options presented in the questions were not relevant due to limitations in their health system, such as lack of resources, availability, long waitlist, insurance coverage, and financial limitations. Experts observed: *"But for us, the only way you can get genetic testing is if you have a family member who has had a genetically tested cancer… somebody who's had a BRCA gene or something, then you become eligible for further testing… But yes, it's relevant to discuss. The question is relevant, particularly because people come asking about it. But in that particular case (the vignette) it would not be relevant to that patient unless there had been genetic testing already done. So yes, it's relevant…just not available."* Another expert added, regarding seeking a second opinion at a diagnosis stage: *"It depends on where you are, or how much money you have. Because it's also financial…if you have the capacity to pay for another person to give (provide care) you…because you're going to go through, maybe, another test if they ask, right?"*

We investigated specific relevance concerns in detail for the three questions that had an I-CVI rating of 0.50. The first question, Q2-CV2, addresses genetic testing in the context of colon

cancer at a detection stage. fifty percent (n = 5) of the experts expressed that the clinical scenario lacks sufficient information to make this question relevant. They suggested that relevance could be improved by including details about the family history of colon cancer and clarifying the hereditary nature of types of cancer. One expert noted*, "…just getting some more information about past history in there. And because quite clearly, if there are several family members with colon cancer, then that becomes much more important that somebody does get regular testing and goes forward to have the genetic testing done."* Additionally, twenty percent (n = 2) of the experts highlighted relevance limitations, noting the unavailability of the test without a family member with a confirmed genetic mutation that predisposes to colon cancer, such as in familiar syndromes, like Lynch syndrome. Ten percent (n = 1) of the experts mentioned that this question was not relevant as the decision to get genetic testing should be left to the family relative, not the patient.

The second question, Q3-CV3, relates to seeking a second opinion in the context of AML diagnosis. 60% (n = 6) of the experts indicated that this question lacked relevance because patients are unlikely to seek a second opinion at the diagnosis stage due to factors such as trust in their physician, urgency for receiving treatment, or long waitlist to be seen by another specialist. One expert remarked, *"If you find that the physician has been really investigating, and you feel like you trust the person, and you feel like it was doing the job…I don't see any necessity to find others' (other specialists') opinions when they really… you trust the person from the beginning. I think it's better to have one person, trust the person, follow the treatment."* Another expert noted when comparing their experience with a friend's: *"He's going through cancer at the moment. He's just at the beginning, but the way he's going about it seems like nice and slow, where he's given a chance to get a second opinion where mine was…I had to get into surgery, and everything was decided for me at that point (at diagnosis)."* Two experts said the following regarding the feasibility of seeking a second opinion: *"First of all, getting a*

*second opinion is not possible", and "…It's hard to even get a first opinion in our (healthcare) system."*

The experts agreed that seeking a second opinion is more likely to happen at a later stage of the cancer care continuum, such as treatment and recurrence. One expert observed: *"…for this particular scenario, for me, they'd be, they would have gone to the emergency room. So, I mean, the second opinion might, for me, would come in terms of treatment options. Not, you know, not diagnostic options."* A second expert added: *"So, if it is not working, the treatment, maybe…I'm going to seek another opinion."* Another one noted, *"I don't think I've ever had anybody say: I don't believe you, and I want a second opinion in terms of diagnosis---it would be a good question for the treatment scenario (CV4)."*

The third question with an I-CVI of 0.50 for relevance is Q3-CV5, which asks about informing family members about test results of possible recurrence of prostate cancer. 60% (n = 6) of the participants mentioned that the question is not relevant for two reasons: 1) at this stage, there is only suspicion of cancer, not a confirmed diagnosis, and 2) they felt this decision is personal and not discussed at the oncologists' office. One expert noted*, "I just wasn't sure about the relevance of it. I mean again, that's just about, very much a matter of personal choice, isn't it? Whether I mean, here it's still at this sort of observation stage, isn't it? Still a so sort of at the monitoring stage."* Another expert added; *"I think it's still too early to, you know, to just go to a doctor's appointment, and then they say, you know, your levels are rising again. And I think that you always want to keep that to yourself until you know exactly what's going on before you start having everybody worry for you."* And a third one observed, *"I just don't know if that's a decision that like, could be discussed at the oncologist's office. So, like I felt like that wasn't particularly relevant to this scenario."*

### Step 3. CV-Ca Revised Version. Integration of Results

**Changes to the First Version of the CV-Ca**. Based on the results of the quantitative and qualitative components of our study, we conducted major revisions in three CVs. Overall, we revised the clinical scenarios to ensure they reflect accurate information and align with current practice, we removed and replaced four questions, and we moved two questions to a different case scenario. (Appendix 4 contains the second version of the CV-Ca.)

We first revised CV2 (colon cancer detection). We adjusted the symptoms in the clinical scenario to reflect a more realistic presentation that would prompt earlier detection testing with colonoscopy. We also changed the findings of the initial colonoscopy. These updates led us to modify the follow-up options in the questions to reflect clinical practice. We removed Q2 since it was no longer relevant to the revised scenario and replaced it with Q1, adding more information to enhance comprehensibility (e.g., recommended follow-up frequency for colonoscopies in patients with precancerous polyps). We then created a new Q1, which presents follow-up options for low-risk polyps, consistent with current recommendations.

Second, we revised CV3 (AML diagnosis). Based on the recommendations from our clinical and patient experts, as shown in the content analysis results, we changed the AML diagnosis to a leukemia diagnosis. This will ensure a better understanding of the clinical scenario, and the diagnostic options presented in the questions. Additionally, we adjusted the timeline in the clinical scenario to reflect the progression from the onset of symptoms to the patient seeking medical care, aligning with real-life presentation. Although Q2 had an I-CVI of 1 for relevance and clarity, we removed that question because it does not represent a diagnostic option commonly offered in leukemia diagnosis and replaced it with a new question related to cytogenetic and molecular testing, which is part of standard diagnostic testing. Moreover, we moved Q3-CV5 to this CV, as it is more relevant here.

The third CV that required significant revisions was CV5 (prostate cancer recurrence). We changed the follow-up intervals of PSA testing and added reference values to enhance comprehensibility. We removed Q1, even though it had an I-CVI of 0.80 and 1 for relevance and clarity, respectively, and replaced it with the option of getting a bone scan because the option of an imaging test seemed more appropriate in the context of the clinical scenario and current practice. Although Q2 had an I-CVI of 0.90 for relevance and clarity, we removed it because the patient in the clinical scenario most likely had undergone surgical resection of the prostate, which is the first treatment option. Therefore, a biopsy of the prostate would not be indicated. Finally, we replaced Q3 with Q3-CV3, as our results showed that asking for a second opinion is more suitable in a recurrence clinical scenario.

Across the CV-Ca, we added explanations and definitions for medical terms and procedures where necessary, ensuring the language was clear, consistent, and easy to understand. We also replaced words with negative connotations, such as changing ‘genetic mutations’ to ‘genetic variations’ for a more neutral tone.

Our findings indicated that the instructions for completing the online questionnaire were unclear for some participants, therefore, we modified them. We added more information about the original API and the ISP scale, clarifying that the CV-Ca focuses on measuring DMP. This encouraged the experts to focus only on DMP when assessing the relevance and clarity of the second version of the CV-Ca. Additionally, we added a statement about assuming that all options presented in the questions being medically appropriate and feasible, regardless of the healthcare system, to prevent healthcare system limitations from influencing the experts’ ratings of relevance and clarity.

We incorporated the experts’ feedback on the online questionnaire instructions into the final version of the CV-Ca, which will be adapted to the API for end-users. As a result, we included

the feasibility statement mentioned above in the instructions for respondents. Additionally, we added guidance for clinicians administering the instrument, recommending that they ensure the respondent is cognitively sound when answering the API.

## Phase III. Content Validation of Second Version of CV-Ca

The results of the I-CVI and S-CVI/Ave of the second version of the CV-Ca demonstrated an overall improvement with excellent content validity scores across questions and clinical vignettes. The I-CVI scores for relevance and clarity across all questions in all vignettes ranged from 0.80 to 1, and from 0.90 to 1, respectively. The S-CVI/Ave scores for relevance and clarity, calculated for each vignette separately, ranged from 0.90 to 1 for both. The S-CVI/Ave for relevance and clarity across the six vignettes was 0.98 and 0.97, respectively. CVs 1, 4, and 6 received the highest scores, achieving a score of 1 for both I-CVI and S-CVI/Ave in relevance and clarity. The three CVs that underwent major revisions–CV 2, 3, and 5–showed significant improvement in relevance. However, clarity improved only for CV2, while there was no change in clarity for CVs 3 and 5. In Table 4. Comparison of I-CVI and S-CVI/Ave scores for relevance from versions 1 and 2 of the CV-Ca we summarize and compare CVI scores from the first and second versions of the CV-Ca.

### Table 4. Comparison of I-CVI and S-CVI/Ave scores for relevance from versions 1 and 2 of the CV-Ca

| **Clinical Vignette** | | **Relevance version 1 CV-Ca** | | | **Relevance version 2 CV-Ca** | | |
|---|---|---|---|---|---|---|---|
| Item | | Ne | I-CVI | S-CVI/Ave | Ne | I-CVI | S-CVI/Ave |
| CV1 Screening | | | | | | | |
| | Q1 | 10 | 1 | 0.90 | 10 | 1 | 1 |
| | Q2 | 9 | 0.90 | | 10 | 1 | |
| | Q3 | 8 | 0.80 | | 10 | 1 | |
| CV2 Detection | | | | | | | |
| | Q1 | 9 | 0.90 | 0.77 | 10 | 1 | 1 |
| | Q2 | 5 | 0.50 | | 10 | 1 | |
| | Q3 | 9 | 0.90 | | 10 | 1 | |

| Clinical Vignette | | Relevance version 1 CV-Ca | | | Relevance version 2 CV-Ca | | |
|---|---|---|---|---|---|---|---|
| CV3 Diagnosis | | | | | | | |
| | Q1 | 10 | 1 | 0.83 | 10 | 1 | 0.97 |
| | Q2 | 10 | 1 | | 10 | 1 | |
| | Q3 | 5 | 0.50 | | 9 | 0.90 | |
| CV4 Treatment | | | | | | | |
| | Q1 | 10 | 1 | 1 | 10 | 1 | 1 |
| | Q2 | 10 | 1 | | 10 | 1 | |
| | Q3 | 10 | 1 | | 10 | 1 | |
| CV5 Recurrence | | | | | | | |
| | Q1 | 8 | 0.80 | 0.73 | 9 | 0.90 | 0.90 |
| | Q2 | 9 | 0.90 | | 10 | 1.0 | |
| | Q3 | 5 | 0.50 | | 8 | 0.80 | |
| CV6 End-of-life | | | | | | | |
| | Q1 | 10 | 1 | 0.97 | 10 | 1 | 1 |
| | Q2 | 10 | 1 | | 10 | 1 | |
| | Q3 | 9 | 0.9 | | 10 | 1 | |
| CV-Ca total | | | | 0.87 | | | 0.98 |

I-CVI: item level-content validity index, S-CVI/Ave: scale level-content validity index/average method, CV-Ca: clinical vignettes-cancer continuum, N: total number of content experts, Ne: number of content experts rating ≥3 on the relevance and clarity scales, CV: clinical vignette, Q: question.
I-CVI formula: number of experts rating an item ≥3 / the total number of experts. (Polit et al 2007)
S-CVI/Ave formula: sum of I-CVI scores/number of items. (Polit et al 2007)
Content validity scores are excellent when they are ≥0.78 for I-CVI and ≥0.90 for S-CVI/Ave. (Polit et al 2007)

## Table 5. Comparison of I-CVI and S-CVI/Ave scores for clarity from versions 1 and 2 of the CV-Ca.

| Clinical Vignette | | Clarity version 1 CV-Ca | | | Clarity version 2 CV-Ca | | |
|---|---|---|---|---|---|---|---|
| Item | | Ne | I-CVI | S-CVI/Ave | Ne | I-CVI | S-CVI/Ave |
| CV1 Screening | | | | | | | |
| | Q1 | 9 | 0.90 | 0.93 | 10 | 1 | 1 |
| | Q2 | 10 | 1 | | 10 | 1 | |
| | Q3 | 9 | 0.90 | | 10 | 1 | |
| CV2 Detection | | | | | | | |
| | Q1 | 8 | 0.80 | 0.80 | 9 | 0.90 | 0.90 |
| | Q2 | 7 | 0.70 | | 9 | 0.90 | |
| | Q3 | 9 | 0.90 | | 9 | 0.90 | |
| CV3 Diagnosis | | | | | | | |
| | Q1 | 9 | 0.90 | 0.97 | 10 | 1 | 0.97 |
| | Q2 | 10 | 1 | | 10 | 1 | |

| Clinical Vignette | | Clarity version 1 CV-Ca | | | Clarity version 2 CV-Ca | | |
|---|---|---|---|---|---|---|---|
| | Q3 | 10 | 1 | | 9 | 0.90 | |
| CV4 Treatment | | | | | | | |
| | Q1 | 10 | 1 | | 10 | 1 | |
| | Q2 | 10 | 1 | 1 | 10 | 1 | 1 |
| | Q3 | 10 | 1 | | 10 | 1 | |
| CV5 Recurrence | | | | | | | |
| | Q1 | 10 | 1 | | 10 | 1 | |
| | Q2 | 9 | 0.90 | 0.97 | 10 | 1.0 | 0.97 |
| | Q3 | 10 | 1 | | 9 | 0.90 | |
| CV6 End-of-life | | | | | | | |
| | Q1 | 10 | 1 | | 10 | 1 | |
| | Q2 | 10 | 1 | 0.97 | 10 | 1 | 1 |
| | Q3 | 9 | 0.90 | | 10 | 1 | |
| CV-Ca total | | | | 0.94 | - | - | 0.97 |

I-CVI: item level-content validity index, S-CVI/Ave: scale level-content validity index/average method, CV-Ca: clinical vignettes-cancer continuum, N: total number of content experts, Ne: number of content experts rating ≥3 on the relevance and clarity scales, CV: clinical vignette, Q: question.
I-CVI formula: number of experts rating an item ≥3 / the total number of experts. (Polit et al 2007)
S-CVI/Ave formula: sum of I-CVI scores/number of items. (Polit et al 2007)
Content validity scores are excellent when they are ≥0.78 for I-CVI and ≥0.90 for S-CVI/Ave. (Polit et al 2007)

# Chapter 4. Discussion

## Summary of Main Findings

This study aimed to develop and validate clinical vignettes designed to measure decision-making preferences (DMP) across the cancer care continuum, addressing a gap in existing decision-making tools like the API. We developed the CV-Ca, which includes six clinical vignettes based on real-world scenarios, spanning cancer prevention, detection, diagnosis, treatment, recurrence, and end-of-life care. Each of the clinical vignettes is associated with three questions with options for which a patient needs to make medical decisions about their care. End-users rate the level of participation they want to have during the decision-making process. Our instrument offers a comprehensive approach to understanding the extent of involvement in decision making that patients prefer throughout the cancer care continuum.

Our results demonstrated that the final version of the CV-Ca achieved strong content validity. We followed rigorous methodology for instrument development, with a multi-phase, multi-step study design that included an explanatory sequential mix methods approach. We incorporated the CVI as the quantitative component and conducted semi-structured interviews as the qualitative component. The interviews revealed detailed explanations of the participants' ratings on relevance and clarity, along with insights into the nuances of DM in oncology. This approach enabled us to refine the vignettes based on content expert feedback. Through this iterative process, we improved the vignettes' relevance and clarity, ensuring they reflect real-life decision-making challenges in cancer care. These revisions particularly strengthened clinical vignettes addressing complex scenarios, such as cancer recurrence and long-term treatment decisions.

The triangulation of quantitative and qualitative data not only validated the content but also uncovered important thematic insights into patient DMP. Expert feedback highlighted the role of family dynamics, emotional factors, and the evolving nature of patient autonomy in cancer care, underscoring the need for flexibility in DMP instruments.

A key finding was the importance of aligning decision-making tools with the realities of cancer care, where patients' preferences may shift over time due to changing health status, treatment options, and disease progression. The CV-Ca addresses these nuances, filling a gap left by instruments that measure DMP by focusing primarily on acute care decisions with short-term implications. By capturing DMP across the cancer continuum, our vignettes provide a more dynamic and patient-centred framework for understanding decision-making in oncology.

## Alignment with Existing Literature

Our study builds on what has been found in the literature regarding the many factors that impact DMP in patients in the cancer continuum, such as family dynamics, individual differences, and

knowledge of the disease. [62] Our literature search showed that there are few instruments that measure DMP as demonstrated by Scholl et al 2011,[16] the API being the instrument most frequently reported in the literature and validated in different populations and settings, showing good psychometric properties. [18–23] One study validated the API in a population of patients with incurable cancer and developed an additional vignette tailored for these patients. [1] The process of development and content validation for the additional vignette is not described, moreover, the new vignette does not follow the format of the original API vignettes. Another instrument called Control Preference Scale developed by Degner et al 1997, [63] has also been validated in different populations, including one study by the same authors in women with breast cancer. However, the measure of DMP es measured retrospectively and compares DMP before and after the encounter. [3]

In our study, we developed the clinical vignettes specifically to assess DMP in patients with cancer, with clinical scenarios that cover the full spectrum of the cancer care continuum, which potentially allows to showcase differences or changes in patients' DMP depending on the cancer stage.

## Strengths and Limitations

One of the major strengths of our study is the use of a multi-phase, multi-step design, incorporating both quantitative and qualitative methods through an explanatory sequential mixed mixed-methods approach, which was instrumental in developing a robust tool. [57,58,64] This combination of methods ensured that the vignettes were both scientifically valid and contextually relevant to real-life scenarios, enhancing the instrument's practical application in clinical settings. Moreover, we conducted exhaustive research on current clinical practices, consulting guidelines from Canada, the U.S., and Europe. This international perspective strengthens the applicability of the vignettes across different healthcare settings.

Another strength is the use of vignette methodology to represent diverse, real-world cancer care scenarios, ranging from prevention and diagnosis to end-of-life care. [29,32] This design enabled us to capture the complexities and nuances of decision-making that patients face at different stages of the cancer care continuum. The iterative process of refining the vignettes based on expert feedback ensured that the instrument was grounded in actual clinical experiences, making it more relevant and applicable for measuring how much patients want to be involved in their own care decisions. Additionally, the inclusion of experts with both clinical and personal experience with cancer added further validity and depth to the content, strengthening the overall utility of the instrument.

A third strength of this study is its inclusiveness and diversity of participants. There were no geographical restrictions, allowing for a wide range of perspectives. The study included patients with lived experiences of cancer, clinicians with experience in providing care to cancer patients, and a sufficient number of content experts. This sample size aligns with recommendations for content validity index (CVI) validation, [37] ensuring that the instrument underwent thorough and diverse expert review. The variety of expertise and experience contributed to a more comprehensive assessment of decision-making preferences, enhancing the generalizability of the instrument across different clinical and patient populations.

One limitation of this study is the potential for bias due to purposive sampling, which limits the representation of the broader population. Another significant limitation is the homogeneity of the participants in terms of education level. All participants had at least a college degree, meaning that individuals with only high school education or no formal schooling were not represented. This limitation could affect the generalizability of our findings to populations with lower educational attainment. These groups may have different decision-making preferences or face unique challenges when navigating complex healthcare decisions, especially in cancer care.

While we attempted to mitigate this limitation by using plain language and commonly used words in the CV-Ca, the comprehensibility for people with less or no formal education may still be affected.

Additionally, our sample consisted predominantly of females, with 80% of participants identifying as woman. The sex and gender imbalance may influence the applicability of the findings to males and patients who identify as men, whose decision-making preferences and experiences in cancer care may differ.

Finally, although we followed current clinical guidelines to develop our clinical scenarios and questions to increase generalizability and ensure comprehensibility, a content validation process will be necessary in the future as clinical practice evolves and guidelines are updated.

## Implications for Research and Practice

Our study focused on content validation. Future research is needed to further validate this newly developed instrument. The next step will be to conduct a pilot study on a sample from the target population to see how the CV-Ca perform and assess face validity. Afterwards, field testing in a clinical setting is warranted to evaluate construct and criterion validity and measurements of reliability of the CV-Ca.

Integrating the CV-Ca into the original API has the potential to offer healthcare providers a more holistic view of patients' preferences for involvement in decision-making throughout their cancer care, fostering patient-centered care and SDM in oncology. This instrument has practical implications for primary care physicians and oncologists, potentially offering a dynamic and nuanced approach to navigating the complexities inherent in medical DM through the cancer care continuum.

## Conclusion

In conclusion, the CV-Ca represents a significant advancement in measuring DMP in cancer care. It offers healthcare providers a nuanced instrument that can better support shared decision-making, ultimately aligning care with patients' values and preferences. Future research should focus on implementing and testing the instrument in diverse clinical environments to ensure its reliability, applicability, and impact on patient outcomes.

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# Appendix 1. Autonomy Preferences Index (API) scoring system.

According to the original publication, each item is rated from 1 (patient has the weakest desire for decision-making or information seeking) to 5 (patient has the strongest desire for decision-making or information seeking). The DMP and ISP scores are computed as the sum of the 15 and eight answers respectively, linearly adjusted to range from 0 to 100 where 0 refers to a total absence of desire for decision making or wanting to be informed and 100 to the strongest possible desire. To assess the impact of illness severity on the patients' decision making preferences, each of the clinical vignettes scores (URTI, HBP, and MI) are computed from the sum of the answers to the three items, linearly adjusted to range from 0 to 10 where 0 signifies the patient's preference for the doctor to have complete control, 5 indicates the patient's desire for equal involvement with the doctor, and 10 represents the patient's preference for complete control over their healthcare decisions.

## The Autonomy Preference Index (API)

### Part 1A: Decision making preference scale.

General items for decision making preference. Participants respond to each item on a five-point Likert scale, response choices are: strongly disagree, disagree, neither agree or disagree, agree, and strongly agree.

Please select the option that best describes your preferences in the next statements.

1. *The important medical decisions should be made by your doctor, not by you.
2. You should go along with your doctor's advice even if you disagree with it.
3. *When hospitalized, you should not be making decisions about your own care.
4. You should feel free to make decisions about everyday medical problems.
5. *If you were sick, as your illness became worse, you would want your doctor to take greater control.
6. You should decide how frequently you need a check-up.

* Scoring of these items is reversed, and goes from 5 to 1, rather than 1 to 5.

**Part 1B: Clinical vignettes.**

Participants respond to each item on a five-point Likert scale, response options are: you alone, mostly you, the doctor and you equally, mostly the doctor, and the doctor alone.

The cases presented in the following boxes are clinical scenarios which may not be related to your health condition. By imagining yourself in each situation described, can you answer the following questions? Response options are: you alone, mostly you, the doctor and you equally, mostly the doctor, and the doctor alone.

**Upper Respiratory Tract Illness.** Suppose you develop a sore throat, stuffy nose, and cough that lasted for three days. You are about to call your doctor on the phone. Who should make the following decisions?

7. Whether you should be seen by the doctor.
8. Whether a chest x-ray should be taken.
9. Whether you should try coughing syrup.

**High Blood Pressure**. Suppose you went to your doctor for a routine physical examination and he or she found that everything was all right except that your blood pressure was high (170/100). Who should make the following decisions?

10. When the next visit to check your blood pressure should be
11. Whether you should take some time off from work to relax.
12. Whether you should be treated with medication or diet.

**Myocardial Infarction**. Suppose you had an attack of severe chest pain that lasted for almost an hour, frightened you enough so that you went to the emergency room. In the emergency room the doctors discover that you are having a heart attack. Your own doctor is called, and you are taken up to the intensive care unit. Who should make the following decisions?

13. How often the nurses should wake you up to check your temperature and blood pressure.

14. Whether you may have visitors aside from your immediate family.
15. Whether a cardiologist should be consulted.

**Part 2. Information-seeking preference scale.**

Participants respond to each item on a five-point Likert scale, response choices are: strongly disagree, disagree, neither agree or disagree, agree, and strongly agree.

Please select the option that best describes your preferences in the next statements. Response choices are: strongly disagree, disagree, neither agree or disagree, agree, and strongly agree.

1. As you become sicker you should be told more and more about your illness.
2. You should understand completely what is happening inside your body as a result of your illness.
3. Even if the news is bad, you should be well informed.
4. Your doctor should explain the purpose of your laboratory tests.
5. * You should be given information only when you ask for it.
6. It is important for you to know all the side effects of your medication.
7. Information about your illness is as important to you as treatment.
8. When there is more than one method to treat a problem, you should be told about each one.

## Appendix 2. First version of the CV-Ca

**Instructions:** The cases presented in the following boxes are hypothetical clinical scenarios not intended to represent your current health condition. By imagining yourself in each situation described, please answer the following questions with one of the response choices.

1. You alone
2. Mostly you
3. The doctor and you equally
4. Mostly the doctor
5. The doctor alone

**CV1.** Suppose you went to your family doctor because you have been concerned about your risk of developing breast cancer. You are 45 years old; you smoke, and some of your family members have had breast cancer. You and your doctor talk about things you could do to lower your chances of getting it and find it early. Who should make the following decisions?

Questions:

1. Whether you should make lifestyle changes, like attend a smoking cessation program.
2. Whether you should get an imaging screening test, such as a mammogram.
3. Whether you should have genetic testing for gene mutations that increase the risk of breast cancer.

**CV2.** Suppose you went to your family doctor because you have been feeling unwell. In the past month, you have had stomach pain, trouble going to the bathroom, and you have lost weight without trying. Your doctor recommends getting a colonoscopy, which is done with an endoscope to check inside your colon. During the procedure, the specialist finds and removes three polyps (masses that stick out of the lining of the colon) which are tested for the presence of cancerous cells. Who should make the following decisions?

Questions:

1. Whether you should have a colonoscopy more often, if a polyp is found to be precancerous.
2. Whether you should get a genetic test to screen for hereditary (familial) causes of colon cancer that initially present as non-cancerous polyps.
3. Whether you should see a cancer specialist, like a surgeon, if a polyp is found to be cancerous.

**CV3.** Suppose you went to your family doctor because over the past few months you have been feeling very tired and noticed some bruises that you cannot explain. Your doctor recommends doing blood tests and sends you to see a hematologist (a specialist in blood). The hematologist thinks you might have a type of blood cancer called acute myeloid leukemia (AML). They say more tests are needed to be sure and to see if the cancer has spread. Who should make the following decisions?

Questions

1. Whether you should undergo a bone marrow biopsy (collection of tissue from the bone marrow with a special needle).
2. Whether you should have a lumbar puncture (spinal tap) to check if the cancer cells have spread to the brain and spinal cord.
3. Whether you should seek a second opinion from another specialist.

**CV4.** Suppose you are at your oncologist's office because you have been diagnosed with stage III non-small cell lung cancer. Your doctor goes over your medical history and tests with other experts from different subspecialties. They discuss your treatment options and how likely it is that the cancer can be cured. The treatment involves different therapies, which can cause side effects. Who should make the following decisions?

Questions

1. Whether you should start cancer treatment.
2. Whether you should have chemotherapy.
3. Whether you should undergo surgery.

**CV5.** Suppose you were diagnosed with prostate cancer 5 years ago and received treatment. Since then, you have been free from cancer. Yearly, the doctor has monitored the prostate-specific antigen (PSA) levels in your blood for any signs of cancer coming back. At your last

check-up, your doctor says that your PSA levels have started to slowly rise, which means the cancer might be back. Who should make the following decisions?

Questions

1. Whether you should get PSA testing more often, e.g. every 3 months.
2. Whether you should have a biopsy of the prostate.
3. Whether you should tell your family or those close to you about these findings.

**CV6.** Suppose you have stomach cancer that has spread to other parts of your body. You have received many chemotherapy treatments, but your cancer has continued to grow. You are now having a lot of symptoms like stomach pain, feeling sick, throwing up, being tired, and losing weight. At your last visit, your oncologist discusses potential next steps with you. One option might be to stop cancer treatment, and to focus on your quality of life and treating your symptoms instead (known as best supportive care or palliative care). Who should make the following decisions?

1. Whether you should stop cancer treatment.
2. Whether you should receive palliative care involving strong pain medications.
3. Whether you will want aggressive interventions like chest compressions, mechanical ventilation, or going to the intensive care unit in critical situations where your heart or lungs have serious difficulty working.

## Appendix 3. Interview guide

Introduction. Greeting and Purpose/ Confidentiality, Safety, and Consent

Interviewer: Good [morning/afternoon/evening], [Participant's Name]. Thank you so much for taking the time to join us today. My name is Yetiani Roldan, and I'm part of the research team working on the development CV-Ca measurement instrument.

We really appreciate your participation in this study. The purpose of our interview today is to gather your detailed feedback on the new instrument we've developed to measure the level of involvement in decision-making across all stages of cancer care. Your insights are incredibly valuable to us and will help us improve the instrument to better meet the needs of patients living with cancer.

Before we begin, I want to assure you that all the information you share will be kept confidential. If during the interview you feel anxious or uneasy, please tell me. We can pause and stop the interview at any time.

With your permission, we'd also like to record this interview to ensure we capture all your feedback accurately. Is that okay with you? I will also be taking some notes to help me highlight important things you say.

Warm-Up Questions

Background Information

Could you please tell me a little about your experience with decision-making in cancer care?

[For healthcare providers] How long have you been involved in the cancer care continuum?

At what stage of the CCC are you mostly involved with patients?

What are your overall impressions of the CV-Ca measurement instrument?

What did you like most about it?

What did you like least about it?

**Detailed Feedback on the Instrument** (pull out an Excel sheet with the participant's ratings, write as needed in the cell below the item in question)

Relevance of Clinical Vignettes and Questions

Did you find the clinical vignettes relevant to decision-making across the cancer care continuum?

Would you add or change any of the clinical scenarios? Can you describe it?

You rated some items as not relevant. Could you please explain why you felt those items were not applicable?

[Provide with the items rated as not relevant by the participant]

What specific changes would make these items more relevant to your experience or perspective?

Clarity of Items

Were the clinical vignettes clear? Do you have any suggestions on how we could improve the clarity of the clinical scenarios?

You indicated that some items were not clear. Can you describe what aspects of these items were confusing or unclear to you?

[Provide with the items rated as not clear by the participant]

Do you have suggestions on how we could rephrase these items to enhance clarity?

Comprehensiveness of the Instrument

Coverage of the Decision-Making Process

Do you feel that the instrument covers all important aspects of involvement in decision-making throughout the cancer care continuum?

If not, what key areas do you think are missing?

Are there any questions you would suggest adding?

Relevance Across All Stages

Does the instrument adequately address the different stages of the cancer care continuum (screening, detection, diagnosis, treatment, survivorship, recurrence, end-of-life.) and the potential decisions that patients may need to make related to their health in real life?

Are there stages where you feel more questions are needed? Can you describe it?

Comprehensibility of the Instrument

Ease of Understanding

Overall, how easy was it for you to understand the questions in the instrument?

Were there any terms or phrases that you found particularly difficult to understand?

How might we improve the wording to make the instrument easier to comprehend?

Length and Format

Was the length of the instrument appropriate?

Did you find it too long or too short?

Were clinical vignettes clear and appropriate?

Were the questions to each vignette clear and appropriate?

Additional Feedback

Suggestions for Improvement

Do you have any additional suggestions or comments on how we can improve this measurement instrument?

Conclusion

Interviewer: Thank you so much for your time today, [Participant's Name]. Your feedback has been incredibly valuable and will play a crucial role in helping us improve the CV-Ca measurement instrument.

As for the next steps, our research team will analyze all the data collected from these interviews. Based on the insights we gather, we will write a revised version of the CV-Ca. Once the revisions are complete, we will send the updated version to all participants, including yourself, via an online survey. In this survey, you'll be able to rate the revised items on their relevance and clarity.

Your continued participation is greatly appreciated, and we hope you'll be able to provide further feedback on the revised instrument. If you have any questions or thoughts after today's interview, please feel free to contact me by email. I'd be happy to further discuss.

Thank you again for contributing to this important research. I look forward to collaborating with you further.

Have a great [day/evening]!

Notes:

1. Ensure that the interview is conversational and allows the participant to elaborate on their responses.
2. Use prompts and follow-up questions as needed to gain deeper insights.
3. Record responses accurately and take note of any specific suggestions or feedback for each item discussed.

## Appendix 4. Second version of CV-Ca

**Instructions for clinicians:** To ensure the accuracy and reliability of the responses in this questionnaire, please follow these guidelines:

1. Ensure the respondent is cognitively sound and free from any signs of cognitive decline.
2. Avoid administering the questionnaire to respondents who are currently undergoing any treatment or therapy that may alter cognition, such as chemotherapy, strong pain medications, or psychotropic drugs. If the respondent has recently received such treatments, schedule the questionnaire for a time when the cognitive effects of the medications are likely to have subsided.
3. Administer the questionnaire when the participant is not fatigued or overly tired, which can impair their focus and understanding. Ideally, schedule the session during the morning or after a period of rest.

**Instructions for respondents:** The cases presented in the following boxes are hypothetical clinical scenarios and are not intended to represent your real health condition. For each clinical scenario:

1. Imagine yourself in each situation described.
2. Assume all the options given in each question are possible and can happen in real life. This means:
    a. A doctor may suggest any of these options for that clinical scenario.
    b. All options are available in your healthcare system.
3. Read each clinical scenario carefully.
4. Answer the questions in order.
5. Choose one response for each question from these options:
    - You alone
    - Mostly you
    - The doctor and you equally
    - Mostly the doctor
    - The doctor alone

***CV1. Breast cancer screening***. Suppose you went to your family doctor because you have been concerned about your risk of developing breast cancer. You are healthy, 50 years old; you smoke, and some of your family members have had breast cancer. You and your doctor talk about things you could do to lower your chances of getting it and find it early. Who should make the following decisions?

Questions

1. Whether you should make lifestyle changes, like attending a smoking cessation program.
2. Whether you should get an imaging screening test, such as a mammogram.
3. Whether you should have genetic testing to look for genetic variations that increase the risk of certain types of breast cancer.

***CV2. Colon cancer detection***. Suppose you went to your family doctor because you have been feeling unwell. In the past month, you have had stomach pain, diarrhea, and you have lost weight without trying. Your doctor recommends getting a colonoscopy, which is done with an endoscope to check inside your colon (bowel). During the procedure, the specialist finds and removes two polyps (masses that stick out of the lining of the colon) which are tested for the presence of cancerous cells. Who should make the following decisions?

Questions

1. Whether you should have screening with a fecal immunochemical test (FIT, an at-home test that checks for tiny amounts of blood in your stool), in 5 years if the specialist found non-cancerous polyps (low risk).
2. Whether you should have a follow-up colonoscopy sooner (in 3 years instead of 10) if the specialist finds a precancerous polyp (a polyp that can turn into cancer over time).
3. Whether you should see a cancer specialist, like a surgeon, if the specialist finds a cancerous polyp.

***CV3. Leukemia diagnosis.*** Suppose you went to your family doctor because over the past two weeks you have been feeling very tired and noticed some bruises that you cannot explain. Your doctor recommends doing blood tests and sends you to see a hematologist (a specialist in blood). Your tests show that you have a large number of abnormal blood cells. The hematologist thinks you might have leukemia (blood cancer). They say more tests are needed to be sure of the diagnosis and find out the type of leukemia. Who should make the following decisions?

Questions

1. Whether you should undergo a bone marrow biopsy (collection of tissue from the bone marrow with a special needle).
2. Whether you should have cytogenetic and molecular tests (special tests that look closely at your genes) to find out the type of leukemia.
3. Whether you should tell your family or those close to you about these findings if the hematologist confirms you have leukemia.

***CV4. Lung cancer treatment.*** Suppose you are at your oncologist's office because you have been diagnosed with stage III non-small cell lung cancer. Your doctor goes over your medical history and tests with other experts from different subspecialties. They discuss your treatment options and how likely it is that the cancer can be cured. The treatment involves different therapies, which can cause side effects. Who should make the following decisions?

Questions

1. Whether you should start cancer treatment.
2. Whether you should have chemotherapy.
3. Whether you should undergo surgery.

***CV5. Prostate cancer recurrence.*** Suppose you were diagnosed with prostate cancer 5 years ago and received treatment. Since then, you have been cancer-free. Every 6 months, the doctor has monitored the prostate-specific antigen (PSA) levels in your blood for any signs of cancer coming back. At your last check-up, your doctor says that your PSA levels have started to slowly rise (going from undetectable to detectable levels above 0.2 ng/ml). The doctor asks you to repeat the test two weeks later, and the PSA levels remain detectable, which means the cancer might be back. Who should make the following decisions?

Questions

1. Whether you should get a bone scan (a computer creates an image of your skeleton using small amounts of radioactive material to check if the cancer has spread to the bone).
2. Whether you should be under active surveillance (the doctors will watch the cancer carefully, with a plan to start treatment if tests show it's growing faster).
3. Whether you should seek a second opinion from another cancer specialist.

***CV6. Stomach cancer end stage***. Suppose you have stomach cancer that has spread to other parts of your body. You have received many chemotherapy treatments, but your cancer has continued to grow. You are now having a lot of symptoms like stomach pain, feeling sick, throwing up, being tired, and losing weight. At your last visit, your oncologist discusses potential next steps with you. One option might be to stop cancer treatment, and to focus on your quality of life, your mental health, and treating your symptoms (known as palliative care). Who should make the following decisions?

Questions

**1.** Whether you should stop cancer treatment.
**2.** Whether you should receive only palliative care (care that helps with pain and other symptoms, provides emotional and spiritual support, and makes sure you are comfortable).
**3.** Whether you will want aggressive interventions like chest compressions, mechanical ventilation, or going to the intensive care unit if your condition worsens (for example, if your heart or lungs are not working well).