Patient Preference and Adherence

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ORIGINAL RESEARCH

Comparing Methods for Identifying Post-Market Patient Preferences at the Point of Decision-Making: Insights from Patients with Chronic Pain Considering a Spinal Cord Stimulator Device

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Purpose: To compare three methods for identifying patient preferences (MIPPs) at the point of decision-making: analysis of video-recorded patient-clinician encounters, post-encounter interviews, and post-encounter surveys.

Patients and Methods: For the decision of whether to use a spinal cord stimulator device (SCS), a video coding scheme, interview guide, and patient survey were iteratively developed with 30 SCS decision-making encounters in a tertiary academic medical center pain clinic. Burke's grammar of motives was used to classify the attributed source or justification for a potential preference for each preference block. To compare the MIPPs, 13 patients' encounters with their clinician were video recorded and subsequently analyzed by 4 coders using the final video coding scheme. Six of these patients were interviewed, and 7 surveyed, immediately following their encounters.

Results: For videos, an average of 66 (range 33–106) sets of utterances potentially indicating a patient preference (a preference block), surveys 33 (range 32–34), and interviews 25 (range 18–30) were identified. Thirty-eight unique themes (75 subthemes), each a preference topic, were identified from videos, surveys 19 themes (12 subthemes), and interviews 39 themes (54 subthemes). The proportion of preference blocks that were judged as expressing a preference that was clearly important to the patient or affected their decision was highest for interviews (72.8%), surveys (68.0%), and videos (27.0%). Videos mostly attributed preferences to the patient's situation (scene) (65%); interviews, the act of receiving or living with SCS (43%); surveys, the purpose of SCS (40%).

Conclusion: MIPPs vary in the type of preferences identified and the clarity of expressed preferences in their data sets. The choice of which MIPP to use depends on projects' goals and resources, recognizing that the choice of MIPP may affect which preferences are found.

Keywords: patient preferences, decision making, regulatory, preference identification, preference elicitation

Introduction

Patient preferences, broadly defined as the relative desirability or acceptability of different attributes of health interventions,[1] strongly influence the use of medical products. In the specific context of chronic pain management, patient preferences are particularly influential given the large array of available treatment alternatives. For example, patient preferences, driven by direct-to-consumer advertising, may have contributed to the use, overuse, and abuse of opioids.[2] In addition, treatment preferences may be further influenced by gender differences in pain experiences and the quality of health care received when seeking pain management.[3] Where relevant, empirical assessments of patient preferences can provide valuable insights during the regulatory process by which medical treatments and devices are evaluated for safety and effectiveness and ultimately approved to be sold on the market. Although the Food and Drug

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Administration (FDA), the government agency tasked with regulating medical drugs and devices in the United States, is increasingly encouraging the appropriate use of patient preference studies in the regulatory process, efforts have largely focused on pre-market evaluations during medical product development, clinical trial design, and benefit-risk assessments.[4,5] However, these preferences may not reflect how patient preferences affect the use of a drug or device after it becomes available for use (ie, during the post-market phase).

Post-market assessment of patient preferences can shed light on changes in patient perceptions or benefit-harm determinations once a drug or device has been used more widely. Some aspects of post-market preferences can be derived from the experience of those who have adopted and lived with a medical product. Other insights may come from the preferences that patients hold when they are making decisions with their clinicians about product use. These preferences are particularly significant as they likely determine if the patient will adopt the drug or device. Understanding the post-market, pre-adoption preferences that are at play during clinical decision-making can facilitate patient-centered communication of benefit-harm information on drug or device labeling, inform the production of shared decision-making tools, contribute to formulating clinical practice guidelines, and support clinicians in making decisions with their patients.[1,5–7] There is a need to characterize post-market patient preferences as they manifest when making decisions and which then affect drug or device use.

However, the best methods for understanding the nature and role of post-market preferences are underdeveloped,[8,9] particularly methods for understanding the preferences that affect patient's decision-making. Patient preferences are commonly elicited with methods that rely on hypothetical choices or scenarios, such as discrete choice experiments or best-worst scaling.[9] In addition, most patient preference studies are conducted outside of real-time clinical decision-making, asking patients to consider their values and preferences in the abstract, either retrospectively for past decisions or in a speculative fashion for future decisions. Methods to evaluate real—not hypothetical— patient preferences at the point of decision-making are underdeveloped.

General research methods that may be applicable for identifying patient preferences that are more proximal to decision-making include direct from encounter (DFE) methods, involving researcher observation and analysis of a clinical encounter and immediately post-encounter (IPE) methods, which include debriefing or surveying the patient immediately after the encounter. To our knowledge, there are no validated DFE and IPE methods to characterize post-market patient preferences in this context. General DFE and IPE research approaches have apparent strengths and limitations (Table 1) However, the relative advantages and disadvantages of using these methods to identify and understand patient preferences at play in actual decision-making is unclear.

The objective of this study was to compare three distinct methods for identifying patient preferences (MIPPs) as they manifest in decision-making encounters between patients and clinicians: (a) video analysis of clinical encounters, (b) post-encounter interviews, and (c) post-encounter surveys. In this study, we used the decision of whether to use a spinal cord stimulator (SCS) for the management of chronic pain to compare these methods. In the context of the many alternative treatment options available for chronic pain management, the decision to adopt SCS can be described as

Table 1 Direct from Encounter (DFE) and Immediately Post-Encounter (IPE) Methods and Their Strengths and Limitations

Method	Strengths	Limitations
Third-party observation (DFE)	• Not limited to preferences recalled post-hoc or identified a-priori • May capture issues of preference that participants are unaware of • Not contaminated by post-hoc justifications of participants that may not reflect preferences in the actual decision making	• Dependent on observer interpretation • Uninformed by the nuance of participant accounts • Time-intensive for researchers
Post-encounter debriefing (IPE)	• Captures patient perspective • Semi-structured nature allows for flexibility as required as a means of acquiring unexpected issues	• Time-intensive for patients and researchers • Subject to post-hoc justifications that may not reflect in-encounter preferences
Post-encounter surveying (IPE)	• Captures patient perspective • Relatively quick • Straightforwardly amenable to quantification	• Loss of nuance • Subject to post-hoc justifications that may not reflect in-encounter preferences

highly sensitive to patient preferences. Notably, the FDA has identified benefit-harm tradeoffs related to attributes of chronic pain therapy as a patient preference-sensitive priority area.[10]

Methods

Clinical Context

SCS is a neuromodulation treatment for chronic pain that involves implantation of electrical leads in the epidural space connected to an implanted pulse generator. SCS is indicated for patients with chronic pain for whom oral or topical medications, physical therapy, and clinic-administered injections have been ineffective.[11] The first fully implantable SCS device became available commercially in 1981, shortly after the FDA began regulating medical devices under the Medical Device Amendments of 1976.[12] Today, there are nine FDA-approved SCS devices on the market, with variability in features such as battery life and recharging frequency, stimulation settings, magnetic resonance imaging (MRI) compatibility, and need to deactivate while driving.[13] SCS, as a treatment modality, also has different use characteristics than medical approaches.

In general, placement of the stimulator follows a two-stage process consisting of placing temporary leads for one week in the epidural space and connecting to an external trial SCS, followed by permanent implantation of the leads and device. An SCS trial is considered successful when the patient experiences ≥50% reduction in pain level.[14] However, many other considerations influence the suitability of SCS for an individual patient, including ability to attend multiple appointments before, during, and after implantation, history of comorbid conditions that increase risk of infection and postoperative complications, and capacity to follow instructions for postoperative care and ongoing use of the device.[11,14–16]

Development and Comparison of the MIPPs

In the first phase of the study, we developed each of the three MIPP instruments: 1) a coding scheme for video-recorded clinical encounters, a patient interview guide, and a patient survey. The interview and survey coding schemes were designed to be compatible with the video coding scheme for the purpose of comparison. The development process is more fully described in Supplementary File 1. In the second study phase, we compared these three methods using data from real clinical encounters (see Figure 1 for overview of study methods).

Study Setting and Population

All data collection activities, for both the MIPP development and comparison phases, were conducted in the Pain Clinic at Mayo Clinic, Rochester, MN. Eligible patients were 18 or older, had no indication of impaired cognitive function, and were scheduled to have an outpatient consultation or education visit related to SCS with a pain medicine physician, nurse educator, or clinical fellow. Participants were enrolled between November 2019 and November 2021. All study procedures were conducted in accordance with the Declaration of Helsinki and approved by the Mayo Clinic Institutional Review Board (study ID: 19–006857).

Recruitment and Consent

Project investigators identified clinicians at the Pain Clinic involved in SCS consults or patient education. After meeting with each clinician to explain the purpose of the study and obtain their written informed consent to participate, a study coordinator screened their schedules weekly for eligible patients. Clinicians could raise any concerns about the inclusion of any patient prior to their invitation. A total of 28 clinicians (including staff physicians, nurse educators, and clinical fellows) were approached for consent throughout the course of both study phases, with 2 declining to participate (93% enrollment rate).

Shortly before an eligible patient's scheduled appointment time, a study team member entered the exam room to obtain written informed consent from the patient (and oral permission from any patient guests) to participate in the study. During the MIPP development phase, 64 eligible patients were approached in clinic, 28 declined, and 36 consented to have their encounter filmed and complete a post-encounter survey or interview (56% enrollment rate). For the comparison phase, 20 patients were approached, 7 declined, and 13 were enrolled (65% enrollment rate).

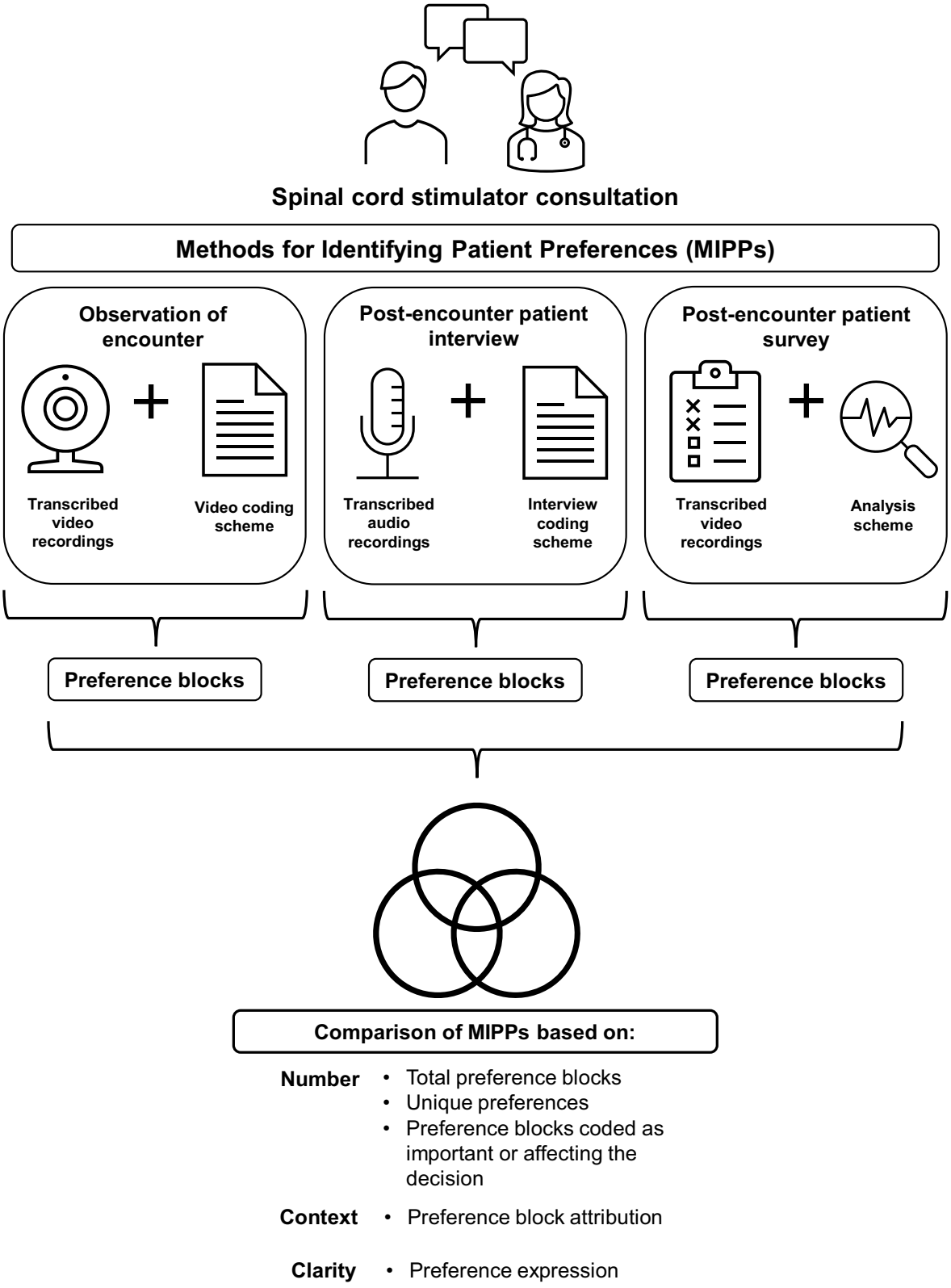

Figure 1 Overview of study methods.

For patients who consented to participate, the study team member then placed a small video recorder in a central position in the exam room such that the patient and clinician would both be captured in the frame. The study team member started the recording, left the room, and returned to the nursing workroom. At the conclusion of the appointment, the study team member retrieved the video recorder from the exam room and stopped the recording.

Any draft surveys or interviews were administered immediately following the encounter. Due to the COVID-19 pandemic, some study encounters were virtual telemedicine visits. In these cases, recruitment, consent, and data collection procedures were adapted to the virtual environment but otherwise remained similar to in-person processes.

Comparators

Comparator 1: Coded Video Observations of Patient-Clinician Encounters

Video-recorded patient-clinician encounters were viewed by the research team, transcribed, and imported to an Excel file. Consecutive transcribed speech turns of the patient, the clinician, or the guest that discussed a single primary topic or issue that was conceivably desirable or undesirable in some way related to SCS were grouped into "preference blocks". Preference blocks ranged in length from a single patient statement or question to multiple contributions from the participants involving a series of back-and-forth verbal exchanges. We set a low threshold to identify a preference block given that preferences are often expressed implicitly, indirectly, or ambiguously in patient-clinician exchanges.[17]

To capture how a topic entered the conversation, we classified each speech turn by the primary expression format used by the interlocutor (eg, a patient's response to clinician question). Preference blocks were coded according to the domains listed in Table 2 to capture, among other things, information about the extent to which a patient expressed the desirability (eg, "I went to a personal trainer in Iowa. He helped me do some stuff, and that's helped some") or undesirability (eg, "See, [my friend] had one of these [an SCS], and it was a pain to charge"), importance, and effect on decision-making of a given preference. Specifically, the key domain of importance was coded using the mutually exclusive categories of "important" (eg, "The risk of the surgery. I worry about that"), "not important" (eg, "I'm not worried about cost. I have good insurance"), or "unclear", (eg, Clinician: "Then afterwards, you would have to have a driver, because you had sedation. We wouldn't want you driving probably the rest of that day". Patient: "Okay"), while

Table 2 Domains and Categories Used for Coding of Video, Interview, and Survey Data

Domain	Domain Description	Domain Categories
Burkean category	What the preference refers to or originates from. (See Supplementary File 1 for a description of Burkean categories)	1. Act 2. Agent 3. Agency 4. Scene 5. Purpose
Description	The subject of the preference expression as identified by a Burkean term.	Descriptive
Desirability	The degree to which the preference block clearly indicates something that is desirable or undesirable.	1. Clearly desirable for the patient 2. Clearly undesirable for the patient 3. I assume the patient finds this desirable based on what is known about the patient 4. I assume the patient finds it desirable based on common sense or universally held values 5. I assume the patient finds it undesirable based on what is known about the patient 6. I assume the patient finds it undesirable based on common sense or universally held values 7. Unclear whether the patient finds it desirable or undesirable

(*Continued*)

Table 2 (Continued).

Domain	Domain Description	Domain Categories
Importance	The perceived importance of the preference for the patient.	1. Important 2. Not important 3. Unclear
Affects the decision	The perceived extent to which a preference affects the patient's decision making.	1. Affects the decision 2. Does not affect the decision 3. Unclear
Interaction with decision partner	Used to designate times in which patient preferences emerged from the interaction between the patient and the guest.	1. Yes 2. No
Theme		Thematic, based on inductively generated themes
Subtheme		Thematic, based on inductively generated themes
Expression format	Indicates the manner in which a preference is expressed.	1. Patient direct expression of will 2. Patient initiated request for something to happen 3. Patient question to clinician 4. Patient response to a clinician answer 5. Patient response to a clinician question 6. Patient response to a clinician statement 7. Patient question to guest 8. Patient response to a guest answer 9. Patient response to a guest question 10. Patient response to a guest statement 11. Patient raising or reacting to information or opinions provided by third parties 12. Patient probing possible modifications to plan or options 13. Clinician direct expression of will 14. Clinician initiated request for something to happen 15. Clinician probing possible modifications to plan or options 16. Guest direct expression of will 17. Guest initiated request for something to happen 18. Guest question to clinician 19. Guest response to a clinician answer 20. Guest response to a clinician question 21. Guest response to a clinician statement 22. Guest question to patient 23. Guest response to a patient answer 24. Guest response to a patient question 25. Guest response to a patient statement 26. Guest raising or reacting to information or opinions provided by third parties 27. Guest probing possible modifications to plan or options

Notes: All domains were coded at the level of the preference block with the exception of "expression format", which was coded at the level of the speech turn.

effect on decision-making was categorized for each preference block as either "affects the decision" (eg, "That's kinda scary with seeing what [the SCS implant] is…I think I'll try the cream first"), "does not affect the decision" (eg, Patient: "If I walk through a metal detector, is it gonna go off for that?" Clinician: "It might". Patient: "I already go off for that

anyway [with my pacemaker], so I just am curious. Okay") or "unclear" (eg, Patient: "How does it stay in your body?" Clinician: "It's implanted underneath your skin. After the trial" after which the patient made no additional comment).

In addition, we used a framework based on Kenneth Burke's Pentad of Motives[18,19] to classify each preference block according to patient motivations for taking action (in this case, proceeding with SCS; see Supplementary File 1). The five Burkean categories were used in this study to distinguish different aspects of SCS that participants indicate may be desirable or undesirable. "Act" refers to qualities of the act of acquiring, utilizing, and living with SCS treatment or other acts involved in pain management (eg, "Is [the SCS implantation] like a laparoscopic kinda thing up there, or is it more of like the opening, like with my lower back?"; "[The SCS device] is waterproof, so I'd be able to shower for that, too?"). "Agent" refers to aspects of a person or group of people, such as the opinion of a clinician or word-of-mouth knowledge of SCS from friends, family members, or acquaintances (eg, Clinician: "One of the things they sent you to talk to us about was something called a spinal cord stimulator. Did they talk to you about that at all?" Patient: "No, but I know quite a few people that's had it done". Clinician: "How have they done with it?" Patient: "They swear by it"). "Agency" refers to attributes of the SCS device itself, including its size, frequency of charging, likelihood of malfunction, and other characteristics (eg, "I worry about when you're laying down on [the SCS device], if there's a wire sticking out getting snagged…"). "Scene" refers to contextual factors that make SCS more or less desirable, including the patients' medical history, current level of pain, and experience with other pain management approaches (eg, "[I've] tried Tramadol. I didn't really like it. It just made me go to sleep"). Finally, "purpose" is used when a participant attributes desirability to the results that SCS may achieve or a favorable alignment with patient goals or values (eg, "My goal would be to get off some of these pain meds. I just do not like that"). Expressions of preference may be attributed to be arising from, or be because of, one of these categories.

Comparator 2: Coded Post-Encounter Interviews

For post-encounter patient interviews, we iteratively developed a semi-structured interview guide that was informed by observing five encounters and debriefing subsequently with their participants (Supplementary File 2). The guide included topics observed in the encounters that were judged by the researchers to be relevant to decision-making. Using the finalized interview guide, interviews were conducted, audio or video recorded, transcribed, and grouped into preference blocks using the same process as for videos. Coding of preference blocks in interviews was performed using the same categories as for the video transcripts, with the exception of the domain "expression format" which was not pertinent to interviews (Table 2).

Comparator 3: Coded Post-Encounter Survey Results

We produced the survey instrument using the same iterative method used to develop the interview guide (Supplementary File 3). We used Likert-type scales for the responder to characterize the importance of each topic and the degree of effect it may have on their decision-making. Each survey question was intended to capture a distinct aspect of SCS preferences, a design choice that resulted in each survey question and its answer counting as a preference block. While this structure resulted in a narrow, pre-determined number of preference blocks obtained from a given survey (unlike the coded videos or interviews, in which the absolute number of preference block could be highly variable), and our goal was to leverage the advantages of a survey by capturing a wide array of preferences efficiently. These preference blocks were analyzed using the same domains as for the videos and interviews, with exception that "interaction with decision partner" and "expression format" were omitted as not pertinent to the survey format (Table 2).

Comparison of DFE vs IPE MIPPs

In a 1:1 alternating order, patients were either video recorded and then surveyed or video recorded and then interviewed. The survey was fielded in Qualtrics on a research touchscreen tablet and completed independently by the patient immediately after their clinical encounter, with a study team member available in the room to address technical issues or answer clarifying questions. The interview took place in person immediately after the clinical encounter. D.G. conducted all interviews for consistency. Video and interview speech turns were blocked and coded by one of the four coders (EG, D.G., I.H., M.L) and then reviewed by the whole group in meetings. A consensus process was used to

resolve disputes. A member of the coding team coded individual participants' preference blocks and the whole coding team reviewed these codes in virtual meetings. As part of this process, themes and subthemes were inductively generated and assigned.

The MIPPs were compared on the basis of two domains: 1) distribution of preference blocks and 2) the context of these preference blocks. Specifically, for distribution of preference blocks, we evaluated the number of unique preferences identified (each theme and sub theme was treated as a preference); the proportion of preference blocks related to each theme or subtheme within each instrument; and the proportion of preference blocks indicating a preference that was important to the patient or affected their decision. In addition, because we judged that preferences that are important or affected the decision are of particular interest for users of MIPPs for regulatory purposes, we combined these two categories and characterized patient preference blocks as "clearly important or clearly affects the decision" if one or both were indicated for a given preference block. To assess the context of preferences, we examined Burkean categories and the clarity of preference expression.

Analysis

All analyses were conducted at the preference block level. Descriptive statistics were computed for each variable and compared across instruments. Comparisons are reported both in aggregate for each instrument as well as for individual participants (ie, comparing results from the video and interview for the same participant).

All analyses were performed in SPSS statistical software, Version 28 (Armonk, NY: IBM Corp).

Results

In total, data from 13 patient participants were included in the comparison of the three MIPPS. Clinical encounters were video-recorded for all 13 patients, with seven participants completing the post-encounter survey (video-survey group) and six participants completing the post-encounter interview (video-interview group). Participants were evenly distributed by gender (Table 3) and were an average of 59 years old (range: 31–77 years). All participants were white and not Hispanic or Latino. Most patients (69%) were accompanied by a guest (eg, spouse or other family member) during the encounter. Clinicians (n = 6) were physicians (including fellows) except for one advanced practice nurse and were evenly split by gender.

In terms of length of time needed to acquire data for each MIPP, videos had an average encounter duration of 01:03:51, followed by interviews (00:13:34) and surveys (00:04:42).

Distribution of Preferences

Overall, we identified more absolute preference blocks per encounter on average from videos (mean: 66 preference blocks; range: 33–106) than from interviews (mean: 25; range: 18–35). Since, by design, there was a direct correlation between the number of survey items and the number of preference blocks, the number of preference blocks per encounter was almost identical among survey participants (mean: 33; range: 32–34).

Nearly three-quarters of preference blocks identified in interviews (72.8%) and surveys (68.0%) were coded as expressing clearly important preferences compared to 21.6% of preference blocks in videos. Videos contained a higher proportion of preference blocks of unclear importance (77.6%) than surveys (24.9%) or interviews (23.2%).

Surveys (63.6%) and interviews (50.3%) contained a higher proportion of preference blocks coded as representing preferences that clearly affect the decision, compared to videos (16.2%). A higher proportion of preference blocks identified in videos were unclear as to whether they affected the decision (83.4%) compared to interviews (45.0%) and surveys (1.3%).

For the combined variable indicating whether a preference block was clearly important and/or clearly affected the decision, interviews (72.8%) and surveys (68.0%) contained higher proportions of preference blocks described as clearly important or affecting the decision compared to videos (27.0%). Conversely, preference blocks described as clearly not important and/or not affecting the decision comprised 26.0% of preference blocks in surveys, followed by 5.3% of preference blocks in interviews and 0.8% of those in videos.

Table 3 Patient (n = 13) and Clinician (n = 6) Sample Characteristics

	Frequency (Percent)
Patient age (mean ± SD)	58.8 years (12.5)
Patient gender	
Women	7 (53.8)
Men	6 (46.2)
Patient race	
White	13 (100.0)
Patient ethnicity	
Hispanic or Latino	0 (0.0)
Not Hispanic or Latino	13 (100.0)
Guest present for encounter	
Yes	9 (69.2)
No	4 (30.8)
Clinician type	
Physician	5 (83.3)
Clinical nurse specialist	1 (16.7)
Clinician gender	
Women	3 (50.0)
Men	3 (50.0)

Among the seven participants in the video-survey group, we found more preference blocks that were judged to be clearly important or clearly affected the decision in the survey than the video for six of the seven participants (Table 4). Among the six participants in the video-interview group, more preference blocks that were clearly important or clearly affected the decision were identified in the interview than in the video for three of these participants, the same number for two participants, and fewer for one participant (Table 5).

Preference Themes

Within preference blocks, a total of 39 distinct preference themes (54 subthemes) were identified from the interviews, followed by 38 themes (75 subthemes) from the videos and 19 themes (12 subthemes) from the survey. Videos and interviews each contained six themes and surveys contained two themes that were not present in the other instruments. The degree of overlap was low between the themes identified within preference blocks as being clearly important or affecting the decision across MIPPs (Table 6).

Context of Preferences

The distribution of Burkean categories to which preferences were attributed varied across the MIPPs. For instance, 65% of preference blocks arose from discussion of a "scene" in videos, compared to 12% for interviews and 6% for surveys (Figure 2). Among the entire sample, there was also variation in which Burkean categories were associated with preference blocks coded as important or affects the decision (Figure 3).

Table 4 Comparison of Themes Identified as Clearly Important or Clearly Affecting the Decision by MIPP for Video-Survey Participants

Participant	Video	Survey	Both
Participant S1	• Family member/guest • Function • Logistics • Medical history • Other therapies used for pain control • Pain relief • Paying • Reason for the visit • To subsequently address other problems • Treatment • Trying another option first	• Improve ability to travel • Improve function • Improve mood • Improve social interaction • Logistics • Maintenance • Multiple current clinicians • Non-clinicians • Other therapies used for pain control • Pain relief • Paying • Reduce medication	• Logistics • Other therapies used for pain control • Pain relief • Paying
Participant S2	• Compatibility • Current clinician • Multiple other clinicians • Opinion of other therapies • Other clinician • Other therapies used for pain control • Pain qualities • Patient • Procedure • Treatment • Trying another option first	• Compatibility • How the device works to reduce pain • Improve ability to travel • Improve function • Improve mood • Improve social interaction • Maintenance • Multiple current clinicians • Non-clinicians • Other therapies used for pain control • Pain relief • Placement of the device • Procedure • Reduce medication • Size of • Treatment • Trying another option first	• Compatibility • Multiple current clinicians • Other therapies used for pain control • Procedure • Treatment • Trying another option first
Participant S3	• Addressing other medical problems before considering SCS • Current clinician • Medical history • Other clinician • Pain qualities • Patient	• Compatibility • Family member/guest • How the device works to reduce pain • Improve ability to travel • Improve function • Improve mood • Improve social interaction • Logistics • Maintenance • Multiple current clinicians • Non-clinicians • Other therapies used for pain control • Pain relief • Placement of the device • Procedure • Reduce medication • Treatment	

(*Continued*)

Table 4 (Continued).

Participant	Video	Survey	Both
Participant S4	• Function • Improve function • Medical history • Pain qualities • Pain relief • Other therapies used for pain control • To be done with this	• Improve ability to travel • Improve function • Improve mood • Improve social interaction • Logistics • Multiple current clinicians • Other therapies used for pain control • Pain relief • Procedure • Reduce medication • Treatment	• Improve function • Pain relief • Other therapies used for pain control
Participant S5	• Function • Treatment • Trying another option first • Opinion of other therapies	• Compatibility • How the device works to reduce pain • Improve ability to travel • Improve function • Logistics • Maintenance • Multiple current clinicians • Other therapies used for pain control • Pain relief • Paying • Placement of the device • Procedure • Reduce medication • Size of • Treatment	• Treatment
Participant S6	• Current clinician • Not the right time to decide • Other therapies used for pain control • Pain qualities • Pain relief • To be done with this	• Compatibility • How the device works to reduce pain • Improve function • Improve mood • Improve social interaction • Maintenance • Multiple current clinicians • Non-clinicians • Other therapies used for pain control • Pain relief • Placement of the device • Size of • To be done with this	• Other therapies used for pain control • Pain relief • To be done with this
Participant S7	• How the device works to reduce pain • Improve function • Not the right time to decide • Other clinician • Other therapies used for pain control • Pain qualities • To be done with this • Trying another option first	• Improve ability to travel • Improve function • Improve mood • Improve social interaction • Multiple current clinicians • Other therapies used for pain control • Pain relief • Reduce medication • Trying another option first	• Improve function • Other therapies used for pain control • Trying another option first

Table 5 Comparison of Themes Identified as Clearly Important or Clearly Affecting the Decision by Method for Video-Interview Participants

Participant	Video	Interview	Both
Participant I1	• Medical history • Other therapies used for pain control • Pain qualities • Pain relief • Trying another option first	• Collaborative group • Compatibility • Current clinician • Improve function • Information • Medical history • Other clinician • Other therapies used for pain control • Pain relief • Procedure • Treatment • Trying another option first	• Trying another option first • Other therapies used for pain control • Pain relief
Participant I2	• Addressing other medical problems before considering SCS • Pain qualities • Procedure • Trying another option first	• Addressing other medical problems before considering SCS • Improve function • Pain qualities • Pain relief • Procedure • Reason for the visit • Trying another option first	• Addressing other medical problems before considering SCS • Pain qualities • Procedure • Trying another option first
Participant I3	• Family member/guest • Function • Improve function • Medical history • Other therapies used for pain control • Pain qualities • Permanently attached • Reason for the visit • Reduce medication • To be done with this • To subsequently address other problems	• Collaborative group • Current clinician • Improve ability to travel • Improve function • Improve mood • Improve social interaction • Other clinician • Pain relief • Procedure • Reduce medication • SCS as a new option • Stop opioids • To be done with this • Treatment	• Improve function • To be done with this
Participant I4	• Current clinician • Function • Improve function • Medical history • Not the right time to decide • Other therapies used for pain control • Pain qualities • Pain relief • Safety of • Trying another option first	• Compatibility • Function • Improve function • Maintenance • Other therapies used for pain control • Pain relief • Paying • Procedure • Treatment • Trying another option first	• Function • Improve function • Other therapies used for pain control • Pain relief • Trying another option first

(*Continued*)

Table 5 (Continued).

Participant	Video	Interview	Both
Participant 15	• Family member/guest • Improve function • Medical history • Other therapies used for pain control • Pain qualities • Reason for the visit • To be done with this	• Improve function • Improve social interaction • Information • Not experimental • Pain relief • Paying • Reason for the visit • Treatment	• Improve function • Reason for the visit
Participant 16	• Acquaintances of the patient or others • Function • Medical history • Other therapies used for pain control • Pain qualities • Pain relief • Procedure • Trying another option first	• Collaborative group • Cyborg concerns • Maintenance • Medical fears or trauma • Pain relief • Patient • Permanently attached • Possibility of device malfunctioning • Procedure • Reason for the visit • Treatment • Trying another option first	• Pain relief • Procedure • Trying another option first

Table 6 Comparison of Mean and Range of Theme Occurrence (Total and Whether Rated as Clearly Important or Clearly Affected the Decision) by MIPP and Grouped by Burkean Category

	Video		Interview		Survey	
	Total	**Important or affects decision**	**Total**	**Important or affects decision**	**Total**	**Important or affects decision**
Act						
Trying another option first	6.5 (0–23)	3.6 (0–15)	2.0 (0–4)	1.8 (0–4)	0.4 (0–2)	0.4 (0–2)
Procedure	2.0 (0–7)	0.5 (0–3)	3.2 (1–6)	3.0 (0–6)	2.1 (2–3)	1.3 (0–3)
Treatment	2.0 (0–8)	0.3 (0–2)	1.8 (1–3)	1.0 (0–2)	1.0 (1–1)	0.6 (0–1)
Addressing other medical problems before considering SCS	0.2 (0–1)	0.2 (0–1)	0.5 (0–3)	0.5 (0–3)	0.0 (0–0)	0.0 (0–0)
Not the right time to decide	0.4 (0–2)	0.3 (0–2)	0.3 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Paying	0.5 (0–2)	0.1 (0–1)	0.8 (0–2)	0.3 (0–1)	1.0 (1–1)	0.3 (0–1)
Logistics	1.4 (0–9)	0.1 (0–1)	0.2 (0–1)	0.0 (0–0)	2.0 (2–2)	0.9 (0–2)
Information	0.2 (0–1)	0.0 (0–0)	0.8 (0–4)	0.3 (0–1)	0.0 (0–0)	0.0 (0–0)
SCS as a new option	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Maintenance	0.3 (0–1)	0.0 (0–0)	1.0 (0–3)	0.7 (0–3)	2.0 (2–2)	1.1 (0–2)

(*Continued*)

Table 6 (Continued).

	Video		Interview		Survey	
	Total	**Important or affects decision**	**Total**	**Important or affects decision**	**Total**	**Important or affects decision**
Agency						
How the device works to reduce pain	0.6 (0–3)	0.2 (0–2)	0.0 (0–0)	0.0 (0–0)	1.0 (1–1)	0.6 (0–1)
Safety of	0.2 (0–1)	0.1 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Compatibility	0.4 (0–3)	0.1 (0–1)	1.0 (0–4)	0.8 (0–4)	1.0 (1–1)	0.6 (0–1)
Permanently attached	0.2 (0–1)	0.1 (0–1)	0.2 (0–1)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Features of the device	0.3 (0–2)	0.0 (0–0)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
The device exists	0.0 (0–0)	0.0 (0–0)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Susceptibility of the device to damage	0.0 (0–0)	0.0 (0–0)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Not experimental	0.2 (0–1)	0.0 (0–0)	0.2 (0–1)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Possibility of device malfunctioning	0.2 (0–3)	0.0 (0–0)	0.2 (0–1)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Cyborg concerns	0.0 (0–0)	0.0 (0–0)	0.2 (0–1)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Placement of the device	0.8 (0–6)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	1.0 (1–1)	0.6 (0–1)
Durability of the device	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Size of	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	1.0 (1–1)	0.4 (0–1)
Agent						
Other clinician	1.5 (0–6)	0.5 (0–3)	0.8 (0–2)	0.3 (0–1)	0.0 (0–0)	0.0 (0–0)
Current clinician	0.5 (0–2)	0.4 (0–2)	0.5 (0–2)	0.5 (0–2)	1.0 (1–1)	0.0 (0–0)
Patient	0.3 (0–1)	0.2 (0–1)	0.2 (0–1)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Family member/guest	0.8 (0–3)	0.3 (0–2)	0.3 (0–1)	0.0 (0–0)	0.1 (0–1)	0.1 (0–1)
Multiple other clinicians	0.5 (0–3)	0.1 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Acquaintances of the patient or others	0.2 (0–1)	0.1 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Collaborative group	0.1 (0–1)	0.0 (0–0)	0.7 (0–1)	0.5 (0–1)	0.0 (0–0)	0.0 (0–0)
Multiple current clinicians	0.0 (0–0)	0.0 (0–0)	0.2 (0–1)	0.0 (0–0)	2.1 (2–3)	2.1 (2–3)
Non-clinicians	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	2.0 (2–2)	0.7 (0–2)
Purpose						
Improve function	0.9 (0–6)	0.8 (0–4)	2.0 (1–4)	1.8 (0–4)	6.0 (6–6)	5.7 (4–6)
Pain relief	0.9 (0–2)	0.7 (0–2)	2.5 (1–5)	2.3 (1–5)	2.0 (2–2)	2.0 (2–2)
To be done with this	0.5 (0–2)	0.5 (0–2)	0.2 (0–1)	0.2 (0–1)	0.1 (0–1)	0.1 (0–1)
To subsequently address other problems	0.3 (0–2)	0.2 (0–2)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Reduce medication	0.1 (0–1)	0.1 (0–1)	0.2 (0–1)	0.2 (0–1)	1.0 (1–1)	0.9 (0–1)
Stop opioids	0.0 (0–0)	0.0 (0–0)	0.2 (0–1)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)

(*Continued*)

Table 6 (Continued).

	Video		Interview		Survey	
	Total	**Important or affects decision**	**Total**	**Important or affects decision**	**Total**	**Important or affects decision**
Improve social interaction	0.0 (0–0)	0.0 (0–0)	0.5 (0–2)	0.5 (0–2)	1.0 (1–1)	0.9 (0–1)
Improve ability to travel	0.0 (0–0)	0.0 (0–0)	0.2 (0–1)	0.2 (0–1)	1.0 (1–1)	0.9 (0–1)
Improve mood	0.0 (0–0)	0.0 (0–0)	0.7 (0–2)	0.3 (0–2)	2.0 (2–2)	1.3 (0–2)
Scene						
Other therapies used for pain control	12.2 (4–18)	2.2 (0–7)	1.2 (1–2)	0.5 (0–2)	2.0 (2–2)	1.0 (1–1)
Pain qualities	21.7 (5–43)	4.1 (0–11)	0.3 (0–1)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Medical history	3.4 (0–6)	1.2 (0–4)	0.5 (0–2)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Opinion of other therapies	0.2 (0–2)	0.2 (0–2)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)
Reason for the visit	0.4 (0–2)	0.2 (0–1)	0.5 (0–1)	0.5 (0–1)	0.0 (0–0)	0.0 (0–0)
Function	4.7 (1–12)	0.8 (0–4)	0.3 (0–2)	0.3 (0–2)	0.0 (0–0)	0.0 (0–0)
Medical fears or trauma	0.0 (0–0)	0.0 (0–0)	0.2 (0–1)	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)
Life situation	0.2 (0–1)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)	0.0 (0–0)

Discussion

In this study, we compared three methods for identifying patient preferences (MIPPs) at the point of decision-making in the context of SCS as a treatment for chronic pain. We found that each of the MIPPs has strengths and weaknesses, making the appropriateness of their use in understanding post-market preferences for purposes dependent on what is sought to be achieved and the resources available to deploy them. Specifically, tensions exist in multiple directions

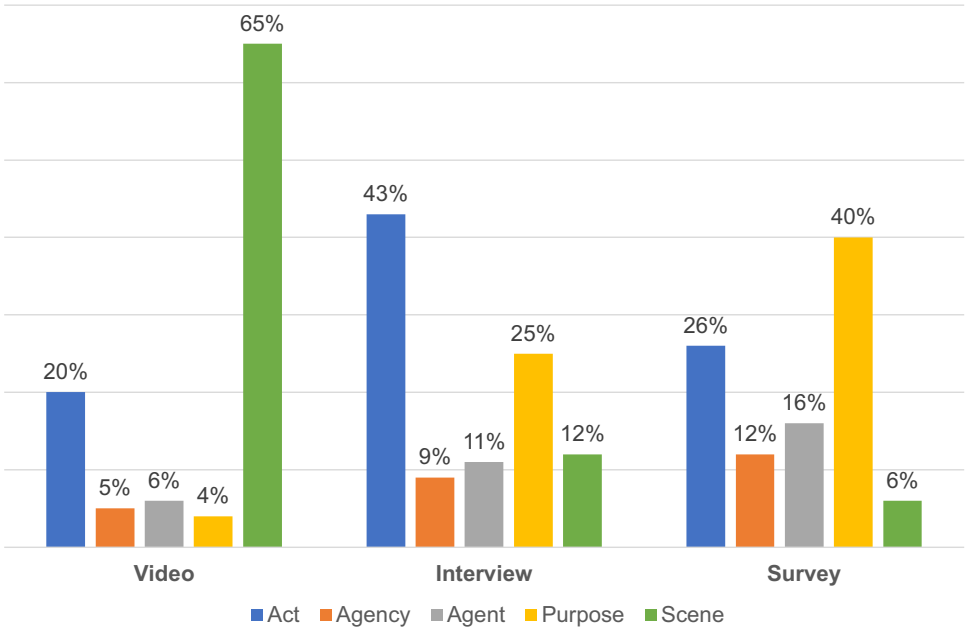

Figure 2 Attribution of preferences to Burkean category by MIPP.

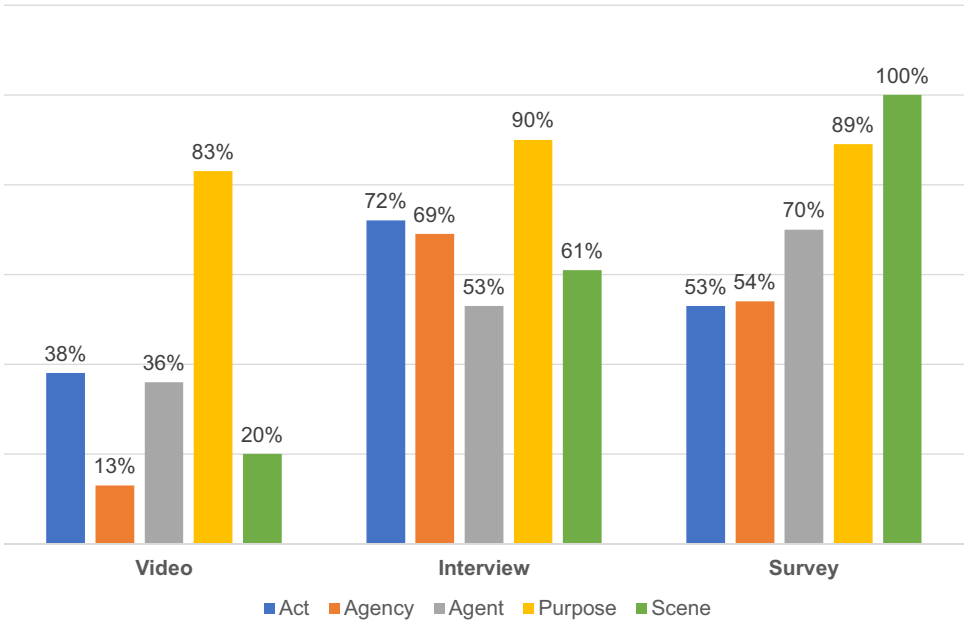

Figure 3 Attribution of preferences identified as clearly important and/or clearly affecting the decision to Burkean category by MIPP.

between the MIPPs, including clarity of preference expression, comprehensiveness and nuance of preferences, certainty of preference, and effort required to employ the method.

Surveys were by far the least time demanding for the researcher both to administer and interpret and yielded clear expression of the importance of a preference to the patient (68% of preference blocks were clearly important and/or clearly affected the decision), but the scope of preference information was constrained to topics explicitly included in the survey. This limitation is reflected in the relatively small range of preference blocks identified among participants receiving surveys (32 to 34) and the low number of themes identified (19) compared to the other methods. Therefore, use of surveys may be inappropriate as an exploratory method for preference assessment in cases where little is known about patient-important attributes or risks of the drug or device. However, these features make surveys helpful in confirming the presence and importance of a limited hypothesized set of patient preferences.

Interviews, while relatively brief to administer, were significantly more time-consuming than surveys to interpret through development and application of the coding scheme. From an average interview duration of 13.5 minutes, they yielded the lowest average number of preference blocks per interview (25) of any instrument but with a similar proportion of preference blocks (73%) identified as clearly important and/or clearly affected the decision as surveys (68%). However, across all participants, interviews were able to garner a broader set of preference themes (39) than surveys (19).

Video-recorded clinical encounters were the most time-consuming for the researcher, given the time required to watch the videos and code the transcripts, as well as the high number of preference blocks per video (mean = 66 blocks) compared to interviews (25) or surveys (33). However, collection of video data did not require the patient to set aside time after a lengthy encounter to complete a survey or participate in an interview. Although videos yielded the highest mean number of preference blocks, the proportion of those blocks expressing preferences that were clearly important and/or clearly affected the decision was by far the lowest among the three MIPPs (27% compared to 73% of interviews and 68% of surveys). In terms of specific preference topics discussed, videos produced a similar number of distinct themes (38) to interviews (39), but differences were apparent at the more nuanced level of sub-themes (75 in videos vs 54 in interviews).

Clarity of preference expression complicated interpretation of the video data. The existence and importance of a preference is easy to establish when a patient makes a clear expression of will (for example, "I don't like this" or "I'd prefer that"). However, such expressions were rare within the encounter interactions, arising only 48 times within 858 total preference blocks identified across all videos. This is in stark contrast with the survey, and to a lesser extent, the

interview, in which patients were asked directly about their preferences regarding particular topics and their importance. Clinicians seldom asked patients to express preferences in this way within consultations.

A further challenge in deriving preferences directly from encounters is the presence of potentially important preferences in conversations that were not clearly expressed because they could quickly be dispensed with as of no concern. For example, if a patient asked if they could have post-implant imaging performed close to home at their local clinic and the clinician responded affirmatively, then the issue may be quickly dropped without any indication of if that fact was important to the patient—which it may have been. Because these preferences are of no concern, they may not emerge spontaneously in interviews. The broad latitude given in identifying preference blocks means that instances such as the imaging example above were identified as suggesting a potential preference, even if the significance of this preference could not be ascertained.

A further sign of the relative ambiguity of preference in video encounters is that for each participant in general, videos yielded many more preference blocks than surveys, while surveys yielded more preference blocks (equivalent to survey item responses) that were marked as clearly important or clearly affecting the decision than video. However, of the three MIPPs, videos yielded greater nuance at the sub-theme level, especially when compared with surveys. In addition, the minimal overlap of themes between MIPPs may reflect an interaction between the method of preference identification (video, interview, survey) and the Burkean category a potential preference originated from or was oriented towards. For example, scene-related preferences (and their corresponding themes) were more prevalent in videos than in interviews or surveys, likely reflecting a focus on medical history in encounters.

Differences in Burkean attribution of preference towards aspects of the SCS therapy were also seen between MIPPs. For example, 65% of video preference blocks indicated desirability in terms of qualities of the "scene", in contrast to interviews (25%) and surveys (6%). Conversely, attribution to "purpose" was lowest in videos (4%) with interviews (25%) and surveys (40%). This may reflect the fact that in discussions between patients and clinicians, the purpose of an intervention is often implied in descriptions of scene. For example, when a patient expresses difficulty in walking for extended periods of time, a purpose of SCS to enhance mobility is implied. Notably, "act" was the first or second most prevalent Burkean category across all MIPPs, while "agency" was consistently at or next to the bottom. This suggests that the practicalities involved ("act") of pursuing, undergoing, and living with SCS were of greater concern than direct attributes of the device ("agency").

The most appropriate MIPP for identifying patient preferences is dependent on the purpose for which it is to be used. If researchers or other stakeholders wish to understand with greater nuance the breadth or universe of potential preferences, collecting data directly from the encounter (in our case, through video-recording) might be helpful. On the other hand, for confirming or testing the relative importance of known or assumed topics, surveys provide an efficient means of doing so. Finally, a middle-ground approach is through interviewing those wishing to explore a known set of preference topics while leaving room for some expansion. Of course, MIPPs may be combined.

In the instrument development phase, we found it necessary to draw on insights garnered through reviewing videos of encounters to create a survey and interview guide that was appropriate for the particularities of SCS therapy and decision-making. In the absence of generally applicable instruments, we recommend a similar process of empirically informed instrument development for other post-market interventions. While working with video data is very time-intensive, the video data drawn upon in designing surveys or interviews are itself useful for triangulating results when surveys or interviews are later used.

Finally, our approach could be used in future research to explore the impact of gender on preference expression in medical decision-making contexts. Observations from our data indicated differences in some areas between men and women in articulating preferences, though our small sample prevents us from drawing firm conclusions. For example, men were more likely than women to situate preferences in the context of information about past therapies and the characteristics of their current pain (eg, duration, intensity), while women were more likely to discuss the influence of family, friends, and health care providers on their preferences and treatment decision-making. However, the prevalence of specific themes and topics identified within each instrument were similar for men and women. While there is a large research literature detailing the influence of gender on pain expression, communication styles, and medical decision-making, respectively, little is known specifically concerning differences in medical treatment preference expression or measurement in the context of chronic pain management. Widely used frameworks suggest that socialized differences in communication styles lead men to rely on "report talk" (ie, conveying objective or

instrumental information) and assertive language, while women tend to emphasize relationships and rapport-building.[20,21] Similarly, in health care settings, women have been found to place a stronger focus than men on social and contextual factors when reporting symptoms and describing past treatment experiences.[22] Given well-documented treatment disparities that result in inadequate pain control among women,[23,24] future research should explore how differences in preference expression by gender impact treatment decisions.

The key strength of this study lies in its comprehensive exploration of methods to identify patient preferences at the point of decision-making. However, there are important limitations. The small sample size (n = 13) reduces the reliability, validity, and ability to draw definitive conclusions from these data. Nevertheless, we hope that future studies will build on and extend this exploratory work with larger samples. Next, the instruments used to assess patient preferences were developed for this study by the research team and have not been formally evaluated for their measurement properties or soundness. However, in the absence of any gold standard methods for identifying patient preference, steps were taken to ensure a high level of quality for all methods used. For example, the survey was reviewed at multiple points by an expert in survey research methods and pilot tested extensively with patients before arriving at the final version.

Another limitation of this study lies in the nature of patient decision-making, which is a complex, non-linear process. Although we designed data collection procedures to capture patient preferences as close as possible to the point of actual decision-making (ie, during or immediately following the encounter), we recognize that our approach may exclude important aspects of patient thought processes. Future work could follow patients longitudinally and explore how preferences evolve throughout the process of choosing to adopt or not adopt a medical intervention, it could also illuminate if and how preferences change between the consultation and when patients call back to confirm their decision or schedule SCS procedures.

In addition, the generalizability of our findings beyond the specific context and patient population of this study, which was limited to patients seeking a pain medicine consultation at Mayo Clinic in Minnesota, is unclear. The application of these methods for post-market preference exploration or elicitation in other clinical contexts will likely uncover additional insights into the relative advantages or limitations of each method. For example, although we found all three methods of data collection (ie, video recording the encounter, post-encounter interviews, and post-encounter surveys) to be both feasible and acceptable to most clinicians and patients, studies employing these methods in other settings might encounter challenges to their use (for example, when the health condition of interest is particularly sensitive or stigmatized). In addition, the clinicians involved in our study practice in an academic medical setting and may have the benefit of more exposure to or training in shared decision-making and preference elicitation than clinicians in other settings, which may further limit the generalizability of the MIPPs described in this study.

Conclusion

Patient preferences regarding regulated medical products are an important consideration in the regulatory decision and ongoing assessment of interventions post-market. Relevant preferences may arise when patients gather information to determine what and if options may be available, at the time that preferences play an active role in decision-making, and after patients have experience living with an intervention. Relatively little attention has been given to the expression, function, and use of preferences at the point of decision-making even though these preferences greatly influence intervention adoption and indicate important patient-centered criteria for judging the usefulness, desirability, and ongoing sustainability of interventions. This study has both opened a view into the complexities of preference and the strengths and limitations of methods for identifying preferences at the point of decision-making. Future work may build on this to illuminate how patients and clinicians use or operationalize preferences to make decisions with important implications for shared decision-making and patient-centered care.

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Disclosure

Victor Montori works at Mayo Clinic's Knowledge and Encounter Research Unit where we design, test, implement and disseminate shared decision-making interventions. We release free to use and derive no income from their use. The authors report no other conflicts of interest in this work.

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