Technical Report

Patient Perspectives on Value in the Treatment of Non-Small Cell Lung Cancer

Version: 1.0

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Disclosures

Suepattra May-Slater, PhD, MPH and Caroline Huber, MPH both hold the position of Associate Director at Precision Health Economics, a health economics consultancy providing services to the life sciences industry. Alison Silverstein, MPH holds the position of Research Scientist at Precision Health Economics.

About the Innovation and Value Initiative

The Innovation and Value Initiative (IVI) is a nonprofit organization that seeks to advance the science and improve the practice of value assessment in the U.S. healthcare system. To achieve this, IVI pursues the following goals:

- Establish best practices for measuring the real-world value of healthcare technologies using both existing and innovative scientific methods;
- Provide a range of marketplace stakeholders – including patients, consumers, providers, healthcare systems, and payers – with salient, accurate, and actionable information about value in healthcare;
- Develop and test innovative approaches to link healthcare spending to value.

The IVI is hosted by Precision Health Economics, a health economics consultancy. IVI’s direction and research agenda are determined in collaboration with its Strategic Advisory Panel, which includes representatives from patient advocacy organizations, pharmaceutical firms, academia, insurers, and health systems. All funding supports IVI’s overall activities, with no funding or funder tied to specific activities or research projects.

Acknowledgements

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# List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>AAHRPP</td>
<td>Association for the Accreditation of Human Research Protection Program</td>
</tr>
<tr>
<td>AE</td>
<td>Adverse event</td>
</tr>
<tr>
<td>ASCO</td>
<td>American Society of Clinical Oncology</td>
</tr>
<tr>
<td>EGFR</td>
<td>Epidermal growth factor receptor</td>
</tr>
<tr>
<td>IVI</td>
<td>Innovation and Value Initiative</td>
</tr>
<tr>
<td>ICER</td>
<td>The Institute for Clinical and Economic Review</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>MSKCC</td>
<td>Memorial Sloan Kettering Cancer Center</td>
</tr>
<tr>
<td>mNSCLC</td>
<td>Metastatic Non-Small Cell Lung Cancer</td>
</tr>
<tr>
<td>NCCN</td>
<td>National Comprehensive Cancer Network</td>
</tr>
<tr>
<td>NSCLC</td>
<td>Non-Small Cell Lung Cancer</td>
</tr>
<tr>
<td>OHRP</td>
<td>Office for Human Research Protections</td>
</tr>
<tr>
<td>OSVP</td>
<td>Open-Source Value Platform</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of Life</td>
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</table>
1. **Executive Summary**

**Rationale and Background**

In recent years, a number of value frameworks have been developed to inform the value of innovations in healthcare and guide treatment pricing and reimbursement decisions. These frameworks, however, broadly under-represent a critical factor in treatment decision-making: the patient perspective. In support of the Innovation and Value Initiative’s development of a new Open-Source Value Platform (OSVP) model focused on non-small cell lung cancer (NSCLC), and specifically sequential treatment strategies for patients with epidermal growth factor receptor positive (EGFR+) NSCLC, we conducted structured qualitative data collection with metastatic NSCLC (mNSCLC) patients to investigate patient perspectives of disease burden, experiences with treatment, and the impact of cancer therapy on patients’ lives and treatment decision-making. In particular, we sought to understand how patients valued and prioritized various factors and attributes associated with NSCLC therapy across their treatment journeys and at a time when the landscape of treatment options for cancer is rapidly changing.

**Objectives**

The primary research aim was to identify the aspects or attributes of NSCLC cancer treatment that are most meaningful to mNSCLC patients in order to identify key factors and determinants of value.

**Methods**

Qualitative study utilizing mini focus groups and in-depth telephone interviews with metastatic NSCLC patients who had received systemic therapy within the past five years. Data were analyzed using thematic analysis to identify emergent themes across participants and determinants of value in treatment decision-making.

**Key Findings**

A total of 19 participants completed enrollment in the study. Qualitative data analysis revealed several overarching themes:

- Even with a metastatic diagnosis, participants in our study cited a number of trade-offs that they were required to make after receiving their diagnosis and throughout their treatment journey. These include weighing treatment efficacy against the potential impacts of treatment on QOL and day-to-day functioning (particularly given an uncertain or poor long-term prognosis), tolerance of side effects, and availability of therapies to mitigate side effects.

- The metastatic nature of participants’ cancer often influenced their treatment decision-making, as they could not afford to choose options that were potentially ineffective or risky, while also wanting to maintain quality of life.

- Many patients perceived the potential for new therapies to hold metastatic disease at bay, and accordingly the potential for cancer to be a chronic, rather than acute, disease – making the associated unforeseen and unanticipated costs more salient. Many participants observed that the cancer experience today is not what it used to be, given more expansive and tailored treatment options, greater efficacy, and continuous innovations in therapy. Even when a particular therapy had proven ineffective, patients remained hopeful about
additional treatment options and surviving long enough to experience further innovations in care.

In addition to these broad themes, participants identified specific determinants of value in their experience of treatment, including:

- **Care personalized to individual needs and goals that was also coordinated and comprehensive.** Patients sought out treatment facilities that could offer a wide range of services from genetic testing to insurance assistance to mental health support.

- **Treatments and care that were affordable throughout their treatment journey.** For many participants, value in care equated to affordability and treatments that were covered by their insurance with low out-of-pocket costs. Access to clinical trials and financial assistance programs were also considered key components of financial value, as they were stopgaps when treatments were not covered.

- **Treatments that offered convenient administration and tolerable side effect profiles.** These elements of value were associated with a preserved quality of life (QOL), which has become feasible with targeted treatments. For many participants, the “feeling” of cancer only manifested itself through treatment side effects. Among participants who experienced significant side effects, they were forced to make tradeoffs between continuing treatment or switching to something that may be more tolerable but potentially less efficacious.

**Conclusions**

Our data reveal that while the clinical endpoints of overall survival and treatment efficacy are important, patients derive value from other non-clinical factors.

Participants in our study reported mixed experiences with approaches to disease management and with treatment preferences influenced by a lack of alternatives, particularly after multiple lines of therapy. No two participants in our study reported the same diagnosis and treatment journey. This further highlights the limitations of value frameworks’ treatment of patients as one collective entity, rarely acknowledging the spectrum of factors that may influence and affect treatment preferences and decision-making. A lack of attention to these other considerations that constitute significant determinants of value for patients can lead to inadequate decision-making by healthcare stakeholders. Findings from this study underscore the need to enhance all healthcare stakeholders’ understanding of the value determinants most meaningful to patients, ensuring that such factors are incorporated into patient-centered value assessment.
Introduction

1.1. Background

In recent years, a series of value frameworks have been developed to inform the value of healthcare innovations and guide treatment, pricing and reimbursement decisions.\[1-4\] Value frameworks typically utilize evidence from published clinical studies to assess the value of different treatments and quantify associated health benefits, costs, and impact on outcomes. At present, the American Society of Clinical Oncology (ASCO) \[3, 5\], National Comprehensive Cancer Network (NCCN)\[6\], Memorial Sloan Kettering Cancer Center’s (MSKCC) Drug Pricing Lab \[7\], and The Institute for Clinical and Economic Review (ICER) \[8\] have frameworks to evaluate drugs within the oncology space.

The development and use of these frameworks have led to broader discussions about the meaning of “value” across healthcare stakeholders. In particular, there has been growing recognition that traditional assessments of value in healthcare, including health technology assessments and value frameworks, largely under-represent the patient perspective.\[9-11\] Endpoints prioritized by certain healthcare stakeholders in value assessment may not be those that are most meaningful to patient stakeholders. This is especially salient in cancer care, where patients may value attributes of treatment, such as impacts on quality-of-life (QOL), that are not traditional clinical endpoints. While meaningful, value frameworks utilizing data derived from clinical trials largely depend upon proxies (such as healthcare provider input) to report patient perspectives, rather than directly soliciting patient feedback. Even from a clinical standpoint, clinical trial endpoints do not adequately capture patient-valued endpoints in real-world settings.

To more comprehensively assess the value of treatments, numerous academic researchers, professional organizations, advocacy organizations, and framework creators themselves, have proposed strategies to include more patient-centered inputs in future value assessments.\[12-16\] Fundamentally, patient-centricity must consider and incorporate the preferences, values, and experiences of patient stakeholders when ascertaining the true value of a new therapy. This includes how patients prioritize and assign value to different elements of their treatment.

Ensuring the patient-centricity of research and value model development is a central goal of the Innovation and Value Initiative (IVI). In IVI’s Partnering with Patients Framework and Principles guidance document\[17\], IVI recognizes the critical need for patient input into research that contributes to decision-making in value assessment and the ongoing dialogue actively occurring among patients, payers, providers, and innovators about how best to define and evaluate treatment value. In keeping with these principles, capturing patient perspectives and including patients in ongoing dialogue are key considerations in IVI’s initiative to develop a new Open-Source Value Platform (OSVP) model focused on non-small cell lung cancer (NSCLC), and specifically sequential treatment strategies for patients with epidermal growth factor receptor positive (EGFR+) NSCLC. An estimated 11,200 new cases of EGFR+ NSCLC are diagnosed every year, accounting for approximately 6.4% of all lung cancer and 8% of NSCLC cases in the United States.\[18, 19\] NSCLC more generally accounts for 80% of all lung cancer diagnoses and, in addition to EGFR, multiple oncogenic markers have been discovered within NSCLC.\[18\] In each of these mutation-defined populations, targeted therapies are increasingly available, changing both treatment paradigms and the potential patient journey for those diagnosed with NSCLC.

As an initial step in developing the IVI-NSCLC value model, we conducted structured qualitative data collection with metastatic NSCLC (mNSCLC) patients to investigate patient perspectives of
disease burden, experiences with treatment, and the impact of cancer therapy on patients’ lives and treatment decision-making. In particular, we sought to understand how patients, particularly those who report having oncogene positive mutations, valued and prioritized various factors and attributes associated with NSCLC therapy across their treatment journeys and at a time when the landscape of treatment options for cancer is rapidly changing.

1.2. Objectives
The primary research aim was to identify the aspects or attributes of cancer treatment that are most meaningful to mNSCLC patients in order to identify key factors and determinants of value.

2. Methods

2.1. Methodology and Approach
Using qualitative data collection methods, we conducted focus groups and in-depth telephone interviews with patients diagnosed with mNSCLC. Through interview questions with these patients, we elicited reports of and deliberations around treatment decisions and experiences with clinical care for NSCLC.

Qualitative research methods are particularly appropriate for investigating subjective impressions and are also well-suited to the exploration of topics or issues that stimulate a variety of opinions based on personal experiences.[20, 21] The goal of the two-pronged qualitative approach was to collect and aggregate data on a diverse set of patients’ experiences with and opinions about what factors of treatment they reported to be most important in their treatment for cancer. Furthermore, the data collection methods enabled the elicitation of the opinions of mNSCLC patients such that the interviewer or focus group moderator was able to explore what was most meaningful to patients about their treatment and care experiences.[20, 21]

2.2. Study Population
Patients ages 18 years or older with a self-reported diagnosis of mNSCLC were eligible to participate in the study. The patient population comprised metastatic cancer patients who had been originally diagnosed with an earlier stage of cancer (Stage I-III) that had ultimately progressed to Stage IV or who were initially diagnosed with Stage IV metastatic NSCLC (de novo cases). We included both types of patients, anticipating that patients who progressed from an earlier stage of cancer could potentially have different perspectives than those originally diagnosed with metastatic disease. We excluded patients from participation if they had not received chemotherapy, hormone therapy, immunotherapy, or targeted therapy within the past 5 years. Finally, although IVI’s new OSVP model is being developed for (EGFR+) NSCLC patient populations, we did not restrict the study population to EGFR+ patients alone to ensure we could meet sample size requirements. Specific inclusion and exclusion criteria are as follows:

2.2.1. Inclusion criteria
- Had been told by doctor that they have metastatic, non-squamous, NSCLC
- English language proficient
- Aged 18 years or older
- Had received chemotherapy, targeted therapy, or immunotherapy within the past 5 years
• Comfortable participating in a conversation about personal experiences with cancer treatment decisions
• Comfortable with the knowledge that the (anonymized) information gained from the interview might be used in future publications
• Completed informed consent

2.2.2. Exclusion criteria
• Does not have metastatic, non-squamous, NSCLC
• Had NOT received chemotherapy, targeted therapy, or immunotherapy in the past 5 years
• Under the age of 18
• Not comfortable participating in a conversation about personal experiences with cancer treatment decisions
• Not comfortable with the knowledge that the (anonymized) information gained from the interview might be used in future publications
• Did not complete informed consent

2.2.3. Sample Size
The study aimed to recruit a minimum of 18 patients diagnosed with mNSCLC. Based on the research design and study objectives, we expected the sample size to be sufficient to provide the necessary diversity of opinions and experiences, as well as the ability to confirm and validate shared views in accordance with established qualitative research guidelines for sampling.[20, 22]

2.3. Discussion Guide Development
We designed the discussion guides to investigate patients’ treatment decisions from the emergence of initial symptoms and diagnostic experience through treatment initiation and disease maintenance and monitoring. For the purposes of this study, we define NSCLC treatment decision-making as a process that includes immediate decisions about medical, psychological, and alternative treatments to manage NSCLC disease and its symptoms, as well as ongoing decisions and lifestyle choices to enhance physical and mental health and well-being. Table 1 provides an overview of the type of questions included in the discussion guides. The discussion guides are included as Appendix A.

Table 1. Sample Discussion Guide Questions

<table>
<thead>
<tr>
<th>Domain</th>
<th>Objective</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>Understand diagnosis experience</td>
<td>• What motivated you to see a doctor (symptoms, family history, annual screening, etc.)?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How did your doctor describe your diagnosis to you?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• What questions did you have for your oncologist or care team?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Did you run into any challenges during the diagnosis process? Please explain.</td>
</tr>
<tr>
<td>Domain</td>
<td>Objective</td>
<td>Question</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Initial Treatment Decision Making | Understand how treatment options were presented and prioritized | • After your diagnosis, what types of treatment options were offered to you?  
• I would like to discuss the factors and considerations you thought about before determining your initial treatment. I would like you to jot down on the notepad in front of you, the first three factors or considerations related to treatment that came to mind when your care team mentioned needing to receive treatment for NSCLC.  
• How did you discuss and evaluate the benefits, risks, and costs associated with the various options?  
• How much did you think about the potential side effects of treatment?  
• Overall, what were your goals for treatment? |
| Subsequent Treatment Decision Making | Explore how patients' treatment decisions changed over time | • Throughout the course of your treatment for NSCLC, can you describe the different types of care and/or treatments that your healthcare team has provided or prescribed?  
• How has your doctor assessed your response to treatment? What test results, if any, does your doctor share with you?  
• Earlier we talked about the factors and considerations that were important when you made your initial treatment decisions. Looking back across your cancer treatment journey, how have your decisions about treatment or your approach to decisions about treatment changed over time, if at all? |
| Care Team Collaboration | Explore patients' relationship with care team | • How involved do you feel you are/have been during the treatment decision-making process (or treatment process)? Do you feel that you have had input into the decision-making about your treatment?  
• What are the most important things patients and their clinicians should discuss about cancer treatment? |
| Values and Preferences | Understand what matters to patients and identify determinants of value | • What matters the most to you about the care that you receive for your cancer?  
• When a patient is undergoing treatment for NSCLC, doctors develop a treatment plan by reviewing many factors that contribute to a patient’s response including clinical evidence that helps support a given treatment plan. This "evidence base" can consist of drugs that have a long history of use among patients and from many clinical trials. Other drugs may be newer or more novel, without as much data from clinical trials or from patient experiences. Which do you prefer and why? |
2.4. Participant Recruitment

2.4.1. Institutional Review Board Approval

The Advarra Institutional Review Board (IRB) reviewed the study protocol, informed consent documents, and discussion guides. Advarra IRB is an independent organization accredited by the Office for Human Research Protections (OHRP) and the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The Advarra IRB determined that the study met the requirements for exemption from IRB oversight and granted a waiver of review.

2.4.2 Participant Identification and Approach

The study team collaborated with Schlesinger Associates to identify and recruit study participants. Schlesinger Associates identified potential participants in their existing study database who met basic eligibility criteria and conducted direct recruitment with these potential participants. Potential participants received a study recruitment email. Announcements did not identify IVI as the sponsor of the study but did specify that researchers from Precision Health Economics (PHE) were conducting a study with NSCLC patients. Potential participants were also referred to the study for eligibility screening from participant referrals through snowball sampling. Interested participants contacted the Schlesinger Associates study coordinator to complete eligibility screening by telephone. Participants deemed eligible based upon the specified inclusion and exclusion criteria were scheduled for a focus group or in-depth telephone interview with a member of the study team.

2.5. Data Collection

2.5.1. Mini Focus Group

Eligible participants residing in the two large metropolitan regions were invited to join in one of four scheduled 90-minute mini focus group sessions held at different times throughout the day to maximize participation. Traditional focus groups typically comprise 8-10 participants, with discussion building upon group dynamics. Mini focus groups have the same aim, but are smaller and more intimate with typically up to four participants, allowing for a more intimate group dynamic and each participant more time to elaborate on discussion.\[23\]

The mini focus groups were scheduled to take place at Schlesinger Associates focus group facilities in each region. Schlesinger instructed participants to arrive 15-30 minutes prior to the start of the scheduled group to review enrollment paperwork and to ensure that the group started on time. Upon arrival at the focus group facility, a facility coordinator greeted participants and escorted them to a holding area for the focus group participants.

To protect anonymity, participants did not sign a consent form. Rather, participants were provided a copy of the Information Statement (included as Appendix B) to review. The Information Statement outlined the purpose of the study and the participant’s obligations and protections. Participants received a copy of the Information Statement for their records. After any questions had been answered, the participants were invited into the focus group room for the group discussion. Participants provided consent by verbally agreeing to participate in the focus group and be audio recorded at the time of data collection.

Dr. Suepattra May-Slater, an experienced focus group facilitator with doctoral training in qualitative data collection, moderated the study focus group. The moderator introduced
participants to the 90-minute focus group format, which included time for introductions and topic discussions. Prior to the start of the discussion, the moderator instructed the participants that the audio recording would begin, and then proceeded with the focus group discussion. At the end of the focus group discussion, participants received $150 in remuneration for their participation.

2.5.2. In-depth Interviews

Eligible participants were invited to join in a 60-minute telephone interview at a specified time and date of their convenience. Prior to the interview, participants were provided a Study Information Statement via email, outlining the purpose of the study and the participant’s obligations and protections.

All in-depth interviews were conducted by a member of the study team with graduate training in qualitative data collection using in-depth interview discussion guides. As with the mini focus groups, at the start of the interview, the interviewer introduced the participant to the 60-minute interview format and instructed the participants that with verbal permission, the audio recording would begin. At the end of the telephone interview, participants received $150 in remuneration for their participation.

2.5.3. Additional Data Collection

The project team recorded field notes and other observations after the focus group and each in-depth interview. The project team had regular internal debriefings throughout data collection, which served as an opportunity for project team members to discuss observations from the data collection, including differences and similarities in responses to questions within and across data collection mechanisms.

2.6. Data Analysis

The mini focus group and in-depth interview audio recordings were transcribed verbatim into Microsoft Word documents ready for export to a qualitative data management software program (MAXQDA12; VERBI, GmbH). Qualitative data analysis software enables the manipulation, searching, and retrieval of coded text data to facilitate analysis. Any identifiable information (names of people, institutions, etc.) was redacted, and a standardized layout was applied to all content generated from the focus group and in-depth interviews to facilitate the comparison of data at the analysis stage.\[24\] The transcription method reflects the interpretative approach utilized in qualitative research, which strives to convey as fully as possible the experiences of the participants.\[25\] This includes word-for-word transcription, including utterances and incomplete sentences.\[24\]

We analyzed the qualitative data in multiple stages using the constant comparative method to identify central themes across the data.\[26\] First, members of the study team independently reviewed the transcripts to identify emergent themes. Findings from this initial review, along with topic areas and questions from the discussion guide, were used to generate a list of initial codes. The definitions of these codes were further refined into descriptive categories, resulting in a dictionary of 27 thematic codes based on the discussion guide topics, as well as inductive generation. The coding dictionary is included as Appendix C. The study team then reviewed and coded all transcripts individually, enabling the identification of salient relationships within and among categories across the mini focus group and in-depth interview transcripts. The team met periodically to discuss the themes that emerged from the data, selecting representative quotes to
best illustrate study findings. Through these steps, we identified central themes and determinants of value for mNSCLC cancer treatment.

3. Results

3.1. Study Sample

A total of 19 participants completed enrollment in the study. Of these, 3 (15.8%) participated in a mini focus group, and 16 (84.2%) participated in an in-depth telephone interview. Three additional mini focus groups planned for Chicago and New York were cancelled due to low enrollment. Participants scheduled for the three focus groups were instead offered an opportunity to participate in an in-depth telephone interview.

The majority (80.0%) of the sample was female, and the mean age was 53.8 (12.1). More than half the sample reported being unemployed (57.9%). With respect to race/ethnicity and education level attained, all but one participant reported White/Caucasian race, with 68.4% of the respondents reporting a college education or higher. Patients’ demographic and clinical characteristics are detailed in Table 2.

Table 2. Participant Demographic Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n/mean</th>
<th>% (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>19</td>
<td>100</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td>80.0</td>
</tr>
<tr>
<td>Male</td>
<td>4</td>
<td>20.0</td>
</tr>
<tr>
<td><strong>Age, mean (SD), years</strong></td>
<td>53.8</td>
<td>(12.1)</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
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<td></td>
</tr>
<tr>
<td>Asian</td>
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<td>5.3</td>
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<tr>
<td>Hispanic</td>
<td>1</td>
<td>5.3</td>
</tr>
<tr>
<td>Caucasian</td>
<td>18</td>
<td>94.7</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
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<tr>
<td>Divorced</td>
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<td>21.1</td>
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<tr>
<td>Married, domestic partnership, or living as married</td>
<td>14</td>
<td>73.7</td>
</tr>
<tr>
<td>Single (never married)</td>
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<td>5.3</td>
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<tr>
<td><strong>Educational Attainment</strong></td>
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<tr>
<td>High school (or equivalent)</td>
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<tr>
<td>Some college</td>
<td>4</td>
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<tr>
<td>College</td>
<td>8</td>
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<tr>
<td>Post Graduate</td>
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<td>26.3</td>
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<td><strong>Employment</strong></td>
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<tr>
<td>Employed full-time</td>
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<td>26.3</td>
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<tr>
<td>Employed part-time</td>
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<td>15.8</td>
</tr>
<tr>
<td>Unemployed (retired, homemaker, health)</td>
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<td>57.9</td>
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### Household Income

<table>
<thead>
<tr>
<th>Income Range</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Less than $25,000</td>
<td>4</td>
<td>21.1%</td>
</tr>
<tr>
<td>$25,000-$35,000</td>
<td>1</td>
<td>5.3%</td>
</tr>
<tr>
<td>$36,000-$50,000</td>
<td>7</td>
<td>36.8%</td>
</tr>
<tr>
<td>$51,000-$75,000</td>
<td>3</td>
<td>15.8%</td>
</tr>
<tr>
<td>$76,000-$100,000</td>
<td>3</td>
<td>15.8%</td>
</tr>
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<td>$101,000 or more</td>
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</table>

### Insurance

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<thead>
<tr>
<th>Insurance Type</th>
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</thead>
<tbody>
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<td>Medicare</td>
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</tr>
<tr>
<td>More than one plan</td>
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<td>15.8%</td>
</tr>
<tr>
<td>Private health plan offered through an employer or other organization</td>
<td>9</td>
<td>47.4%</td>
</tr>
<tr>
<td>Private health plan or insurance that you purchased yourself</td>
<td>2</td>
<td>10.5%</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

The geographic distribution of study participants is depicted in **Error! Reference source not found.**. One mini focus group was conducted in Chicago. Because the in-depth interview participants were able to participate in the study irrespective of location, their geographic spread is much more distributed.

**Figure 1. States in which Study Participants Resided**
We provide the self-reported clinical history of study participants in Table 3. The majority of participants (73%) had first presented with de novo disease, with the remaining participants diagnosed with Stage III disease that had progressed to mNSCLC at the time of the study. The most common comorbidities included hypertension and mental health related conditions (anxiety and depression). Because receipt of systemic therapy was an inclusion parameter, all patients had received treatment at some point during their disease course. Nearly half of the study population reported a mutation to EGFR, whereas about 8% of all patients with NSCLC in the US have mutations to the EGFR.[18, 19] Having a mutation was not an explicit study requirement; because we were interested in the perspectives of patients with driver mutations, however, we prioritized scheduling of interviews with patients who self-reported a driver mutation of any kind.

Table 3. Participant Clinical History

<table>
<thead>
<tr>
<th></th>
<th>n/mean</th>
<th>% (range)</th>
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</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>19</td>
<td>100</td>
</tr>
<tr>
<td><strong>Time since diagnosis, mean (range), years</strong></td>
<td>4.1</td>
<td>2.6</td>
</tr>
<tr>
<td><strong>Stage at first diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage III</td>
<td>5</td>
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</tr>
<tr>
<td>Stage IV (de novo)</td>
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<td>73.7</td>
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<tr>
<td>*<em>Mutation Status</em></td>
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<td></td>
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<tr>
<td>ALK</td>
<td>3</td>
<td>15.8</td>
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<tr>
<td>EGFR</td>
<td>9</td>
<td>47.4</td>
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<tr>
<td>KRAS</td>
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</tr>
<tr>
<td>ROS1</td>
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<tr>
<td>Other</td>
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<tr>
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<tr>
<td>Not at all</td>
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<td>52.6</td>
</tr>
<tr>
<td>Daily</td>
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</tr>
<tr>
<td>Less than daily</td>
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</tr>
<tr>
<td><strong>Presence of Comorbidities</strong>*</td>
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<td></td>
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<tr>
<td>Anxiety</td>
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<tr>
<td>Depression</td>
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<tr>
<td>Diabetes</td>
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<tr>
<td>Heart disease</td>
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<tr>
<td>High blood pressure (hypertension)</td>
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<td>Migraines</td>
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<tr>
<td>Psoriasis</td>
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<tr>
<td><strong>Current Treatment</strong></td>
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<tr>
<td>Surgery</td>
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<td>0.0</td>
</tr>
<tr>
<td>Treatment offered</td>
<td>Count</td>
<td>Percentage</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------</td>
<td>------------</td>
</tr>
<tr>
<td>Radiation</td>
<td>3</td>
<td>15.8</td>
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<tr>
<td>Chemotherapy or Targeted Therapy</td>
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<tr>
<td>Immunotherapy</td>
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<td>26.3</td>
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<tr>
<td>Treatment offered through a clinical trial</td>
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<td>10.5</td>
</tr>
<tr>
<td>No treatment</td>
<td>2</td>
<td>10.5</td>
</tr>
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</table>

**Ever Treatment***

<table>
<thead>
<tr>
<th>Treatment offered</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
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<td>Surgery</td>
<td>5.0</td>
<td>26.3</td>
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<tr>
<td>Radiation</td>
<td>12.0</td>
<td>63.2</td>
</tr>
<tr>
<td>Chemotherapy or Targeted Therapy</td>
<td>19.0</td>
<td>100.0</td>
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<tr>
<td>Immunotherapy</td>
<td>9.0</td>
<td>47.4</td>
</tr>
<tr>
<td>Treatment offered through a clinical trial</td>
<td>5.0</td>
<td>26.3</td>
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</table>

**Location of treatment**

<table>
<thead>
<tr>
<th>Location of treatment</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
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<td>31.6</td>
</tr>
<tr>
<td>A hospital that is part of a university/medical school</td>
<td>8</td>
<td>42.1</td>
</tr>
<tr>
<td>At the doctor’s office/clinic</td>
<td>4</td>
<td>21.1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>5.3</td>
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</table>

*Multiple response options

### 3.2. Determinants of Treatment Value

The primary aim of the research study was to identify the aspects or attributes of NSCLC cancer treatment that mNSCLC patients reported as most meaningful in order to identify key determinants of treatment value.

Throughout the interviews, participants described the many factors they considered when evaluating their treatment options and journey. Moderators also asked participants to share all factors they considered in their initial treatment decisions, and specifically, to identify the top three deemed most important in their treatment journey at initial diagnosis as well as at the time of the interview, reflecting what they currently valued, if different. These determinants of value included the following:

- Treatment efficacy
- Duration of progression free survival
- Duration for overall survival
- Mode, frequency, and geographic location of treatment administration
- Risk of side effects, severity of side effects, availability of therapies to manage side effects
- Functional ability (physical, mental, social), productivity, absence/presence of treatment fatigue
- Provider awareness of treatment options
- Patient and provider communication
- Care coordination
- Wrap-around care
- Personalized care
• Out of pocket costs
• Insurance coverage
• Availability of additional financial assistance
• Eligibility for clinical trial participation
• Mutation status and eligibility for targeted therapies
• Hope

Although we asked patients to identify the most important drivers of treatment value, participants did not consider these determinants in isolation. Rather, participants cited a number of trade-offs in their care that they were required to make after receiving their diagnosis as well as throughout their treatment journey. Even though participants generally prioritized efficacy over side effects, the potential impact of side effects was still a very significant consideration of treatment choice. They wanted to know about anticipated side effects and potential toxicity of a given treatment, as well as the availability of therapies to mitigate side effects. Most salient among participants was the trade-off between quality of life (QOL) and survival; the potential impacts of treatment on QOL induced some participants to prioritize options that would minimally impact day-to-day life.

Cancer treatment can considerably impact patients' independence and day-to-day lives. Participants reported weighing decisions about the impact treatment and its side effects will have on QOL. Patients valued treatment that allowed them to maintain as much functional ability and health-related QOL as possible while allowing them to work and participate in activities of daily life. However, treatment itself confers a huge burden on QOL. At the same time, patients were likely to sacrifice QOL for gains in stemming disease progression. This was fluid and changed throughout the course of the treatment trajectory as noted in the following narratives.

"Well, I think quality of life ties in to the side effects and the dosing, right? So it's a better quality of life if you can take the medication at home and not have to go into an infusion center. So there's a pro in terms of the dosing choice, but it's also a quality of life issue because you don't have to travel. You don't have to drive. So a lot of those things kind of have a double or triple benefit in a way. It's also more safe and tolerable. So quality of life ties into that in terms of you don't feel so sick all the time."

"...part of it, too, is where are you at in your treatment. I mean, hopefully, when someone's going on first line, they have a lot of optimism, right? Okay, they're feeling overwhelmed in terms of the diagnosis, but they're really hopeful that whatever they go on is going to work. But, obviously, as you go later down lines of therapy, patients can get fatigued. And so then they might say, "You know what? I was looking for something that would give me the best survival rate, but now I'm just looking for quality of life with no side effects." So your priorities change, I think. And part of that is just line of therapy, don't you think?"

"So I'm always looking at what's going to improve my quality of care and my ability to be mobile and things like that. That's the most important thing to me. I don't mean that I need to climb mountains or anything...I need to be able to have a decent quality of life, be able to-- you know. I don't want to live for 60 years laying in bed. I want to be able to do normal, regular activities with my family, with friends."

While patients valued having knowledge about risk of treatment side effects, as well as the potential severity of side effects (not just the clinical grade but how it could potentially impact
QOL and functional ability), patients also valued treatments or therapies that would help to manage, tolerate, and mitigate side effects experienced as a result of treatment. As noted, patients were willing to take risks of side effects but weighed the risks differently as they became more experienced with treatment and its side effects.

"The only downside to the [targeted therapy] was that I was hospitalized four times with pneumonia and it was because the [targeted therapy], for me, caused the pneumonia. That was one of the big side effects. And even though a lot of people didn't have it, I was then four times—the first time for a week, the second time for a week, the third time 18 days. They almost lost me. We had hospice come in and we thought that was the end. And anyway, to make a long story short, I had a wonderful support team, wonderful doctors, and we say it's a miracle. After about 15 days, 14 days, I started to do a little turnaround. And 18 days later I went home. Needing a lot of help at home. Of course, I had lost so much weight, I needed physical therapy. I didn't have any [targeted therapy] or any kind of chemo for, I think, two months because they felt like I wasn't strong enough. So they determined that, obviously, even though the drug was helping, it was also killing me."

"Well, every therapy had some side effects. I mean, you're not going to not get side effects. But basically, I was looking for something that had fairly low adverse events in terms of the more serious. They look for things like if there's things like cardiovascular, things like some therapies increasing—things like a little bit of diarrhea or nausea, I mean, that's not a big deal. You're looking for more serious: anything respiratory, CV, some kind of anemia, things like that...I mean, I was fairly fortunate because, other than my diagnosis, I'm healthy. So the way the oncologist explained it to me, it's much more challenging when people have what they call other comorbidities. So maybe they come in and they've got other conditions that can really impact the way the therapy works because of the potential for side effects to work against each other...so you're weighing the efficacy of the therapy, but you're also weighing...well, what are the side effects? And what are the potential...adverse events."

"So it's kind of been a learning process to try and manage some of those symptoms in a way that it doesn't impact my work life or my home life. But I think now—what am I, probably six, seven, eight months into it?—I kind of have it down with the nausea meds. I don't get sick in the morning anymore. And I've learned that when my belly starts rumbling, I need to pay attention to it right away or I'm going to be in trouble. The only other thing is just weird visual things at night and the morning. It kind of looks like tracers on everything you see. But it's manageable, and I'll take that compared to feeling sick and losing my hair."

Participants who experienced challenges in responding to treatment or had exhausted many options had different considerations than participants who were early in their treatment journey. The range of treatment options for NSCLC has altered the disease prognosis for many patients but also can lead to “treatment fatigue” where patients become overwhelmed by the treatment demands of their cancer[27], as demonstrated by the following patient narratives.

"Do you want something that's the most aggressive treatment, that might give you side effects, but you want to prolong your life or hopefully get a really good response? Or do you want something that's not going to be as aggressive? You won't live as long, but you have a better quality of life. And I think that's where that balance has to be decided and then from there, you can go on and make good treatment decisions."

"I mean, hopefully, when someone's going on first line, they have a lot of optimism, right? ...But, obviously, as you go later down lines of therapy, patients can get fatigued."
The metastatic nature of the participants’ cancer often influenced their treatment decision-making, as they could not afford to choose options that were potentially ineffective or risky. For some participants, this meant deciding not to participate in clinical trials. Among our participants, there was strong interest in targeted and immunotherapies because of known efficacy for certain genetic driver mutations, as well as convenience in the route of administration and side effect profile. Conversely, many participants wanted to avoid conventional treatment, such as chemotherapy, because of its perceived toxicity and potential impact on QOL.

“The doctors always stress your quality of life is most important. And we all know chemo was a poison… But I have been rethinking this new treatment, this other treatment that they have added because my quality of life has been horrible.”

“But there’s some days that I lay there and I'm just like, "Am I making a mistake? Should I switch? What should I do?”

“Well, I would definitely prefer to have a drug that had a long history of successful treatment against my particular type of tumor. But I think that with this particular cancer and where we’re at with research, that many of us are being forced into accepting anything that we think will work because you get to a point where the one that’s FDA approved, when you develop resistance and you have to find something else, you’re going to be willing to try just about anything to keep going.”

Regardless of their individual preferences for treatment, participants had consensus around the factors that influenced their decision-making throughout their disease course. Many noted they initially relied on their care teams’ recommendations about treatments, as they were trying to understand their diagnosis and options. As participants learned more about their cancer and gained experience with treatments, their preferences evolved and became more influential in their choices. The rapidly changing landscape of NSCLC treatments and disease understanding was also cited as an influence on decision-making. For some participants, this meant a willingness to participate in clinical trials and try new treatments because of the therapeutic advances they have witnessed throughout the course of their disease.

In addition to the QOL considerations, participants prioritized route of treatment administration. This included ease and convenience, mechanism/mode of administration (e.g. oral vs. intravenous), ease of obtaining the medication if self-administered, and ability to adhere to therapy. Treatments that were self-administered and offered convenience further allowed participants to maintain the activities of their daily lives.

Participants wanted to know how frequently they would need to have treatment administered and the potential impact of having to travel to a clinic or location (as opposed to being able to self-administer at home).

"If you talk to somebody, and they say, "You know, I really have challenges with driving," or, "I've got my work," it’s like, "Okay. An infusion every week, probably not the best thing for this person.""

For those participants who were required to receive their treatment at a clinic, this often necessitated lifestyle or work changes.

"The facility I'm with...I could literally walk over there before work and have it done and get back to work by 8 o’clock, so everything worked out fine. When I did start chemotherapy...I’d do it on a Wednesday so that my bad day would come on a Friday. So I always would take Friday off work, and by Monday, I'd feel good enough to be back to work. And then my employer...allowed me to work from the infusion center. So I could work remotely and didn't lose a day of pay."
3.3. Additional Themes and Key Findings

Although the primary purpose of the data collection was to investigate the most meaningful aspects or attributes of mNSCLC treatment in order to identify key factors and determinants of value, the qualitative data analysis also revealed several overarching themes undergirding patients’ treatment deliberations, which were integral to the value determinants identified. We describe the themes and associated key findings here.

3.3.1. Delays in Diagnosis

Across the focus group and interviews, participants repeatedly described the overwhelming experience and shock of receiving their lung cancer diagnoses. They shared the circumstances around their diagnoses, including how providers conveyed the information and their initial comprehension and reactions to this information. Moderators asked participants what questions they had at the time of diagnosis as a proxy for what factors were meaningful about the diagnosis and treatment.

Many patients reported having questions about the disease itself, their prognosis, and the impact of treatment on their lives.

Several participants discussed their experiences receiving mis- and delayed diagnoses. These patients did not exhibit traditional lung cancer symptoms or risk factors, and as such, their time to diagnosis was often delayed. The challenges associated with receiving the appropriate diagnosis is illustrated by the following narrative of a patient who had been misdiagnosed twice before confirmation of her mNSCLC:

""Doesn't look like asthma. Looks like allergies. I'm going to prescribe you an inhaler." And he pretty much gave me the prescription, left the room. I left the appointment, and as I was sitting kind of on the road leaving the appointment, I'm like, Wait a minute. If I have allergies, what am I allergic to? What should I avoid? So I went the following day for a chest X-ray, and by the time I left the imaging center and got to work, I got a phone call from him, saying, "Stay in your car. Don't go into work. We're pretty sure you have tuberculosis." How could I have tuberculosis? I'm not sick. I'm not a doctor, but I'm pretty sure tuberculosis is pretty serious, and you would know if you had it. We did all the testing... Came out of quarantine and my doctor said, "Well, I'll send you to a pulmonologist. They can do more." The pulmonologist was fantastic. She had a very gentle delivery, not like my family practitioner, and said, "From my experience, looking at your X-ray, just your X-ray alone, I would guess it's lung cancer." She did a series of tests and by the next afternoon, I had the results back."

Participants who reported delays in their diagnoses were understandably frustrated with not receiving their diagnosis sooner, and perhaps even at an earlier stage. Even after diagnosis, some patients were not provided with appropriate effective treatment options because they had driver mutations. Participants who were offered genetic testing by their providers to determine if a driver mutation was present expressed satisfaction with their care, as this enabled them to received targeted treatment options.

3.3.2. Financial Burden of Care

All participants in our study sample reported having a current form of health insurance; however, many reported that insurance coverage did not alleviate the financial burden of their cancer care. For most participants, the NSCLC diagnosis was accompanied by concerns about maintaining employment status and insurance coverage to pay for treatments and ancillary costs. While
participants often incurred significant costs during their diagnosis and initial treatment, they still faced expenses for treatments that prolonged their lives.

Patients’ perceptions of the value of their care was not equated with the actual costs to them, but out-of-pocket costs, financial considerations, and insurance coverage and approvals were key considerations in patients' treatment deliberations. This included not only the direct costs related to the treatment but also the costs associated with supplemental treatments or costs of therapies to mitigate side effects, which may not be covered by insurance, as well as ancillary costs.

"Obviously, the impact on will I be able to continue to work? Do I need to quit my job?... How am I going to do this? How am I going to afford this?"

"How the treatment was going to affect me, how it would affect my work situation because it's sort of a catch 22. I had to work to be able to afford treatment and insurance, so that was a big concern."

"He wanted to add kind of a supplemental treatment, and my insurance had initially pre-approved. And after the third treatment, they denied it and sent me a bill for $60,000."

For some participants, the demands of cancer treatment exhausted their financial resources and required them to seek disability or other assistance programs. Participation in a clinical trial was also cited by several participants as a way to access expensive and innovative treatments without incurring financial costs. For some participants, financial considerations required tradeoffs in their care, such as skipping appointments or scans to save costs.

"My husband had lost his job. I couldn't work... so we had a whole financial thing going on. I finally got approved for disability. The first time, I should have just said I was stage IV, but I didn't because in my mind I refused to believe that I was stage IV. So I didn't put that down, and I got denied the disability."

"And then I'm calling everyone, and I'm saying, "What can I do? What do I need?" And they say, "You can do nothing. You let us call your oncologist." And we wait to talk to them and get the right person. And then I call my oncologist, and they're like, "We can't reach your insurance."

"That was actually why some people wanted to get on trials because the costs, particularly the immunotherapies, are quite costly. I mean, we're talking hundreds of thousands of dollars."

Put simply, continuous treatment for cancer created financial instability and fluctuations for many participants.

3.3.3. The Importance of a Patient-Centered Healthcare Team

Another important factor in deliberating treatment options was the relationship participants had with their oncologist and oncology care team. Many participants reported that the quality of the relationship with their care team was critical to the treatment journey, and good patient-provider communication was shaped in the formative phase following diagnosis. Patients in our study reported valuing providers who have deep knowledge of the risks and benefits of treatment as well as who were up to date on the most recent advances in the field.

Participants emphasized that their primary goal for treatment was to shrink their tumors, reduce metastases, or stop progression in order return to a normal life. Many highlighted the daily activities that they considered for their threshold of “normal,” which ranged from washing dishes to running a half marathon. Participants praised providers who supported these individualized
goals. The following excerpts demonstrate the participants’ priorities around treatment goals and how they valued their care teams’ support:

“My goal was to get the treatment with the best response. So I wanted something that could potentially give me a complete response or a very good partial response and stop disease progression. So I was looking for the therapy that had the best results.”

“[The oncologist] said, ‘What do you want from me? What's your end result?’ And I said, 'Obviously, I want to get rid of this stuff, and I also want to run a half marathon in six months.’ And he was like, ‘What?’… I said, ‘I already signed up for it. I'm going to go to Hawaii, and I'm going to run a half marathon. And that's going to be my prize for myself for doing everything I can.' And he was like, 'All right. Let's get you there.' So he was on board with that too. And I did. And he's got the pictures on his walls.”

“I want to go to my appointment and then forget about it. And then go to my appointment and then forget about it. I want to have that normal— I have a husband, I have my sister, I have a nephew. I want to be able to live my life with them. I want to be able to go to work. I work part-time, so I work two days a week. I want to go to work and want to travel. That's the important things for me.”

In addition to sharing their personal goals for treatment, patients valued when their providers assessed their goals for treatment to inform their courses of therapy. One interviewee succinctly said:

“I think the doctors should make the inquiries right up front about what the patient wants out of treatment.”

Another described a conversation that might take place between a patient and a provider discussing the tradeoffs to consider and the patient’s goals when beginning treatment:

“I think it really has to start with an open dialogue, and I think the doctor and the patient need to decide up front what are your long-term goals. Do you want something that's the most aggressive treatment, that might give you side effects, but you want to prolong your life or hopefully get a really good response? Or do you want something that’s not going to be as aggressive? You won't live as long, but you have a better quality of life. And I think that that's where that balance has to be decided and then from there, you can go on and make good treatment decisions.”

3.3.4. The Importance of Shared Decision-Making

Two important factors in how participants described positive relationships with their providers were trust and mutual respect. These themes were repeated across most interviews and often surfaced more than once within an interview or focus group. Most participants indicated that they preferred to be the primary decision maker, but others expressed preference for some input into a decision that was ultimately that of the clinician.

Even with these different approaches to decision-making, trust and mutual respect remained priorities for the patient-provider relationship. Patients valued providers who were knowledgeable about the risks and benefit of treatments, but also those who fostered collaboration in treatment decision-making. The following quotes describe the variety of participant preferences and their approaches to treatment decision-making:

“But my oncologist, she told me at the very first visit I had outside of the hospital with her, she's like, 'I know we haven't talked about...[prognosis]...And she said, 'Some people like to know
so they can plan, and others don’t." But she said, "The only thing I can tell you is what the research says." And I looked at her and I was like, "I've thought about it, and I guess that is the only thing you can tell me. But I also don't want to know because I don't think you can tell me how much longer I have. I don't think anyone can tell me that." And she looked at me and she agreed, and so she kind of just respected my wishes and left it at that.”

“I felt that I was – how can I put it? – consulted. I felt like I was part of the decision process, and so I felt that it was collaborative.”

“I totally like my provider. I don't think we're equal. I think he's the doctor and I'm the patient, and he kind of leads the care. I think that he leads the care by his best judgment. But I think if something came up and I just felt it just was not right, I definitely believe that we would listen to me…So I really put a lot of trust in his decisions, but like I said, I think I would be able to stop something if it wasn't what I agreed to.”

“…largely in my opinion I've been driving my treatment decisions with my doctor's concurrence. Obviously, we discussed them and I get advice from him, but I tell people, "Some call it's your decision making, I call it taking advice from my doctor and making my own decisions." And that's the way I see the way I handled this.”

“I felt like we were part of a team…I mean, obviously, he's more of a coach. He has a little more seniority. He has a little more experience than I do because he's gone to medical school…but I never felt that he was talking down to me. I felt like he would spend time with me. He answered questions. He welcomed me doing my own research. I didn't feel like he was threatened by me challenging or asking questions, which I think is what you want…”

“I would like options given to me. Not that my oncologist doesn’t want my opinion, but I feel like she makes the final decision without my input.”

Participants emphasized that they valued compassionate care from their clinicians, where they felt they were treated as a whole person, not just a cancer patient, as illustrated in the following narrative.

“I am more than just the tumor that's living inside me. There are side effects, and it impacts my work life and my home life, and so that conversation around the whole person is really important.”

3.3.5. Care Coordination

Patients reported valuing coordinated care among their provider team, such as specialists who regularly conferred about their patients’ treatment journeys. Interviewees and focus group participants noted that their primary provider’s communication with other care team members was essential to a positive patient-provider relationship, as highlighted by the participant who said:

“It's extremely important that my primary care doctor stay in communication with the pulmonologist, the pulmonologist be in communication with the oncologist, and the radiation—and I had a radiation oncologist too…So the communication is key amongst all the doctors.”

Comprehensive, frequent, and transparent patient-provider communication were also of value to the participants. They noted providers who developed relationships with family members and those who made themselves accessible through alternate modes of communication, such as video conferencing or text messages as described in the excerpts below:
“I go every three months for a CT scan. At that three-month appointment, my oncologist has either a FaceTime or a three-way call...with my son, every time...So she'll take pictures with my phone, she sends it to him, explains it. She'll talk to him, tell him what's expected.”

“I think I've got a very good rapport with the whole team. And I have never in all this time - and they don't pay me to say this - I have never been disappointed in my communications with them.”

“And when she tells me that I can text her, and she will text me back, that to me-- I tell her every time I see her that I am just floored by that because she will text me back. And I never had a doctor that would do that.”

3.3.6. Wrap-Around Care and Support

Wrap-around care and support services beyond the cancer treatment itself was prioritized by many patients. Examples of these services include financial counseling, mental health, social services, therapy, and family support. Many participants sought out treatment at facilities that could provide this comprehensive care and noted that it enhanced their treatment experiences.

Study participants spoke about the avenues of support they sought out and received throughout their diagnosis and treatment journeys. They valued services beyond the cancer treatment that could help them cope with the challenges associated with mNSCLC and treatment. These include emotional support from family and friends, encouragement from the care team, online or in-person patient support groups, and psychiatric care. The excerpts below detail some of these supportive experiences.

“I got a lot of support from my friend, Tom', because...he was diagnosed with stage IV adenocarcinoma two years earlier. So we would compare notes as far as my treatment to what he was getting. So in the beginning, he was sort of my peer I would look up to as far as what to ask and things like that. And to this day - it's almost 10 years later - I still take a bicycle spin class with him twice a month.”

“And nobody ever gave the impression that the treatment wasn't going to work. Nobody gave the impression like, "Okay, you've got stage IV lung cancer and you're doomed." So I think the positive people that are there helped quite a bit.”

“...I went to that support group throughout all of this. I mean, that's the one single thing that helped me the most.”

“The best advice I got was to find a local support group and that's the one thing that I tell everyone that I counsel, "You can call me anytime on the phone, but you need to find a group in your location. It's the best thing that will happen to you." So that was the best thing that happened to me, and it's certainly what I recommend to anybody that I get scheduled to counsel.”

“I've been on under psychiatric care or psychotherapy ever since then...I'm on antianxiety medication and antidepressant medication, and it helps because it's hard to fight it.”

In addition to support for themselves, a few participants sought out supportive services for family members, notably their children. It was important for patients with families to know that their care extended to their families.

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1 All names have been changed to protect the anonymity of participants.
“And then you get the whole team of everything you need. The social service end of it is offered to you, and they have counselors. And I was like, "What do I do for my son?" was one of my biggest concerns because he was at an age where he was too old for camp and things like that, but he’s not really an adult to be like, "Oh, no. He’s got this," type of thing. That was a bit of a concern for me. But they also had counselors there covered with my care that he could go and talk to, which was super helpful.”

“I will say my kids have taken advantage of some of the therapy support that was available…and my husband too. They all needed some help with the diagnosis.”

Several participants also described how they have become a support resource for more-recently diagnosed NSCLC patients. Some have become patient advocates, some serve as a guide through the diagnosis and treatment process, and others organize events around fundraising for research or public education.

“I got involved in advocacy work myself, both with patients through [advocacy organization] and I do a lot of research-related lung cancer advocacy work.”

“Once a month…[I attend]…a Living Room where…expert oncologists and pathologists, surgeons come in, so I attend things like that. I sit on panels. I’m very involved in social media. I moderate a number of lung cancer groups for immunotherapies and targeted therapies. I’ve actually started my own Facebook closed group for combos, triplets, and the vaccines, and we compare notes…And so a lot of it is flipped from me reaching out for support to giving support. And it helps me keep on top of the latest treatments, not only for my lung cancer but for other people’s mutations.

“In fact, since 2016, I have been…doing those calls to people who are newly diagnosed and helping them understand the human side of what I went through with it and try and help them come to terms with it.”

A few participants also described their negative experiences during their diagnosis and treatment where they lacked support, often in navigating the financial or healthcare systems or because the support groups they found did not meet their needs.

“And then I'm calling everyone, and I'm saying, "What can I do? What do I need?" And they say, "You can do nothing. You let us call your oncologist." And we wait to talk to them and get the right person. And then I call my oncologist, and they're like, "We can't reach your insurance." And they need a different kind of piece of paper. So I don't know.”

“I honestly wish there was mental health offered right away as a form of treatment because you need someone to talk with. It can't just be family because all they can do is listen, but you need someone unbiased.”

“I finally found one group, and I went there, and it was so horribly depressing. I was like, "Nope. Never going back. Never going back." It was like what you see in a really poorly made TV movie with everybody sitting in the dimly lit room with the stale donuts in the back...”

“I think the biggest thing I wish I would’ve had was more recommendations or suggestions from my initial oncologist of the support groups kind of thing or how to reach other patients.”

3.3.7. The Value of Hope for Future Treatment Options

After receiving their NSCLC diagnosis, participants expressed a range of emotions including fear and shock, as metastatic NSCLC historically has been associated with a poor prognosis.[28] A
knowledgeable care team and access to information and education, however, shifted many participants’ perceptions of their disease. There was a recognition among our participants of the heterogeneity of NSCLC and individualized treatment response, which provided motivation to find the optimal treatment. Many participants received oral targeted therapies, enabling them to continue their daily functions without the side effects associated with chemotherapy and radiation. Others were provided with multiple treatment options, giving them hope about managing their disease in the present and surviving to see additional options.

An increasing recognition among patients of cancer as a chronic, rather than acute, disease made the unforeseen and unanticipated costs more salient. Many participants observed that the cancer experience today is not what it used to be, given more expansive and tailored treatment options, greater efficacy, and continuous innovations in therapy. Even when a particular therapy had proven ineffective, patients remained hopeful about additional treatment options and surviving long enough to experience further innovations in care. The following excerpts illustrate this point:

“And now that I’m on my second targeted therapy, what’s next? And lo and behold, I found out there is another one. So I do look at it— I think you were the one who said chronic before. Because I do consider it a chronic illness.”

“I don’t think about cancer every day anymore. I used to. I don’t anymore because I, too, wanted to live a normal life. I went back to work full-time.”

“I guess for me, it’s realizing that cancer’s not a life sentence. I think back to when I was a kid and people would whisper the letter, "It's the Big C," or whatever.”

“You can’t let cancer take your hope away from you. That’s the only thing you can hang to. The changes in treatment and-- the protocol for my kind of cancer today at [cancer center] is none of the same things that I’ve had. It’s all targeted therapy and immunotherapy and other things. It’s clinical trial drugs and all of that. I was given stuff that was being used for 30 years. The last five to ten years and at least in lung cancer treatment, there’s just been dramatic change.”

"...it’s that we figure out how to make this particular cancer into a manageable disease. So it’s not unlike having diabetes where you take a medication for the rest of your life but you can live and enjoy life, and you’re not suffering with your quality of life, but you have a way to manage the disease. So, yes, I do want to hang on for the next therapy, but my hope is that that therapy that comes down the line is going to be the one that allows me to just manage this lung cancer for the long term."

"I hope for the longest amount of progression-free time that I can have on this drug because the longer I can have on this drug, the more opportunity there is for something else to be developed and come down the pipe for late."

"It almost feels like-- did you ever play Frogger when you were young? The old version of Frogger where you’re trying to hop across the stream and the rocks are sinking underneath your feet? That’s what it feels like. I’m on that first rock, and I’m waiting for the next one to pop up so I can hop onto it before the one I’m on sinks."

Most participants in our study, however, have redefined what “normal” means to them. Treatment side effects and impacts of the cancer have necessitated lifestyle changes. Further, it should be noted that the participants in our study were survivors who were healthy enough to participate and may not reflect the opinions of others with the same disease and stage.
Nevertheless, an understanding of and experience with treatment advances gave many of our study participants hope and optimism about their disease course.

3.3.8. **Genetic Mutation Testing**

Not surprisingly, patients in our study – of which 87% reported a known oncogene – highly valued genetic mutation testing because it was critical to ensuring targeted therapy and tailored treatment. As mutation-specific evidence generation becomes available, patients are seeing that there is greater availability of treatment options for mutation-specific populations. Thus, patients valued investment into treatments for patients who have known driver mutations but for which there remains an unmet need because drugs may not have yet been developed or prioritized. Beyond that, patients placed high value in providers who demonstrated knowledge about genetic mutations and the need for testing, as well as connecting with and the support of other patients with the same mutation, giving way to a new genetic sub-group identity.

With growing mutation-specific information and treatments, patients have begun to create smaller communities based on their mutations within the large umbrella of NSCLC. Patients value connecting with and the support of other patients with the same mutation. Participants here describe that these communities largely form and thrive through support groups:

“But the support group did have patients that were EGFR, had that mutation. So I was learning from those people. There were a couple of people in the support group that had actually gone through trials for certain therapies and then talked about their experience.”

“… it is a group that is all ROS1 positive cancer survivors, and on Facebook, it’s a really tight-knit community where people are posting when they go for their scans and their results. And then what I find valuable now is that there are people that are on there that have been on the drug I was on-- or I am on for 5 to 10 years and have just started to develop resistance, and they’re talking about what their next steps are. So it’s kind of nice to know that it does work for a while and there are plans coming up next.”

“I know people think online’s great to find people, but for me, I still haven’t found the right track to take to find those people. So that’s hard because I do want to find someone who has my mutation. Mine's EGFR X921. And I found a girl who has 19 and she doesn't-- I don't know. She’s doing some other thing on her own. She said she has a friend who has 21. And I was like, "If he ever wants to talk, give my contact info to him," or something. I would really like to find someone who has my mutation.”

Although genetic testing and mutation identification has increased in practice, patients noted an unmet need where specific drugs have not been developed or prioritized. They expressed concerns about research agendas and funding for the research. They discussed how they conduct their own research on potential treatments, investigating clinical trials, discovering therapies approved in other countries, and soliciting experiences from other group members. Several also described their involvement in education about NSCLC and their particular mutation, their contributions to clinical research for their mutations, and their fundraising events for research, with the support of their mutation sub-groups.

“Yeah, the funding is not what it should be. But now I think they're doing more for it because a lot of people who are getting diagnosed were nonsmokers. So I think because of that, they're finally looking into it a little bit more. And that's where they've come up with these drugs.”

“Well, my perspective with the ROS1 is that, right now, there's a very limited pool of therapies that applies directly to this mutation. So we have one that's FDA approved, and after that, it's a
series of clinical trials. So being in this group, it almost feels like you have to step up your knowledge; you have to start reading research studies and keep abreast of what's happening because it's changing so fast that if you don't have a wider pool of knowledge to draw from, it might be hard to know that your oncologist was also staying on top of it as well.”

“We call the number and arrange for our extra tissue or extra fluids to be shipped off to this research lab, and they're creating more cell lines for use for ROS1 research. One of the difficulties with us is that we're only one to two percent of the non-small cell lung population, so it's hard to have ROS1-focused research because there's just not enough of us out there to do it on.”

“So we're going to see this cancer's not so rare. So it's going to get more research dollars for it. We're going to get more awareness of it. And everybody in the future's going to benefit from us pushing forward with it.”

“I'm constantly educating people, constantly. I've got stickers on my car and, "Ask me about lung cancer." I educate anybody that ever asks me anything about it. I try to make them aware, because there were no signs. There was no cough. There was no shortness of breath. There was nothing.”

“And this knowledge is now out there and obviously we still face the stigma every day with cigarettes. And again people aren't are aware that tens of thousands of Americans are diagnosed every year who haven't ever smoked. I'm a non-smoker, but there are thousands and thousands of people out there just like me...When I was diagnosed and also ignorant about the disease, uneducated about it. I too thought, "Well, you know, I hate cigarettes, but they're bringing on themselves." I wasn't nasty about it, but I thought that just like people still do it for the most part. And then when I started to become educated about it and realized that still obviously we have to again be realistic. Smoking is the leading cause, though it's certainly not the only cause.”

“And I started a fundraiser that goes right to the [foundation], right for ROS1 cancer research. It's all us ROS1ders are doing that. We're all starting fundraisers just for this kind of cancer research. And donating fluids and body tissue to be put into [inaudible] models, so that we can continue to get more research, because we're rare and unusual.”

“There are a lot of different things that are going on in that group. There are nonprofits being created. And myself, a group of my friends and I created a nonprofit after diagnosis – it's called [name] - and we're running a race in October that's going to raise funds for research. So, because of that group, I knew where I could send money that would help fund research into this mutation. So that's a positive outlet.”

3.3.9. Summary

In summary, when asked about the issues most salient to them when making treatment decisions, participants reported a number of different factors that shaped and influenced their treatment decision-making. These included: logistical considerations such as the duration, mode, and frequency of the treatment regimen; QOL; financial considerations; maintenance of physical appearance; the impact of cancer treatment beyond measurable clinical endpoints; and the ability to live “normally”. However, those who experienced collaborative care from their oncology providers were better prepared to face the impact of cancer and its progression than those who experienced poor communication and expectation-setting with providers. Finally, while the full sample comprised patients with metastatic disease, some had been diagnosed at Stage III and later progressed to metastasis while others had been diagnosed with metastatic disease de novo. What distinguished the two types of patients was not stage at original diagnosis, but rather the
length of time since diagnosis, the experience of having undergone multiple lines of therapy, and how experienced they had become as cancer patients.

3.4. **Strengths and Limitations**

While this work has yielded suggestive findings, it is not without sampling-related limitations that merit consideration before interpreting the study and its implications. First, the current findings represent the views of a convenience sample of individuals who may be more vocal than the general mNSCLC cancer patient population. The study participants were self-selected in that they volunteered for the study. Larger-scale work is needed to establish generalizability of the findings. While this study cannot reasonably obtain population-representative views from a sample of this size, the purpose of the qualitative data collection was to obtain insights from mNSCLC patients about their cancer treatment decision-making and care experiences and how these can help to identify attributes of treatment most meaningful to patients. Finally, the study sample was educated, largely insured, and English-proficient. Other less advantaged populations – due to race/ethnicity, acculturation, language proficiency, socioeconomic status, access to care, or insurance status – may deliberate other factors related to cancer treatment decision making that merit investigation. However, despite the stated limitations, this study provides preliminary data on the attributes of treatment that are found to be meaningful to mNSCLC cancer patients who carry a form of genetic mutation and may be eligible for certain types of treatments.

4. **Conclusions**

The objective of this study was to identify and evaluate the elements of treatment that mNSCLC patients found to be most valuable about their treatment for the disease. Our data reveal that while the clinical endpoints of overall survival and treatment efficacy are important, patients derive value from other non-clinical factors.

Participants in our study reported mixed experiences with approaches to disease management, and with treatment preferences influenced by lack of alternatives, particularly after multiple lines of therapy. Many patients with metastatic disease reported having very few options. When they did have some choice, the trade-offs around quality and quantity of life were particularly salient. Clinical trial designs and endpoints cannot adequately measure these variations in disease and treatment preference heterogeneity. As such, value frameworks that rely exclusively on clinical trial endpoints do not capture or reflect the true elements of value in NSCLC care.

Survival and efficacy, which are highly prioritized in value frameworks, were also the most important treatment factors for participants in our study. For some participants, however, treatment goals evolved to include a better quality of life or ability to engage in daily activities. Value frameworks are limited in their ability to reflect shifting patient goals and priorities, thereby only providing a static assessment of treatment value for key stakeholders and potentially leading to inadequate decision-making.

While this study demonstrated the importance of traditional value framework inputs like survival, it also further highlighted the need for incorporation of value determinants that are most meaningful to patients. In recent years there has been tremendous innovation in NSCLC, which has allowed patients to prioritize quality of life and functional abilities. As NSCLC treatments continue to evolve and allow patients to live with a chronic disease, stakeholders of value assessments should prioritize methods and framework structures that can reflect a patient’s unique treatment journey.
5. References

Appendix A: Discussion Guide

Introduction
Thank you for meeting with us today. We very much appreciate your time and insights. My name is [name] and I will be moderating the discussion today. We are joined by [names] from the study team. They will be here to observe our discussion.

Background

Purpose and Overview of study
We have asked you here today to speak with us about your non-small cell lung cancer (NSCLC) diagnosis, your decisions about cancer treatment, and your treatment experiences. We are developing a survey for patients diagnosed NSCLC. The purpose of the survey is to ask patients about their treatment deliberations and decisions, their treatment experiences, and their satisfaction with their NSCLC treatment. Speaking to you today will help us to understand the range of experiences patients with NSCLC have, what they look for in treatment, and those elements of treatment that they find valuable as well as identify gaps in care delivery

[FOCUS GROUP ONLY]

Ground Rules

Confidentiality
Before we begin, we want to emphasize that whatever is discussed here today is confidential and should not be shared with anyone outside of this setting.

It is important that we respect one another’s privacy so I ask you to not reveal the identities of those who are present or disclose what was discussed during our session to others outside of this group. If you inadvertently refer to anyone by their name, please be assured that any such identifying information will be removed once today’s audio recording is transcribed.

Discussion

So that we may be fully engaged with one another during the discussion, we would like to ask that you please turn off your phones or place them on silent.

Before we start with the questions, I want to emphasize that while we recognize that there may be some commonalities between your cancer treatment experiences, we also recognize that everyone’s cancer journey is unique, as is every patient living with cancer.

As we ask questions, please share your perspective based on your personal experiences.

Please also let us know if you think the questions or discussion topics we bring up today are relevant or important to NSCLC cancer patients. These are the topic areas that we think may be important, but our goal is to find out what is most meaningful for patients when making treatment decisions.

Lastly, we are not looking for consensus and we don’t expect you to always agree with each other. We want to hear about a range of thoughts and experiences. If you tend to be more openly communicative, I hope you won’t mind if I moderate so that we can hear from everyone. If you are shy, I hope you’ll try stepping out of your comfort zone to participate in the discussion.

Before diving into the session, I would like to go around the room and each introduce ourselves to one another.

- Your first name
- Whether or not this is the first time you’ve participated in a focus group
- When you were diagnosed with NSCLC and the stage at diagnosis
- Ice breaker – If you could go on a vacation anywhere, where would you go and why?

**Discussion Questions**

**Diagnosis**

Objective: Understand patient diagnosis experience

During our discussion today, I would like to focus on your personal experience living with non-small cell lung cancer, knowing that each of your experiences are likely to differ.

To start, I would like you to think back to when you were first diagnosed with NSCLC.

- What motivated you to see a doctor (symptoms, family history, annual screening, etc.)?
  - How long ago was this?
- How did your doctor describe your diagnosis to you?
  - Probe: How well did you understand the diagnosis?
- What questions did you have for your oncologist or care team?
  - Probe: What did you think about the information that was provided to you?
  - Probe: Was it provided in a way that was digestible or easily understandable?
  - Probes: What type of information did you want? What type of information did you seek out? Where else did you seek out additional information?
- Did you run into any challenges during the diagnosis process? Please explain.
  - What do you wish had gone differently? Why?

**Treatment Decision-Making at Diagnosis**

Objective: Understand how treatment options were initially presented and prioritized

*Now I’d like to discuss your initial treatment decisions focusing on systemic therapies, like chemotherapy and immunotherapy.*

- After your diagnosis, what types of treatment options were offered to you?
  - Probe: What information was given to you given about your treatment options?
  - Probe: How confident were you that you understood the treatment options for your diagnosis?
- I would like to discuss the factors and considerations you thought about before determining your initial treatment. Before we discuss this as a group, I would like you to jot down on the notepad in front of you, the first three factors or considerations related to treatment that came to mind when your care team mentioned needing to receive treatment for NSCLC.
- FOCUS GROUP ONLY: Now, let us go around the room and I would like each of you to share with the group your list. I will capture them on this flipchart/whiteboard.
- What other factors did you have that are not captured by this list? Feel free to call them out, and we will add these to the list.
Listen for and prompt as needed:

- Significant others/caregiver burden
- Impact on relationships
- Impact on everyday life
- Co-morbid conditions (other diseases/illnesses)
- Doctors/nurses/caregiver opinions
- Finances/insurance coverage
- Relief from pain and fatigue
- Treatment regimen (dosing, schedule, mode or route of administration, frequency, switching)

- Chance of side effects/adverse reactions to treatment
- QOL/Impact on ADLs
- Chance of benefit/stemming progression
- Strength of evidence/effectiveness
- Experience of other patients
- Out of pocket costs
- Doctor recommendation

How did you discuss and evaluate the benefits, risks, and costs associated with the various options?

- Probe: How was this explained to you?
- Probe: Who explained this to you?
- Probe: Who else did you consult with about this (loved ones, caregivers, etc)

How much did you think about the potential side effects of treatment?

- Probe: Were there any treatment side effects that you particularly want to avoid?

Overall, what were your goals for treatment? Probes (including but not limited to):

- Reaching life milestones (e.g., graduation, wedding)
- Survival for x months/years
- Overall quality-of-life
- Minimal disruption to normal life
- Maintaining emotional well-being and activities of daily life (ADLs)
- Stopping progression of disease or secondary conditions (PFS)
- Cure
- Not being reminded about the cancer
- Timely and convenient care

Besides your care team, did you talk to anyone else about your treatment options and what to do?
Treatment Decision-Making Post Diagnosis

Objective: Explore how patients' treatment decisions changed over time

Now we are going to move beyond your initial treatment decisions and talk about your treatment preferences and decisions over time since diagnosis.

- Throughout the course of your treatment for NSCLC, can you describe the different types of care and/or treatments that your healthcare team has provided or prescribed?
  - Probe: What specific services or treatments have you received?
  - Probe: What were you told about how successful your treatment(s) might be?
  - Probe: What types of treatments do/did you prefer and why?

- How have you personally assessed your response to treatment?
  - Probe: Clinical endpoints
  - Probe: Progression free survival
  - Probe: Treatment milestones, measures of success

- How has your doctor assessed your response to treatment? What test results, if any, does your doctor share with you?
  - Probe: When discussing different types of treatment, does your doctor share with you any data, figures, or results from clinical trials or studies?

- Has your doctor ever had to switch treatments to find something that would work better for your condition? If so, how often have you had to switch treatment regimens?
  - Probe: What prompted the switch?
  - Probe: If you had known you would have to switch treatment regimens, would you have preferred another type of treatment to begin with?

- Are you currently/or did you eventually receive the type of treatment that you prefer/preferred to be on?
  - Probe: If yes, why do/did you prefer this treatment?
  - Probe: If not, why not?
  - If you aren’t currently or haven’t been on your preferred treatment, what has prevented you from being on your preferred treatment?
    - Probes: Costs, insurance restrictions, doctor/health care provider, access issues, mode of administration

Moderator: go back to flip chart with list of questions/factors from earlier in conversation

- Earlier we talked about the factors and considerations that were important when you made your initial treatment decisions. Looking back across your cancer treatment journey, how have your decisions about treatment or your approach to decisions about treatment changed over time, if at all?
  - Probe: Do you value certain types or attributes of treatments differently now, compared to around the time you were first diagnosed?
Probe: Did your thoughts about treatment change after progression or recurrence? If so, in what way?

Care Team Collaboration
Objective: Explore how patients interact with their physician and the relationship they have

• How involved do you feel you are/have been during the treatment decision-making process (or treatment process)? Do you feel that you have had input into the decision-making about your treatment?
  o Probe: Feel you are an equal member of your care team?
  o Probe: Cooperative or shared decision-making type experience?
  o Probe: Role preference (i.e. who should make decisions about the treatment?)
  o Probe: Shifting or continuous loci of control/responsibility – autonomy changing over time?

• What are the most important things patients and their clinicians should discuss about cancer treatment?

• What do you wish your care team had known about your experiences?

Values and Preferences
Objective: Understand what matters to patients

We’ve talked a lot today about your preferences and considerations when determining your treatments for NSCLC. Now I’d like to discuss about your priorities related to the care you receive for cancer.

• What matters the most to you about the care that you receive for your cancer?
  o Probes (including but not limited to):
    ▪ Importance of doctors being up-to-date on treatment options
    ▪ Care team experience
    ▪ Care team candor
    ▪ Care team coordination
    ▪ Being informed about treatment options/alternative treatment options
    ▪ Being involved in decisions
    ▪ Being asked about own preferences
    ▪ Effectiveness of the treatment
    ▪ Finances/Costs/Insurance
    ▪ Minimal impact on life
    ▪ Returning back to normal before cancer life

• For some patients with cancer, adhering to treatment can be challenging for a variety of reasons. What, if any, barriers have you experienced to accessing your treatment?
  o Probes:
Access to treatment (changes in health plan, pharmacy issues, lack of transportation)

- Out of pocket costs
- Side effects
- Forget to take it
- Practical issues like transportation to/from treatment.

- When a patient is undergoing treatment for NSCLC, doctors develop a treatment plan by reviewing many factors that contribute to a patient’s response including clinical evidence that helps support a given treatment plan. This “evidence base” can consist of drugs that have a long history of use among patients and from many clinical trials. Other drugs may be newer or more novel, without as much data from clinical trials or from patient experiences. Which do you prefer and why?

- In healthcare, there are many different types of stakeholders that make decisions about what cancer drugs are covered by an insurance plan. Each plan is different but usually has what is called a “drug formulary” – a list of drugs covered by the given plan. These plans are developed by looking at lots of different information to determine a cancer drug's value. This can include the cost of the drug, how well it can help to stop a cancer from spreading, the types of side effects, and how many clinical studies have been conducted. What, do you think that these stakeholders, like your insurance company, your employer, or policy-makers should know about when they are making these types of formulary coverage decisions?

Closing

- Based on your experiences and all that you have shared, is there anything that we did not ask about that you would like to share or think is important to address about this topic?

- Thank you all for your time. We really appreciate the experiences and insights you have shared with us today.

- Ask about feedback for the session.
Appendix B: Information Statement

INFORMATION STATEMENT

Study Title: Harnessing the Voice of the Patient in the Assessment of Value of NSCLC Treatment

Principal Investigator Name: Suepattra G. May-Slater, PhD, MPH

Research Site Address(es): Precision Health Economics
11100 Santa Monica Blvd. Ste 500
Los Angeles, CA 90025

Daytime Telephone Number(s): 310-984-7741

SUMMARY
You are invited to participate in a study about the elements of treatment that patients diagnosed with advanced non-small lung cancer (NSCLC) find most valuable. The purpose of the study is to learn about what patients with lung cancer find most meaningful about their treatment. You were selected as a possible participant in this study because you have been diagnosed with NSCLC.

You are being asked to be in a research study. The purpose of this information statement is to help you decide if you want to be in the research study. Things to know before deciding to take part in a research study:

• The main goal of a research study is to learn things to help patients in the future.
• You are free to choose whether or not you want to take part.

PURPOSE OF THE STUDY
The purpose of this study is to assess the elements of lung cancer treatment that patients define as most valuable.

PROCEDURES
If you decide to participate, you will be asked to take part in the following study procedures:

You will be asked to participate in a focus group or interview and complete a brief survey. The focus group discussion will last approximately 90 minutes. The in-depth interview will last approximately 60 minutes. Questions will be asked about your background, your experience with your lung cancer treatment and what things you considered as you made decisions about different treatment options. You are free not to answer any questions you do not wish to answer.

RISKS AND DISCOMFORT
No physical risks are anticipated, however there is the possibility that the study procedures may introduce anxiety or other uncomfortable emotions when responding to some of the questions. However, you may skip any question at any time or stop participating in the research at any time.
BENEFITS
There will be no direct benefit to you for participating in this study. However, it is hoped that advances in our understanding of lung cancer patients’ treatment preferences will benefit future patients. Information gained from this research could lead to improved understanding about how patients decide what treatments to pursue and how their choices are related to individual preferences. It cannot be promised that you will receive any benefits from being in this study.

COSTS AND COMPENSATION
There are no costs to you for being in this study. You will receive $150 for participating in the focus group discussion or interview.

CONFIDENTIALITY
Participation in research may involve a loss of privacy. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. Privacy will be protected through several procedures. The only people who will know that you are a research subject are members of the company who invited you to participate in the study, unless research records are inspected by a regulatory agency. The results of this research study may be presented at meetings or in publications. When the results of the research are published or discussed in conferences or publications, your identity will not be disclosed in those presentations.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is completely voluntary. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, the Innovation and Value Initiative, is paying for this research study.

QUESTIONS
Contact the study lead, Dr. Suepattra May-Slater at 310.984.7741 for any of the following reasons:

- if you have any questions about your participation in this study,
- if you have questions, concerns or complaints about the research

CONTACT INFORMATION
If you have any questions regarding the group or this study in general, please contact the study principal investigator Suepattra May-Slater at 310-984-7741 or via email at suepattra.mayslater@precisionhealtheconomics.com. You should contact the study principal investigator first if you have questions, complaints or concerns about the study.
### Appendix C: Coding Dictionary

<table>
<thead>
<tr>
<th>Code</th>
<th>Description of Code</th>
<th>Short Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographic/Background data</td>
<td>Any information related to a participant’s personal background, including but not limited to employment, area of expertise, education, marital status, religious identity, type of cancer patient, practice type etc. as applies to each of the stakeholder participant types.</td>
<td>Dem_Back</td>
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<tr>
<td>2. Diagnosis</td>
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<tr>
<td>a. Circumstances</td>
<td>Any information related to the circumstances around a patient’s diagnosis. Specifically, how the cancer was detected, how the diagnosis was conveyed, the patient’s experience navigating the care system, the surgical experience, staging, and diagnosis experience. Also can include the type of information and the way the diagnosis was conveyed to the patient.</td>
<td>Diag_circ</td>
</tr>
<tr>
<td>b. Tumor type</td>
<td>Anything related to the cancer diagnosis (i.e. Metastatic, genetic characteristics, stage etc.)</td>
<td>Diag_type</td>
</tr>
<tr>
<td>c. Comprehension</td>
<td>Anything on how well patients may understand or comprehend their diagnosis; and the types of questions patients reported having at the time of diagnosis, and how confident they felt they understood. This specifically relates to what they needed to know in order to make their treatment decision. May also include anything related to a patient’s degree of acceptance or denial.</td>
<td>Diag_comp</td>
</tr>
<tr>
<td>d. Challenges</td>
<td>Anything describing challenges the patient faced during diagnosis or anything the patient wished had gone differently</td>
<td>Diag_chal</td>
</tr>
<tr>
<td>3. Treatment</td>
<td></td>
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<tr>
<td>a. Treatment options</td>
<td>Types of treatment a patient reported they were offered</td>
<td>Trt_opt</td>
</tr>
<tr>
<td>b. Benefits and risks</td>
<td>Any discussion around risks, benefits, and side effects of particular approaches as well as personalized approaches based on tumor characteristics, how treatment options were presented to the patient</td>
<td>Trt_ben_risk</td>
</tr>
<tr>
<td>c. Costs/insurance coverage</td>
<td>Any discussion of costs or insurance coverage associated with treatment. May be co-coded with financial impact code.</td>
<td>Trt_costs</td>
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<tr>
<td><strong>d. Clinical trials</strong></td>
<td>Any discussion of clinical trials as a treatment option, including if a patient reported being told about clinical trials</td>
<td>Trt_clin_trial</td>
</tr>
<tr>
<td><strong>e. Retrospective</strong></td>
<td>Anything a patient mentions that they wish they would have known about at the time of diagnosis or asked about, or would have liked to know more about, in retrospect.</td>
<td>Trt_retro</td>
</tr>
<tr>
<td><strong>f. Treatment goals</strong></td>
<td>Any discussion related to a patient’s treatment goals and expectations. (e.g., family concerns, survival, life milestones, QoL, physical appearance, etc.) This is specifically related to the “Wishes” question.</td>
<td>Trt_goals</td>
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</table>

**4. Treatment decision-making**

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<tr>
<td><strong>a. Decision-making factors</strong></td>
<td>Any discussion of the factors that patients take into consideration when making treatment-related decisions. This includes but is not limited to treatment efficacy, provider reputation, potential side effects, suffering, significant others, dosing or administration schedules, finances, regimen, sociocultural or socio-demographic factors, perceived burden to caregivers, and evidence/efficacy of the treatment. This also includes anything the patient expresses being concerned or worried about at the time they were making decisions about treatment. This is distinct from the questions they had or what they needed to know, but rather based on the factors and knowledge they had in hand in order to make the decision.</td>
<td>Trt_dm_factors</td>
</tr>
<tr>
<td><strong>b. Switching</strong></td>
<td>Any discussion related to the need to switch treatments.</td>
<td>Trt_switch</td>
</tr>
<tr>
<td><strong>c. Trade-offs</strong></td>
<td>Any discussion related to the trade-offs patients may make in making decisions either reported by the patient or observed by the provider, e.g. willingness to suffer through the side effects, incremental gains in OS or PFS (quant) relative to quality of life, etc.</td>
<td>Trt_dm_tradeoff</td>
</tr>
<tr>
<td><strong>d. Involvement in decision-making process</strong></td>
<td>Any discussion related to how involved the patient reported being in their treatment decision-making process. This includes any discussion about the patient’s role preference as well as perspectives on who should make decision about patients’ treatment.</td>
<td>Trt_dm_involve</td>
</tr>
<tr>
<td><strong>e. Evolving treatment decisions</strong></td>
<td>Any discussion related to how a patient’s treatment decisions may evolve</td>
<td>Trt_dm_evolve</td>
</tr>
<tr>
<td>f. Evidence base</td>
<td>Any discussion related to the evidence base of treatment, including lots of real world data vs novel tx, limited data question.</td>
<td>Trt_evidence</td>
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<td>g.</td>
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<tr>
<td>h. Other opinions</td>
<td>This code can be applied to any discussion of who else a patient may discuss or deliberate treatment options with outside their primary oncology care team. This would also include 2nd opinions as well as any discussion of deliberations with friends, family members, social support groups.</td>
<td>Trt_dm_oo</td>
</tr>
<tr>
<td>5. Outcomes</td>
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</tr>
<tr>
<td>a. Side effects</td>
<td>Discussion about toxicity of treatment and side effects patients actually experienced that were related to treatment (including but not limited to, hair loss, nausea, loss of fertility, etc.)</td>
<td>Out_side_effects</td>
</tr>
<tr>
<td>b. Treatment response/results</td>
<td>Any discussion about what patients are or were told by a doctor or believe about their efficacy, treatment response, and gauging response during treatment (not at diagnosis). Also includes discussion around how they assessed response to treatment (including, but not limited to, tumor markers, clinical endpoints, treatment milestones, PFS).</td>
<td>Out_trt_resp</td>
</tr>
<tr>
<td>6. Provider-patient relationship</td>
<td></td>
<td></td>
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<tr>
<td>a. Communication and interactions with care team</td>
<td>Any discussion related to communication between the care team and the patient, including but not limited to provider’s “bedside manner”, frequency and mode of communication, accessibility, trust, confidence, etc. The degree to which they felt their physician listened to their needs. This also includes how characteristics such as sociocultural and gender characteristics may impact the relationship between provider and patient as well as satisfaction or lack thereof with the provider, the facility, or quality of care.</td>
<td>Ppt_comm</td>
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<tr>
<td>7. Patient values</td>
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<tr>
<td></td>
<td>Category</td>
<td>Description</td>
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</tr>
<tr>
<td>a</td>
<td>Value in care</td>
<td>Any discussion related to what patients view as determinants of value in their treatment. This can include what they value about the care they receive for cancer, and in particular what these elements of value are, and should be included in evaluating treatments.</td>
</tr>
<tr>
<td>b</td>
<td>Barriers to treatment</td>
<td>Any discussion of challenges or barriers to adhering to or accessing treatment.</td>
</tr>
<tr>
<td>c</td>
<td>Drug formulary decisions</td>
<td>Any discussion regarding how patients view the factors that should contribute to formulary decisions made by insurance companies, employers, policymakers, or other stakeholders</td>
</tr>
<tr>
<td>d</td>
<td>Value determinants</td>
<td>A code to identify any specific determinants of value as described by the patients. This will be co-coded with other codes and will be used to get a short list of value determinants.</td>
</tr>
<tr>
<td></td>
<td><strong>Navigating the disease and treatment</strong></td>
<td></td>
</tr>
<tr>
<td>a</td>
<td>Coping and response to impact of disease</td>
<td>This includes any discussion related to coping with and responding to the impact of the diagnosis and its treatment, including alternative medicine, changing diet, turning to religion, etc.</td>
</tr>
<tr>
<td></td>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>a</td>
<td>Other</td>
<td>This includes any passages of interest that otherwise cannot be classified as one of the categories above.</td>
</tr>
</tbody>
</table>