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## Patient satisfaction while enrolled in clinical trials: A literature review

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### Cover Page Footnote

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## Patient satisfaction while enrolled in clinical trials: A literature review

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### Abstract

Patient satisfaction surveys may not adequately reflect organizations that conduct research in patients who enroll in clinical trials. The purpose of this systematic literature review was to summarize the current state of knowledge of patient satisfaction while enrolled in clinical trials utilizing a widely used, validated patient satisfaction instrument. A comprehensive literature search was conducted using CINAHL, EMBASE, PsycInfo, PubMed and Web of Science. Studies were evaluated in terms of clinical trial participation; assessment conducted during or after participation; utilization of a validated instrument; a pharmacological intervention; and the paper was published in English. Only nine studies met this review's inclusion criteria. Eight studies utilized investigator-developed patient satisfaction instruments and only one study used a widely-used, validated patient satisfaction instrument. Two studies evaluated patient satisfaction during the development of the instrument. Of the nine studies identified, only five patient satisfaction domains were common across the studies and only study evaluated the associations of patient satisfaction responses with clinical outcomes. Given the importance of patient satisfaction surveys, future studies need to focus on this subset of patients enrolled in clinical trials to evaluate a patient's experience and its impact on protocol compliance and protocol outcomes. Future studies need to focus on domains associated with clinical trial participation and look beyond the current patients' general expectations about healthcare accessibility, facilities, healthcare team clinical skills, and their ability to focus and listen to the patients' concerns.

### Keywords

Patient satisfaction, patient experience, clinical trials, clinical research

### Introduction

Today, healthcare organizations are faced with evaluating quality indicators derived from scores reported by patients on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey or its approved equivalent.<sup>1</sup> These scores provide insight into understanding the patients' perspective on the delivery of care.<sup>2</sup> However, the information obtained from these surveys may not entirely reflect organizations that conduct clinical research, as the surveys may not adequately capture the experience of patients enrolled in clinical trials.

Healthcare organizations engaged in clinical trials are significant contributors to the development of new discoveries.<sup>3</sup> Clinical trials are recognized by healthcare professionals, policy makers and the public at large as beneficial to advancing science and treatment options for existing and future patients.<sup>4</sup> The success of clinical trials is

dependent upon patient participation and their overall experience.<sup>5</sup>

Findings regarding treatment compliance of patients in clinical trials have suggested that evaluating patient behavior and experience is one of the most important activities researchers can perform.<sup>6-8</sup> However, the majority of these studies have focused on adherence to clinic appointments, taking medication or following specific study activities (e.g., diet, exercise).<sup>6,9</sup> Therefore, evaluating for positive patient experiences in a clinical trial may lead to compliance with treatment, which can be an important determinant for the outcome of a clinical trial.<sup>7</sup> Additional research is warranted to evaluate the entire patient encounter with the healthcare team, as well as their compliance to a protocol, which may be more reflective of a patient's satisfaction with a clinical trial.

While scientists continue to translate their bench research into clinical trials,<sup>10</sup> no studies were identified that evaluated for patient satisfaction in a clinical trial utilizing a widely used, validated clinical trial patient satisfaction instrument. Therefore, this review focused on studies of patient satisfaction with their own research experience while enrolled in a clinical trial, evaluated by utilizing a widely used, validated patient satisfaction instrument as an initial effort to describe their experiences. When patients do not feel satisfied with their clinical trial experience, they may choose to prematurely discontinue participation in a trial, compromising the study's validity.<sup>7,11</sup> Therefore, the evaluation of patient satisfaction in a clinical trial is an important strategy in overcoming challenges experienced in research.

Patients enrolled in clinical trials will continue to be a salient part of the equation for accelerating advancements in new treatments and medicine. However, the limited amount of research with patient satisfaction while enrolled in pharmacological medical intervention clinical trials may influence research protocol outcomes without evaluating a patient's experience and its impact on protocol compliance. No comprehensive review has summarized the findings from studies utilizing a widely used, validated patient satisfaction instrument that evaluated associations between patient satisfaction and clinical trials experience. Therefore, the purposes of this review are to: 1) describe the most common patient satisfaction instrument; 2) describe the most common patient satisfaction domains measuring the experience reported; and 3) summarize the

associations identified between patient satisfaction and clinical trial experience. We hypothesized that positive patient satisfaction scores when enrolled in a clinical trial would influence protocol compliance and lead to well-founded protocol outcomes.

## Methods

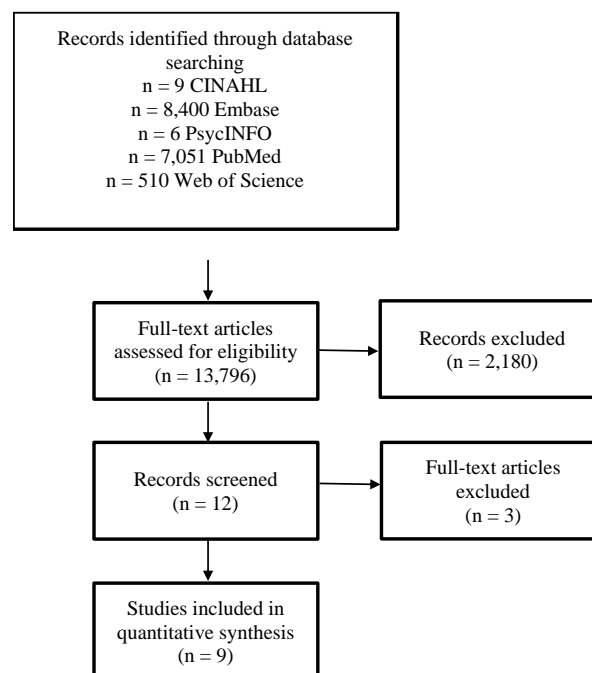
### Search Strategy

For this review, a systematic electronic literature search was conducted using Cumulative Index to Nursing and Allied Health Literature (CINAHL®), Excerpta Medica Database (EMBASE®), PsycInfo®, PubMed® and Web of Science® databases. Key words used when searching the databases were *patient satisfaction AND clinical trial AND clinical research AND clinical study*. The initial search yielded 9 studies identified in CINAHL, 8,400 studies identified in EMBASE®, 6 studies in PsycINFO®, 7,051 studies identified in PubMed®, and 510 studies in Web of Science®. Studies were included if they met all of the following inclusion criteria: (a) participants enrolled in a clinical trial, (b) patient satisfaction assessment conducted during or after the trial, (c) utilization of a validated patient satisfaction instrument, (d) a pharmacological medical intervention was utilized in the clinical trial and, (e) the paper was published in English.

### Inclusion and Exclusion Criteria

As shown in Figure 1, in the final search, after removing for duplicate articles across the databases and studies that did not meet the inclusion criteria, nine unique studies

**Figure 1. PRISMA Diagram of Studies of Patient Satisfaction While Enrolled in Clinical Trials: A Literature Review**



were identified.<sup>12-20</sup> The majority of the studies were removed from the analysis because they focused on patient motivation/satisfaction before the initiation of a clinical trial, non-pharmacological medical interventions (e.g., behavioral, dentistry, medical devices), qualitative studies, or assessments that did not report the utilization of a validated instrument.

To answer the specific aims of this review, findings from the nine studies are summarized into two tables. Table 1 summarizes one study<sup>16</sup> of patient satisfaction scores in a clinical trial utilizing a widely used validated patient satisfaction instrument, and Table 2 summarizes the eight studies<sup>12-15,17-20</sup> of patient satisfaction scores in a clinical trial utilizing an investigator-developed validated patient satisfaction instrument.

### Study Selection and Assessment

From a methodological perspective, the following criteria were evaluated: author, year, purpose, study design (i.e., cross-sectional, longitudinal), and sample characteristics (i.e., sample size, age, gender, therapeutic focus, setting). To describe patient satisfaction, the following criteria were evaluated: instrument, number of items assessed, and patient satisfaction domains. The final objective of this review is to evaluate the major findings of each of the studies.

## Results

### Description of the studies

Six of the nine studies that evaluated patient satisfaction in patients who participated in a clinical trial used a descriptive, cross-sectional design,<sup>12,14-17,19</sup> one used an exploratory survey study<sup>13</sup> and one used a descriptive case study.<sup>18</sup> Only one study used a descriptive longitudinal clinical trial design.<sup>20</sup> The sample size ranged from 80<sup>12</sup> to 4,281.<sup>17</sup> Across the nine studies, the age ranged from 18<sup>18</sup> to >80<sup>19</sup> years and gender percentages ranged from 38.2%<sup>13</sup> to 81%<sup>17</sup> female. In four of the nine studies,<sup>12,16,17,19</sup> the therapeutic areas focused on clinical trials with specific disease states (i.e., ophthalmology, cardiovascular, cognitive impairment, infectious disease). The remaining five studies focused on clinical trials with various disease states.<sup>13-15,18,20</sup>

Six of the nine studies were conducted in outpatient settings.<sup>12,14-17,19</sup> The remaining three studies were conducted in both inpatient and outpatient settings.<sup>13,18,20</sup> Two of the nine studies evaluated patient satisfaction during the development of the investigator-developed instrument.<sup>15,18</sup> Four were conducted in the United States,<sup>15-18</sup> one study was conducted in Australia,<sup>12</sup> one in the Netherlands,<sup>20</sup> one in South Korea,<sup>13</sup> one in Sweden,<sup>14</sup>

**Table 1. Patient Satisfaction While Enrolled in Clinical Trials Summary of Studies Utilizing A Widely Used, Validated Patient Satisfaction Instrument**

Author, Year, Purpose, Study Design	Sample Characteristics (Sample Size, Age, Gender, Therapeutic Focus, Setting)	Patient Satisfaction Assessment (Instrument, No. of Items Assessed)	Domains Assessed	Major Findings
<p><b>Author:</b> Sano et al. (2018) (United States)</p> <p><b>Purpose:</b> To determine factors affecting motivation and satisfaction of participants in dementia prevention trials</p> <p><b>Design:</b> Cross-sectional study</p>	<p>N=422</p> <p><b>Age:</b> 81 ± 4.4 years old (average)</p> <p><b>Gender:</b> 68% Female</p> <p><b>Therapeutic Focus:</b> Dementia Setting: Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Research Satisfaction Survey: Modified Client Satisfaction Questionnaire and Open-Ended Questions</li> </ul> <p><b>Number of Items Assessed:</b></p> <ul style="list-style-type: none"> <li>8</li> <li>3 open-ended questions</li> </ul>	<ul style="list-style-type: none"> <li>Consumer satisfaction with interventions in health and human services programs. Questions what was liked most, what was liked least, and what the respondent would change about the study.</li> </ul>	<ul style="list-style-type: none"> <li>Overall satisfaction scores was high with means of each individual item near or above a value of 3 on a scale from 1 (worst) to 4 (best).</li> <li>Individuals who completed the survey scored higher than those who did not on item responses related to if you had a chance to redo your decision to participate in this research program, as well as do you think you would choose to participate.</li> </ul>

**Table 2. Patient Satisfaction While Enrolled in Clinical Trials Summary of Studies Utilizing Investigator Developed Patient Satisfaction Instruments**

Author, Year, Purpose, Study Design	Sample Characteristics (Sample Size, Age, Gender, Therapeutic Focus, Setting)	Patient Satisfaction Assessment (Instrument, No. of Items Assessed)	Domains Assessed	Major Findings
<p><b>Author:</b> Au et al. (2015) (Australia)</p> <p><b>Purpose:</b> To evaluate what motivated patients to participate in clinical trials for retinal disease and to determine if the experience was a satisfactory one.</p> <p><b>Design:</b> Exploratory, non-comparative cross-sectional study</p>	<p>N=80</p> <p><b>Age:</b> 61-70 (median)</p> <p><b>Gender:</b> 53% Male</p> <p><b>Therapeutic Focus:</b> Ophthalmology</p> <p><b>Setting:</b> Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Investigator developed: Patient Experiences in retinal Trials - PERT Questionnaire</li> </ul> <p><b>Number of Items Assessed:</b></p> <ul style="list-style-type: none"> <li>37</li> </ul>	<ul style="list-style-type: none"> <li>Decision making process and entry into the trial</li> <li>Perceived benefits and problems with trial participation</li> <li>Trial outcomes</li> <li>Relationship with medical staff</li> <li>Overall patient impression of the clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Overall impression of trial participation was mostly positive, majority of the patients felt that taking part of the trial was important for their condition and would recommend participation to another person.</li> <li>Improved relationship with care provider.</li> <li>Primary reasons for participation were to contribute to science and receive increased eye monitoring.</li> </ul>
<p><b>Author:</b> Chu et al. (2012) (South Korea)</p> <p><b>Purpose:</b> To understand the decisions of clinical trial participants to enter research study, to measure participants' knowledge of clinical trials, to investigate participant satisfaction and to compare responses between patients and health volunteers</p> <p><b>Design:</b> Exploratory Cross-sectional study</p>	<p>N=291</p> <p><b>Age:</b> 36.4 SD=2.35</p> <p><b>Gender:</b> 38.2% Female</p> <p><b>Therapeutic Focus:</b> Oncology (13.3%) Cardiology (13.0%) Endocrinology (19.3%) Gastroenterology (9.6%) Immunology (35.2%) Neurology (2.6%) Others (7.4%)</p> <p><b>Setting:</b> Inpatient and Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Investigator developed: name not reported</li> </ul> <p><b>Number of Items:</b></p> <ul style="list-style-type: none"> <li>21</li> </ul>	<ul style="list-style-type: none"> <li>Experience with trial participating decision making</li> <li>Participants overall knowledge of clinical trials</li> <li>Participant satisfaction with clinical trial participation</li> <li>Overall perceptions on the favorability, necessity, safety and willingness to re-participate</li> </ul>	<ul style="list-style-type: none"> <li>Non healthy volunteers were influenced by medical personnel regarding decision making process for participation.</li> <li>No differences were found between the two groups in willingness to participate and satisfaction with clinical trials.</li> <li>More than 50% thought their physicians could persuade them to participate or that all participants would receive a new drug or treatment.</li> </ul>
<p><b>Author:</b> Godskesen et al. (2015) (Sweden)</p> <p><b>Purpose:</b> To evaluate patients' motivation for participating in phase 3 RCTS and to find out how patients perceived the information concerning the trials and to describe their experiences related to their trial participation.</p> <p><b>Design:</b> Cross-sectional study</p>	<p>N=88</p> <p><b>Age:</b> 61.1 ± 9.1 years</p> <p><b>Gender:</b> 60.2% Female</p> <p><b>Therapeutic Focus:</b> Oncology</p> <p><b>Setting:</b> Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Investigator developed: name not reported</li> </ul> <p><b>Number of Items:</b></p> <ul style="list-style-type: none"> <li>60</li> </ul>	<ul style="list-style-type: none"> <li>Decision making process</li> <li>Understanding and Experiences</li> <li>Overall impression of participation</li> </ul>	<ul style="list-style-type: none"> <li>Most participants reported one major reason for participation in RCT's and some cited several reasons.</li> <li>Results: most stated that 'the hope of getting well/slowing the disease' and 'contributing to research that can help others in the future'.</li> <li>Majority said they were satisfied with the information they received.</li> <li>96% reported high levels of satisfaction with trial participation.</li> </ul>

**Table 2 Cont'd. Patient Satisfaction While Enrolled in Clinical Trials Summary of Studies Utilizing Investigator Developed Patient Satisfaction Instruments**

Author, Year, Purpose, Study Design	Sample Characteristics (Sample Size, Age, Gender, Therapeutic Focus, Setting)	Patient Satisfaction Assessment (Instrument, No. of Items Assessed)	Domains Assessed	Major Findings
<p><b>Author:</b> Pflugeisen et al. (2016) (United States)</p> <p><b>Purpose:</b> To assess patient satisfaction tailored to clinical trial participants who consented to and/or completed a clinical trial in the prior year.</p> <p><b>Design:</b> Cross-sectional study</p>	<p>N=222</p> <p><b>Age:</b> 24.3% &gt;55 years</p> <p><b>Gender:</b> 52.4% Female</p> <p><b>Therapeutic Focus:</b> Cardiology Endocrinology Internal Medicine Neurology Oncology Pediatrics Pulmonary Not Reported</p> <p><b>Setting:</b> Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Investigator developed: MultiCare Institute for Research &amp; Innovation</li> </ul> <p><b>Number of Items Assessed:</b></p> <ul style="list-style-type: none"> <li>27</li> <li>3 free text options</li> </ul>	<ul style="list-style-type: none"> <li>Study visits</li> <li>Study staff</li> <li>Study</li> <li>Future participation</li> </ul>	<ul style="list-style-type: none"> <li>Patient-staff interactions received the highest percentile ranks.</li> <li>Facilities cleanliness and environment were well rated.</li> <li>Questions related to enrolling in future trials, enjoying visits, and believing that medical care was enhanced by the study ranked below the 62<sup>nd</sup> percentile.</li> </ul>
<p><b>Author:</b> Schron et al. (1997) (United States)</p> <p><b>Purpose:</b> To examine participants' attitudes and perceptions at the end of a long-term clinical trials.</p> <p><b>Design:</b> Cross-sectional study</p>	<p>N=4,281</p> <p><b>Age:</b> 60-69 years 70-79 years &gt;80 years</p> <p><b>Gender:</b> 81% Female</p> <p><b>Therapeutic Focus:</b> Cardiovascular</p> <p><b>Setting:</b> Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Investigator developed: Satisfaction/attitude questionnaire</li> </ul> <p><b>Number of items assessed:</b></p> <ul style="list-style-type: none"> <li>10</li> </ul>	<ul style="list-style-type: none"> <li>Benefits from participation in the trial</li> <li>Motivation for joining</li> <li>Satisfaction with clinical staff and operations</li> </ul>	<ul style="list-style-type: none"> <li>Primary reasons given for participation were altruistic, contributing to science and helping to improve the health of others.</li> <li>Reasons for joining trial differed by age, race, gender and education.</li> <li>93% responded yes and more than 98% would recommend SHEP or a similar program to a good friend.</li> </ul>
<p><b>Author:</b> Smailes et al. (2016) (United States)</p> <p><b>Purpose:</b> To evaluate the development of a survey to assess research patient satisfaction among those participating in clinical research studies at an academic medical center.</p> <p><b>Design:</b> Descriptive case study-development</p>	<p>N= 341</p> <p><b>Age:</b> 18-25 years (18.8%) 26-35 years (44%) 36-55 year (19.4%) 56-64 year (12.8%) ≥65 years (5.3%)</p> <p><b>Gender:</b> 76% Female</p> <p><b>Therapeutic Focus:</b> Disease agnostic (81.2%) Gynecology-oncology (6.7%) Dermatology (2.6%) Other Departments (&lt;10%)</p> <p><b>Setting:</b> Inpatient and Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Investigator developed: Research Study Participant Survey</li> </ul> <p><b>Number of Items Assessed:</b></p> <ul style="list-style-type: none"> <li>25</li> </ul>	<ul style="list-style-type: none"> <li>Ways participants learned of a study</li> <li>Motivating reasons for participation</li> <li>Research study site experiences</li> <li>Future participation and study promotion</li> </ul>	<ul style="list-style-type: none"> <li>Highly positive ratings regarding research study site experiences ranging from courteousness and knowledge of study staff to understanding consent and study procedures.</li> <li>Overall positive experience rating of 87.9% at the author's academic medical center.</li> </ul>

**Table 2 Cont'd. Patient Satisfaction While Enrolled in Clinical Trials Summary of Studies Utilizing Investigator Developed Patient Satisfaction Instruments**

Author, Year, Purpose, Study Design	Sample Characteristics (Sample Size, Age, Gender, Therapeutic Focus, Setting)	Patient Satisfaction Assessment (Instrument, No. of Items Assessed)	Domains Assessed	Major Findings
<p><b>Author:</b> Squires et al. (2013) (United States and Canada)</p> <p><b>Purpose:</b> To examine participants enrolled in the GRACE clinical trial experiences and opinions about study participation, as well as exploring statistically the associations between survey responses and adherence to study medications, study discontinuation, and virologic response.</p> <p><b>Design:</b> Cross-sectional study</p>	<p>N=243</p> <p><b>Age:</b> 44 (Median); 19-78 (Range)</p> <p><b>Gender:</b> 64.6% Female</p> <p><b>Therapeutic Focus:</b> Infectious Disease</p> <p><b>Setting:</b> Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Investigator developed: GRACE participant survey</li> </ul> <p><b>Number of Items Assessed:</b></p> <ul style="list-style-type: none"> <li>40</li> <li>Open ended questions</li> </ul>	<ul style="list-style-type: none"> <li>Adherence</li> <li>Discontinuation and virologic response rates</li> <li>Survey participants experiences during the trial</li> <li>Opinions about the trial</li> <li>Associations of response with clinical outcomes</li> </ul>	<ul style="list-style-type: none"> <li>Access to treatment (41%) and too many blood draws (26%) were reported as the best and worst part of the study, respectively.</li> <li>Support from study site staff was reported as the most important factor in completing the study (47%).</li> <li>68% would be interested in sharing their GRACE experience, and 96% would recommend participation in a clinical trial to others. Factors associated with non-adherence, study discontinuation, and poor virologic response were being the primary caregiver for children, unemployment, and transportation difficulties, respectively.</li> </ul>
<p><b>Author:</b> Verheggen et al. (1998) (Netherlands)</p> <p><b>Purpose:</b> To assess how patients experience and evaluate their participation in a clinical trial and which factors influence patient satisfaction with trial participation</p> <p><b>Design:</b> Prospective study</p>	<p>N=172</p> <p><b>Age:</b> 57.8, SD=13.8</p> <p><b>Therapeutic Focus:</b> Experiment and non-experimental diagnostics studies</p> <p><b>Setting:</b> Inpatient and Outpatient</p>	<p><b>Patient Satisfaction Instrument:</b></p> <ul style="list-style-type: none"> <li>Investigator developed: name not reported</li> </ul> <p><b>Number of Items Assessed:</b></p> <ul style="list-style-type: none"> <li>30</li> </ul>	<ul style="list-style-type: none"> <li>Satisfaction with various aspects of clinical trial participation</li> <li>Satisfaction with own personal benefit and that of future patients</li> <li>Satisfaction with medical treatment</li> <li>Satisfaction with learning about one's health condition</li> <li>Satisfaction with extra check-ups of health condition</li> <li>Satisfaction with the way information was disclosed</li> <li>Satisfaction with the trial clinician as a person</li> <li>Satisfaction with the way discomforts were experienced and effort had to be made during the trial</li> <li>Satisfaction in relation to compliance with trial participation</li> </ul>	<ul style="list-style-type: none"> <li>Prior expectations and general attitudes toward medical care and research before entering a clinical trial have an impact on satisfaction with aspects of trial participation.</li> </ul>



and one 19 in multinational countries (i.e., United States, Canada).

### ***Clinical trials and patient assessment instruments***

**Patient assessment instruments.** A number of instruments were used to evaluate patient satisfaction when enrolled in a clinical trial. Eight studies utilized investigator developed patient satisfaction instruments (i.e., Patient Experiences in Retinal Trials-PERT Questionnaire<sup>12</sup>; Systolic Hypertension in the Elderly Program Satisfaction/Attitude Questionnaire<sup>17</sup>; Research Study Participant Survey<sup>18</sup>; Gender, Race, and Clinical Experience Participant Survey<sup>19</sup>). Four of the studies<sup>13-15,20</sup> did not report the names of the investigator developed patient satisfaction survey instrument and only one study used a widely used validated patient satisfaction instrument (i.e., Modified Client Satisfaction Questionnaire).<sup>16</sup>

### **Number and domains of the patient satisfaction**

**assessment instrument.** The number of patient satisfaction items assessed ranged from a minimum of eight<sup>16</sup> to a maximum of 60.<sup>14</sup> In these studies, several patient satisfaction domains were assessed (e.g., entry into clinical trial decision-making,<sup>12-14,17,18</sup> adherence,<sup>19,20</sup> re-participate in a clinical trial or recommend<sup>12-20</sup>). Only five domains (i.e., clinical trial participant motivation, healthcare team interaction, knowledge and benefits of clinical trial participation, re-participate and recommend, overall impression of the clinical trial) were common across the nine studies.

### ***Clinical trial participant motivation***

While studies evaluating the motivation/satisfaction to participate in a clinical trial were excluded from our inclusion criteria, five of the nine studies that met our criteria examined this patient satisfaction domain. In one study,<sup>12</sup> the reasons varied, but one of the most popular responses was that participants ‘wanted to contribute to medical science’. In another study,<sup>14</sup> ‘contributing to research that can help others in the future’ achieved a median 9.7 on a scale from the lowest score of 0 to the highest score of 10. In another study,<sup>17</sup> two of the most important reasons for joining the clinical trial were the desire to contribute to science and to improve health of others (i.e., 96%, and 96%, respectively). Moreover, in one study,<sup>19</sup> the most common reason to participate in the clinical trial was the desire to contribute to something bigger/help others.

Of the five studies, two included financial motivations. In one study,<sup>13</sup> 54.1% of the patients cited the purpose for participation was based on economic benefits and was reported as statistically significant ( $p < 0.001$ ). In another study,<sup>18</sup> 49.6% of the patients reported the motivating reason for clinical trial participation was to earn study payment.

### ***Healthcare team interaction***

The encounters between the patient and the healthcare team were evaluated in four of the nine studies. The responses obtained were relatively positive and achieved high percentile ranks or percentages. In one study,<sup>12</sup> 93% of the patients thought the medical staff always treated them with courtesy and respect, 96% thought staff were always helpful and 86% felt, from their perspective, that the team always worked well together. In addition, the investigators reported that greater contact with the healthcare team may have improved patient outcomes in their study. In another study,<sup>15</sup> the highest positive responses were related to patient-staff interactions, with 80% indicating “strongly agree” for staff friendliness, 75.6% for respect for patients and 77.2% time spent with patients, 66.7% for explaining their role in the study, and 65.6% for answering questions fully. In one study,<sup>17</sup> 99.8% of the patients agreed the staff were friendly and 99.4% felt they provided good care. In another study,<sup>18</sup> 90.6% of the patients reported they felt the research staff were courteous and 89.7% felt they were professional. Moreover, in another study,<sup>20</sup> 94% of the patients were satisfied with the clinician as a person and had a positive attitude towards them and 97% reported trust and friendliness was important.

### ***Knowledge and benefits of clinical trial participation***

Four of the nine studies evaluated knowledge and benefits of trial participation. In one study,<sup>14</sup> more than 80% reported that they had received sufficient and relevant information related to the clinical trial. In addition, the investigators suggested patients with adequate knowledge of their trial were less likely to experience regret in their decision to participate and potentially complete the study. In another study,<sup>18</sup> 80.4% of the patients reported they understood the possible benefit(s) involved with participating in a study. In another study,<sup>15</sup> 63.3% of the patients reported they were fully informed of the risks/benefits of clinical trial participation. Moreover, Chu et al. discussed the satisfaction of understanding the benefits of trial participation, which assists in participant satisfaction.<sup>13</sup>

### ***Re-participate and recommend***

While the one patient satisfaction domain of re-participating and recommending a clinical trial was present in eight out of the nine studies, the responses related to this domain varied. In one study,<sup>12</sup> 77.5% of the patients reported they would volunteer for another trial. In another study,<sup>13</sup> the mean score of participating in another clinical trial was 7.95 (SD, 2.05) on an 11-point Likert scale. In another study,<sup>20</sup> 88.9% of the respondents indicated they would volunteer again in a similar type of study. In terms of recommending another individual to a clinical trial, four of the eight studies evaluated this patient satisfaction domain. In one study,<sup>12</sup> the majority of patients would recommend participation to another

person. In another study,<sup>14</sup> 82% of the respondents answered they were positively inclined to recommend others to participate in cancer trials. Smailes et al. reported 88.3% of patients in their study would recommend others to consider participation in a research study at the institution.<sup>18</sup> In another study,<sup>19</sup> 96% of the patients on the trial would recommend participation in a clinical trial to others. Moreover, the means across the three study arms in one study,<sup>16</sup> were reported as statistically significant ( $p < 0.01$ ) when the patients responded to the question if they would recommend the research program to a friend.

While six of the eight studies reported relatively positive data, two studies reported low percentile rankings and/or non-statistically significant results. In one study,<sup>15</sup> which evaluated the patient's desire to participate in another study and encourage others to participate, the investigators reported low percentile ranks of 61.3% and 52.1%, respectively. While in one study,<sup>16</sup> the mean scores were relatively high on a scale from 1 (worst) to 4 (best) when patients were asked if they would recommend the research program to a friend, the differences between the groups were not statistically significant.

#### ***Overall impression of the clinical trial***

The overall impression of participation in a clinical trial was assessed in six studies. In one study,<sup>12</sup> the patients' overall impression of the clinical trial was mostly positive and 85% of the patients reported that taking part in the trial was important for their condition. Godskesen et al. reported 96% of the respondents in their study were satisfied with their participation in the clinical trial.<sup>14</sup> In another study,<sup>18</sup> 87.9% of the patients strongly agreed that their overall experience was positive.

In another study,<sup>13</sup> the mean score for overall satisfaction with the clinical trial was  $8.40 \pm 1.60$  on a scale from 0 (not at all) to 10 (completely agree). In another study,<sup>16</sup> overall satisfaction scores were high, with means near or above a value of 3 on a scale from 1 (worst) to 4 (best). Moreover, in another study,<sup>15</sup> the investigators reported participant intention to seek future medical care at the facility and enjoyment of their visits were positive and reported as statistically significant ( $p = 0.0016$ ).

#### **Discussion**

This review is the first to summarize the findings from studies that examined patients' experiences while enrolled in clinical trials utilizing a widely used, validated instrument. Across the nine studies included in this review, only five patient satisfaction domains were common among the articles. Given that >70% of the general population believe in opportunities to participate in clinical trials<sup>21</sup> and the importance of positive trial participation, it is disappointing that only nine studies have systematically

evaluated patient experiences while enrolled in a clinical trial.

#### ***Clinical trials and patient assessment instruments***

Of the nine studies identified for this review, only one study used a widely used validated patient satisfaction instrument (i.e., Modified Client Satisfaction Questionnaire).<sup>16</sup> This is not surprising given the limited number of valid and reliable patient satisfaction instruments developed for clinical trials. In addition, a salient question remains regarding the identification of the most appropriate patient satisfaction instruments to use for patients enrolled in clinical trials. Findings from this review suggest that little is known about the most appropriate patient satisfaction instrument to utilize and how to apply the domains of these existing instruments in patients who enroll in a clinical trial. Moreover, qualitative studies are warranted to identify appropriate patient satisfaction domains associated with clinical trials.

#### ***Clinical trial participant motivation***

Altruism was the most popular and/or main motivation reported for clinical trial participation. This finding is consistent with studies that have evaluated personal motivations for clinical trial participation and found that participation is driven by a desire to benefit others, which is an important factor for participation.<sup>22-24</sup> In addition, the potential for improving the chances of one's health/condition were reported in the same four studies and is consistent with studies that have examined personal health factors or seeking best treatment options as a contributing factor to participation.<sup>25,26</sup>

A surprising finding is the limited number of responses to seek out financial gains when participating in a pharmacological medical intervention clinical trial. Empirical evidence suggests that reasonable financial reimbursement is utilized by many studies as an effective strategy to improve patient recruitment, retention rates and participation.<sup>27</sup> For example, in one study,<sup>28</sup> financial incentives were implemented and an increase in patients' enrollment was reported from 24.7% to 31.6%, respectively. In addition, two systematic reviews<sup>26,29</sup> found financial incentive/reward was the greatest influencing factor and/or motivation for patients to engage in clinical trials. While debates both for and against financial incentives have been cited in the literature<sup>30</sup> and significant regulatory advancements have been made to ensure that the ethical application of financial compensation to patients when participating in clinical trials is not compromised, additional studies are needed to further evaluate the role of financial incentives in clinical trials and their potential role in patient satisfaction.<sup>7</sup>

#### ***Healthcare team interaction***

The studies that evaluated patient satisfaction with the healthcare team encounter domain were relatively positive.

These results are consistent with other studies evaluating this patient satisfaction domain. For example, in one study,<sup>31</sup> the patients reported trust in the hospital and trust in the doctor were motivating factors for participation in a clinical trial. In addition, these findings are consistent with two systematic reviews<sup>32,33</sup> that evaluated the patient-clinician therapeutic relationship in randomized clinical trials are seen as a positive influence in clinical trials participation.

In terms of the effect of the patient-clinical relationship to healthcare outcomes, only one study reported that less adherence to treatment medication was associated with not being very comfortable with study site and staff.<sup>19</sup> This finding is consistent with one study that reported the estimate of the overall effective size of the healthcare team encounter as small ( $d = .11$ ), but statistically significant ( $p = .02$ ).<sup>32</sup> While the effect size for the influence of the clinical relationship on health outcomes in this study was small, the review utilized objective and validated subjective medical outcomes to assess the relationship, which is more reflective of the patients' experience. Moreover, it may be salient for researchers to de-emphasize accuracy in performance of key study activities and shift the focus on the importance of participation and completion of research visits to ensure protocol treatment compliance.<sup>16</sup>

#### ***Knowledge and benefits of clinical trial participation***

Only four studies<sup>13-15,18</sup> evaluated knowledge and benefits of clinical trial participation. While the data reported suggests positive associations between a patient's knowledge and understanding the benefits of clinical trial participation, it was not clear if overall satisfaction was sustainable as data were collected at various time points across the studies and were cross-sectional. In addition, researchers from one study suggested that participating in a clinical trial can show a positive association to understanding benefits and knowledge of clinical trial participation.<sup>34</sup> Given that four studies evaluated for this association between knowledge and benefits of clinical trial participation, and that those patient satisfaction scores were positive, a more detailed evaluation is warranted to identify if additional information and assessments yield an increase in patient satisfaction throughout enrollment in a clinical trial.

#### ***Re-participate and recommend***

Six studies reported relatively high responses to re-participate or recommend others to participate in clinical trials. This finding is not surprising as patients whose physicians are also investigators become aware of clinical trials and, subsequently, enroll in these studies and are willing to re-participate.<sup>21,35</sup> In addition, the amount and type of information obtained has been associated with decision making regarding participation and re-participation in clinical trials.<sup>5</sup> In terms of recommending others to participate, studies have focused on the

physician's motivations and/or communication to recommend,<sup>36,37</sup> but there are limited studies that have reported on patients who participate in clinical trials and their desire to re-participate and/or recommend others to participate.<sup>38</sup> While these studies did not evaluate decision making related to recommending others to participate and/or re-participate exploring these processes further may enhance clinical trial participation and patient satisfaction.<sup>35</sup>

#### ***Overall impression of the clinical trial***

Six studies<sup>12-16,18</sup> evaluated the overall impression of the patients' participation in a clinical trial. While positive responses were reported, only one study<sup>16</sup> evaluated the patients' experience with a widely used, validated patient satisfaction instrument. However, the instrument used in this study was developed to assess consumer/client satisfaction with health, human services, governmental and public benefit programs and services.<sup>39</sup> No studies utilized a widely used, validated patient satisfaction instrument before, during, or following medical intervention treatments.

One of the primary purposes of this review was to evaluate the associations between patient satisfaction while enrolled in clinical trials. While protocol compliance and outcomes may be related to a patient's satisfaction with aspects of trial participation,<sup>20</sup> only one study addressed this question. In this study,<sup>19</sup> the associations of patient satisfaction responses with clinical outcomes were evaluated. Therefore, while interest in participating in clinical trials remains high and the increasing focus on the patient experience remains salient in healthcare, additional research is warranted to determine if current existing instruments will assist in understanding this subset of patients receiving research-related healthcare.<sup>15,40,41</sup>

#### **Conclusions**

Given the importance of patient satisfaction surveys and their link to hospital value-based purchasing and reimbursement, as well as healthcare outcome metrics, additional studies focused on this subset of patients enrolled in clinical trials is warranted.<sup>42</sup> In addition, only one study evaluated patient satisfaction while enrolled in a clinical trial utilizing a widely used, validated non-research patient satisfaction instrument. Future studies need to focus on domains associated with clinical trial participation and look beyond the current patients' general expectations about healthcare accessibility, facilities, healthcare team clinical skills, and their ability to focus and listen to the patients' concerns.<sup>42</sup> Moreover, data obtained from studies focused on the actual experiences of patients enrolled in clinical trials may increase patient satisfaction with their clinical trial experience, which may assist in ameliorating patients choosing to prematurely discontinue and/or not

comply with the study protocol, compromising a study's validity.

### Author's Note

At the time the research was conducted and submitted for publication, the author was affiliated with Northwestern University and Northwestern Medicine.

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