Patient Preference and Adherence

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REVIEW

Eighteen Years of Measuring Treatment Satisfaction in Clinical Research: A Scoping Review of Instruments and Contexts of Use

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Purpose: Despite the widespread use of Patient Reported Outcomes (PRO) instruments to assess treatment satisfaction in clinical trials and academic research, a comprehensive review mapping these tools across therapeutic areas has been lacking. This scoping review addresses this gap by examining the application of PRO instruments over the past 18 years.

Methods: Following Arksey and O'Malley's framework and mixed-method principles, we searched Ovid MEDLINE and Ovid EMBASE from 2004 to June 2022. Data extraction was structured according to review objectives and key domains.

Results: Of 3,497 articles retrieved, 1,398 studies reported using PRO instruments for treatment satisfaction. The most common therapeutic areas were endocrine, nutrition, and metabolic disorders, followed by mental and behavioral conditions. Most studies were conducted in academic settings (53.1%) or Phase III clinical trials (27.5%). The Treatment Satisfaction Questionnaire for Medication (TSQM) was the most frequently used generic instrument, while the Diabetes Treatment Satisfaction Questionnaire (DTSQ) was the leading disease-specific tool. Many instruments lacked psychometric validation, limiting comparability.

Conclusion: PRO instruments for treatment satisfaction are primarily used in chronic disease contexts. Their widespread adoption underscores the need for validated tools to ensure robust, comparable data and support better patient outcomes.

Plain Language Summary:

- The objectives of this scoping review were to summarize, understand, and disseminate findings from a broad body of literature where treatment satisfaction was used as an outcome in clinical research and academic settings.
- Most studies used treatment satisfaction instruments without proper psychometric validation.
- The TSQM was identified as being a validated generic instrument most frequently utilized in all studies reviewed (both in industry and academia).
- The second most frequently utilized treatment satisfaction instrument is a disease-specific instrument, the DTSQ, which evaluates treatment satisfaction in diabetes.

Keywords: treatment satisfaction, PRO, clinical trials, academic research, TSQM, DTSQ

Introduction

The role of patients in clinical research and routine practice has evolved during the last decades.[1] In routine care, patients have transitioned from being passive recipient of medical decisions to active participants in shared decision-making processes.[2] In clinical research, and particularly drug development research, there is a growing emphasis on capturing data directly from patients, This shift acknowledges patients' unique ability to report on their lived experiences, treatment impacts, and outcomes that matter most to them.[3] Regulatory authorities have responded by raising expectations for patient input.[3] For instance, the US Food and Drug Administration (FDA), for example, has launched the Patient-Focused-Drug Development (PFDD) initiative to incorporate and submit patient experience data into regulatory decision-making.[4,5] Similarly, the European

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Medicines Agency (EMA) has developed a framework to promote patient engagement and encourage patients, consumers and their organizations[6] the collection of Clinical Outcome Assessment (COA) data during drug development.[7,8]

COAs are structured and validated instruments that measure how a patient feels, functions, or survives, and they provide a structured approach to capturing both observable and subjective health concepts.[9] Among the four types of COAs (Clinician-Reported Outcomes (ClinRO), Observer-Reported Outcomes (ObsRO), Performance Outcomes (PerfO), and Patient-Reported Outcomes (PRO)) PROs are particularly valuable because they reflect the patient's perspective without external interpretation.[10]

PROs have become essential in both clinical trials and routine care, supporting communications, monitoring and decision-making.[11] The data collected from a treatment satisfaction PRO can support both intervention development and routine care decisions. As patient-centered care becomes more prominent, treatment satisfaction has emerged as a critical outcome for evaluating therapeutic success. One key concept measured by PROs is treatment satisfaction, which reflects patient's experience with a given treatment including its effectiveness, side effects, convenience, and alignment with expectations.[12]

Treatment satisfaction has been defined as "the degree to which patients perceive that the treatment fulfills their health needs",[13] and further refined as an attitude shaped by comparing perceived treatment quality with initial expectations.[14] A variety of models have been used to describe how patients' satisfaction with medical treatment impacts their health-related decision-making.[15] Various conceptual models have been developed to explain treatment satisfaction, leading to the creation of multiple PRO instruments.[3]

These instruments vary in structure some are single-item, others multi-item and in scope: generic instruments assess satisfaction across treatments and conditions.[15–18] In contrast, disease-specific instruments focus on particular therapies or conditions.[19] Generic instruments allow for broader comparisons across populations and settings, making them useful in multi-condition studies or routine care. In contrast, disease-specific tools offer more tailored insights into a particular condition or treatment, but limit comparability across diseases and populations.[20]

Despite the growing use of treatment satisfaction instruments, researchers face a complex challenge in selecting appropriate tools. The diversity of instruments, varying validation standards, and inconsistent contexts of use make it difficult to identify the most suitable measure for a given study. To date, there is no comprehensive review that maps and evaluates treatment satisfaction instruments across therapeutic areas and research settings. This gap in the literature limits researchers' ability to make informed choices about instrument selection and hinders the comparability of findings across studies. This scoping review addresses that gap by summarizing and analyzing the use of treatment satisfaction instruments over the past 18 years in clinical research and academic settings. By doing so, it aims to provide guidance to researchers and stakeholders seeking to incorporate patient-centered outcomes into their work.

Methods

Scoping Review Methodology

There are four reasons for undertaking scoping reviews: (1) to examine the extent, range, and nature of research activity; (2) to determine the value of undertaking a systematic review; (3) to summarize and disseminate research findings; and (4) to identify research gaps in the existing literature.[21] Using the Arksey and O'Malley's six step framework,[21] we outlined the specific methods for our scoping review below:

Step 1: Research Question

The research question that guided this review was "what measures of treatment satisfaction were used as an outcome in clinical research?". The Population (or participants)/Concept/Context (PCC) research question format[22] was used as a structure for the search strategy design. The population included participants taking treatments to manage any medical conditions. The concept was defined to be any reference to the measurement of treatment satisfaction as relevant to patients. The context was limited to any clinical research published in the scientific literature (peer-reviewed journal articles). The search strategy was limited to original research articles published in English, from January 2004 until June 2022. Excluded were research manuscripts not pertaining to humans, not mentioning any measure of treatment satisfaction, or book chapters, protocol descriptions, or reviews of the literature.

Steps 2 and 3: Relevant Studies and Study Selection

The research team took a broad approach to the concept of treatment satisfaction when selecting search topics and terms. The initial terms aimed at covering all aspects of the PCC and are summarized in Table 1. The search was conducted in 2 databases, Ovid MEDLINE and Ovid EMBASE. An 18-year period, from January 2004 to June 2022, was selected so as to encompass the period where regulatory bodies like the FDA and the EMA started recommending the use of PROs in the industry setting. This criteria allowed for a balance between academic and industry-sponsored research.

Three authors (CN, IVA, and LLA) collaboratively conducted the study selection process, beginning with a systematic literature search across EMBASE and Medline databases from January 2004 to June 2022. The initial search yielded 3,497 records, which were screened for relevance and eligibility. In accordance with PRISMA guidelines[23] an initial exclusion phase removed 1,146 records—including 971 duplicates, 94 studies not involving human samples, and 81 non-English publications.

The remaining 2,351 abstracts were reviewed independently. During this phase, 920 records were excluded for the following reasons: 786 were conference abstracts, 123 were literature reviews, 9 lacked an available abstract, and 2 did not measure treatment satisfaction. Articles with uncertain eligibility were retained for further evaluation.

A full-text review was then conducted on 1,431 publications, during which 33 articles were excluded due to reasons such as unavailability of full text (n=7), lack of treatment satisfaction measurement (n=7), duplicate reporting of the same study (n=6), and other criteria including commentaries, cost-effectiveness analyses, book chapters, retracted papers, meeting reports, protocol descriptions, and physician satisfaction.

This rigorous multi-stage screening process resulted in 1,398 studies being included in the final scoping review. The iterative nature of the review allowed for refinement of inclusion and exclusion criteria as new insights emerged, ensuring a comprehensive and unbiased synthesis of the literature.

Table 1 Scoping Review Search Strategy

ID	Search String	# Hits
1	Treatment Satisfaction	10,471
2	TSQM	825
3	Treatment Satisfaction Questionnaire for Medication	872
4	**1** OR **2** OR **3**	10,540
5	Pharmaceutical industry	33,218
6	Academic research	12,424
7	Interventional study	15,303
8	Observational study	496,407
9	Clinical trial	2,306,427
10	RWE study OR	106
11	Phase I	130,529
12	Phase II	179,322
13	Phase III	123,673
14	Phase IV	8,437
15	**5** OR **6** OR **7** OR **8** OR **9** OR **10** OR **11** OR **12** OR **13** OR **14**	2,945,183
–	**4** AND **15**	**3,497**

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Step 4: Charting the Data

The following data were extracted and classified for the remaining 1,398 papers by two authors CN and IVA: Study population description (disease and therapeutic area; treatment, including mode of administration); study sponsorship and context (academic research or industry-sponsored, including pharmaceutical and medical technology); study design (interventional or observation as well as study phase, if industry-sponsored); study methodology (qualitative, quantitative); outcome measures used to assess treatment satisfaction; general information including authors, year, and location of the study. The data charting form was piloted on the first 20 articles and reviewed to ensure it was clear and comprehensive. This pilot process resulted in changes to the names of some data extraction categories and pragmatic clarifications to the inclusion and exclusion criteria, and ensured the tables included all the salient information for generating the themes as per Step 5 described below.

Step 5: Collating, Summarizing and Reporting the Results

An intervention classification was used to examine and combine study findings. The classification highlighted: (1) the measures used to assess treatment satisfaction; (2) the major therapeutic areas, diseases, and treatments for which treatment satisfaction were measured; (3) the nature and distribution of studies when treatment satisfaction was used as research outcome (academic or industry-sponsored research and study design).

Step 6: Consultation After Classification

Members of the research team who participated in study design but not in data extraction (AMR) were consulted to discuss the themes and ensure agreement. This process resulted in the generation of 3 themes. A summary of the major findings organized under each theme was produced.

Results

A total of 1,398 studies published between 2004 and 2022 were included in the review. The detailed flowchart of the search strategy and its corresponding outcomes is summarized in the PRISMA diagram (Figure 1). Collectively, these studies represent the measurement of treatment satisfaction across 23 therapeutic areas, with sample sizes ranging from 100 to over 20,000 patients, spanning more than 20 countries.

Measures Used to Assess Treatment Satisfaction

The number of studies that used a treatment satisfaction PRO instrument increased from 292 (20.9%) in the period of 2004–2009, to 516 (36.9%) in the period of 2016–2020. The lower number of research papers in the period of 2021–2022 (201, 14.4%) is due to the search strategy being limited to June 2022 (Figure 2).

Interestingly, approximately two-thirds of the studies employed structured PRO instruments specifically designed to evaluate treatment satisfaction and supported by psychometric evidence. In contrast, the remaining third (n=469, 33.5%) relied on self-developed questions or questionnaires that lacked any mention of psychometric validation, or failed to specify the instrument type, often referencing only the scale format, such as Likert, Numeric Rating, or Visual Analog Scales. We classified these as "unvalidated questionnaires." These measures were most frequently applied in research on mental, behavioral, or developmental disorders (n=62, 13.2%), endocrine, nutritional, or metabolic diseases (n=47, 10.0%), genitourinary system diseases (n=47, 10.0%), and skin diseases (n=46, 9.8%).

In total, 42 structured validated PRO instruments were identified (see Figure 3), some of which were specifically developed for treatment satisfaction, while others measured broader concepts such as health status or quality of life but were referenced in the context of treatment satisfaction. Among these, three instruments: Treatment Satisfaction Questionnaire for Medication (TSQM) (15.2%, 213 studies), Diabetes Treatment Satisfaction Questionnaire (DTSQ) was used in 14.7% (206 studies) and the Erectile Dysfunction Index of Treatment Satisfaction (EDITS) was used in 5.7% (79 studies). These are described below and in Table 2. Notably, our review revealed a marked increase in the use of unvalidated questionnaires over time, peaking in 2021, with the count for 2022 reflecting only studies published up to June (Figure 4).

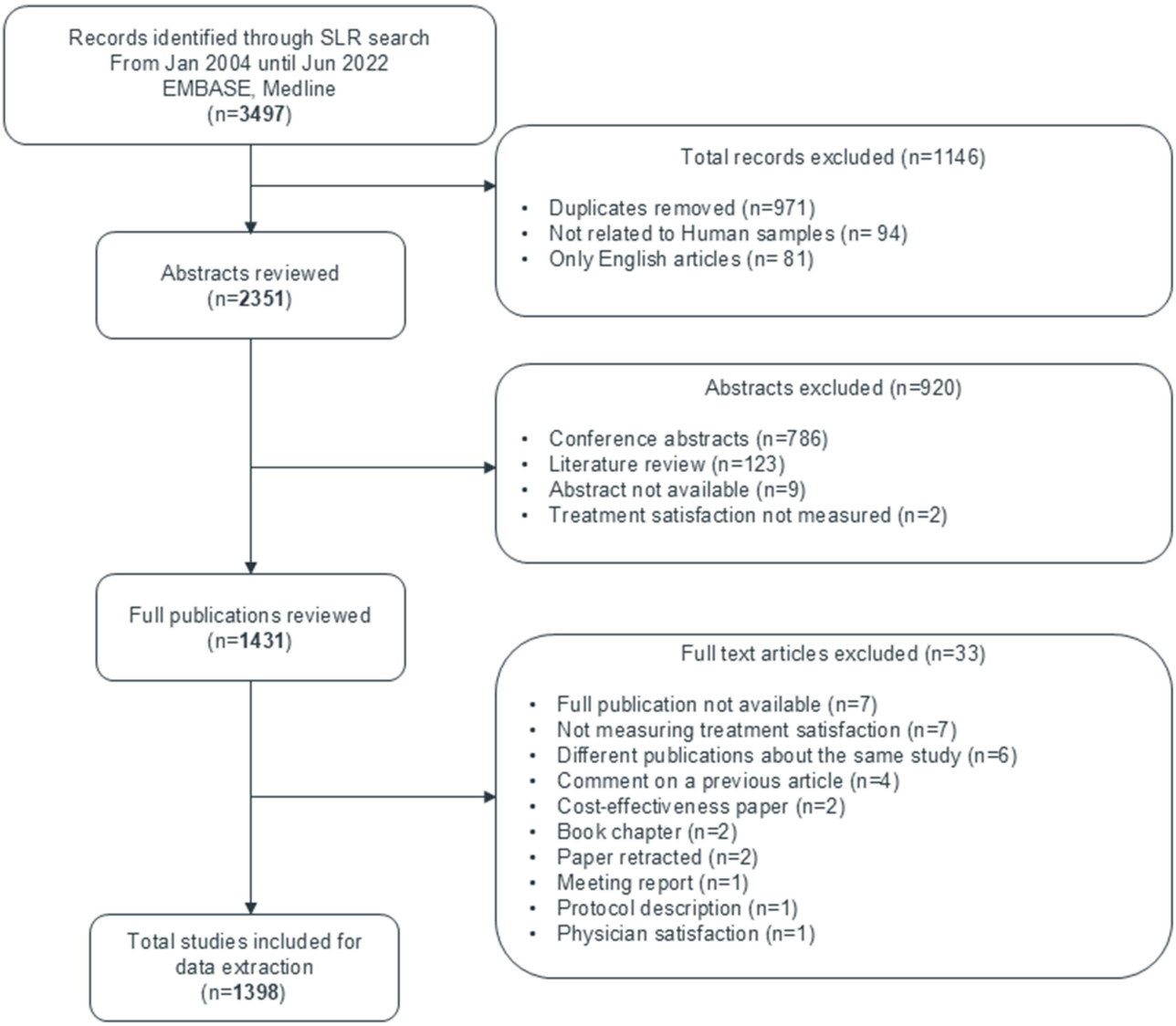

Figure 1 PRISMA flow chart of literature search and review process.

The TSQM is a generic measure of treatment satisfaction that is psychometrically valid and reliably assesses patients' treatment satisfaction with a wide variety of medications.[15] Generic questionnaires can be applied across therapeutic areas and the review identified 5 therapeutic areas across which the TSQM has been used; most frequently: diseases of the nervous system, diseases of the skin, diseases of the circulatory system, mental, behavioral or developmental diseases, and diseases of the respiratory system (Figure 5).

There are three distinct derivatives of the TSQM to examine the patient perspective on treatment experience and its related satisfaction. TSQM-1.4[15] was developed first and covers four different domains: effectiveness, convenience, side effects, and global satisfaction. A subsequent version was developed, removing three items on effectiveness, side effects and global satisfaction domains and rewording a few others, resulting in TSQM-II.[16] TSQM-9[17] was developed to exclude the assessment of side effects to create a measure better suited for naturalistic study designs, in which there is potential that the administration of the side effects domain of the TSQM would interfere with routine clinical care. The most widely used TSQM was TSQM-1.4 (n=118), followed by TSQM-9 (n=50) and finally TSQM-II (n=38) (Figure 6). There are 3 studies in which it is not clear whether TSQM-1.4 or TSQM-II was used because the side effects domain is present, but the specific instrument name is not included. In 4 studies using the TSQM, it could not be ascertained from the publication whether TSQM-1.4, TSQM-II, or TSQM-9 was administered.

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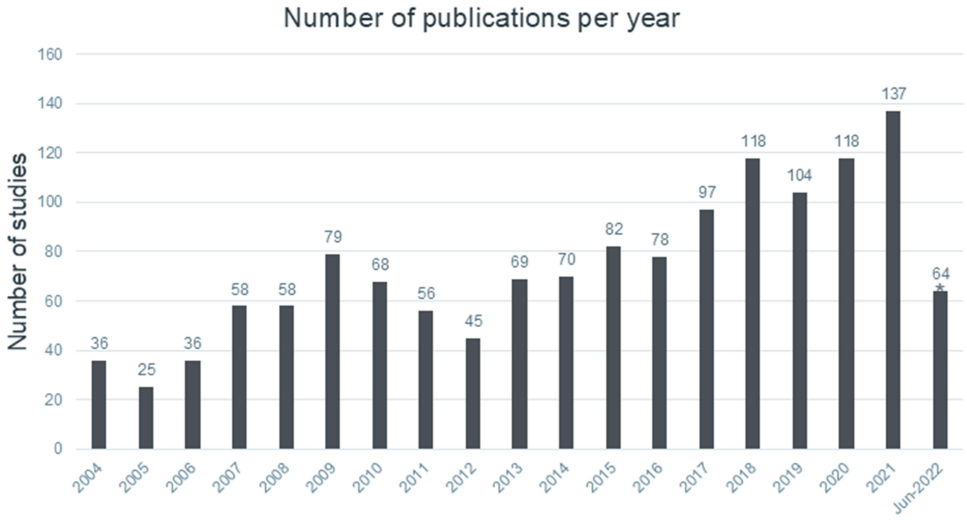

Figure 2 Treatment Satisfaction PRO Instrument publications by year.
Note: *The search was performed until June of 2022.

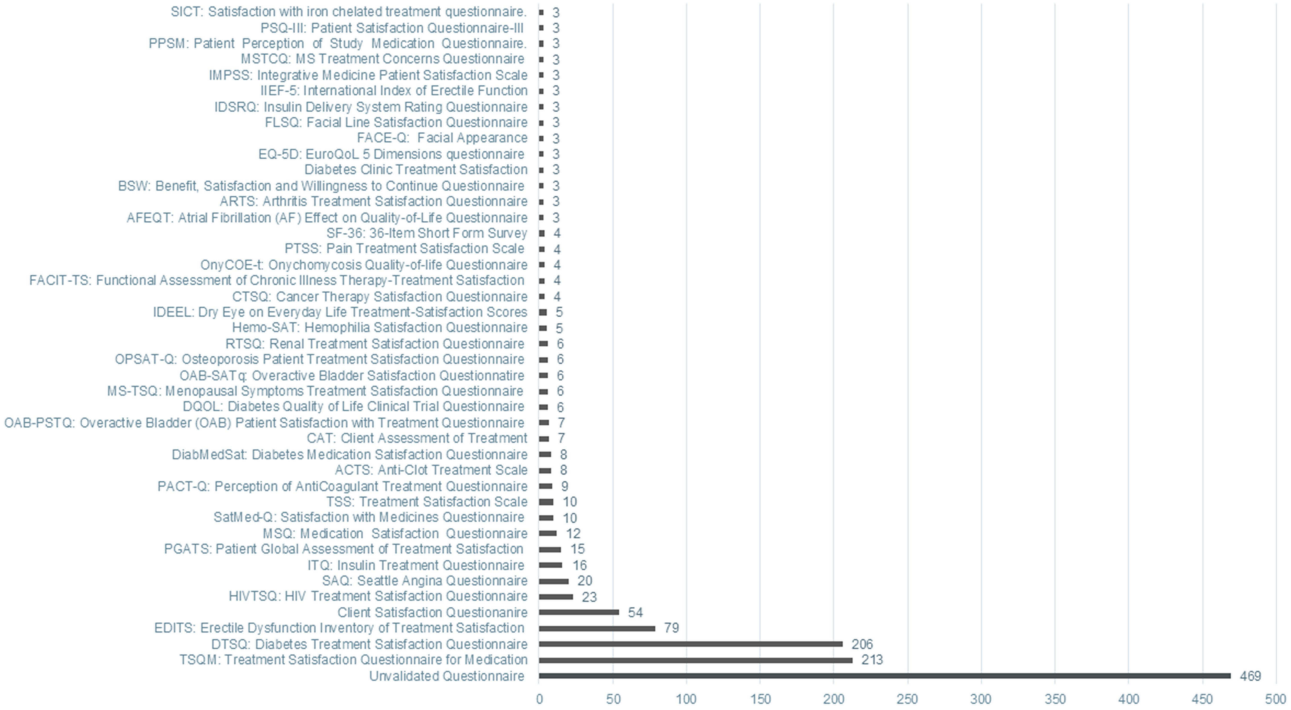

Figure 3 Treatment Satisfaction PRO Instruments identified in this review.

The DTSQ[32] is a validated disease-specific instrument developed to assess patients' satisfaction with medications used to treat diabetes.[35] There are two versions of this measure: the original DTSQ, now referred to as the status version (DTSQs), and the DTSQ change version (DTSQc), which was developed to overcome potential ceiling effects of the status version.[32] The status version contains eight items measuring treatment satisfaction (satisfaction with current treatment, convenience, flexibility, satisfaction with own understanding of diabetes and likelihood of continuing or recommending current treatment) and two items measuring the perceived frequency of hyperglycemia and hypoglycemia. The DTSQc also contains eight items measuring the current satisfaction relative to preceding treatment. Most of the studies did not describe the DTSQ version used (n=157, 76.2%) (Figure 7).

Table 2 Most Commonly Used Treatment Satisfaction Patient-Reported Outcomes

Name	Objective	Sample Population	Recall Period	Items	Domains
Treatment Satisfaction Questionnaire for Medication 1.4 (TSQM-1.4)[15]	To measure patients' satisfaction with medication in chronic diseases such as coronary diseases,[19] cystic fibrosis,[24] hypertension,[25] chronic obstructive pulmonary disease (COPD),[26] multiple sclerosis,[27] autoimmune diseases such as psoriasis[28] and angioedema,[29] and mental diseases such as schizophrenia[30] and depression disorder[31]	Adult	2 to 3 weeks, or since the last medication use	14	Side effects (5 items) Effectiveness (3 items) Convenience (3 items) Global satisfaction (3 items)
Treatment Satisfaction Questionnaire for Medication II (TSQM-II)[16]				11	Side effects (4 items) Effectiveness (2 items) Convenience (3 items) Global satisfaction (2 items)
Treatment Satisfaction Questionnaire for Medication 9 (TSQM-9)[17]				9	Effectiveness (3 items) Convenience (3 items) Global satisfaction (3 items)
Diabetes Treatment Satisfaction Questionnaire (DTSQ):Status (DTSQs)[32]	To measure satisfaction with diabetes treatment regimens in people with diabetes and changes in satisfaction with treatment	Adult	DTSQs: Over the past few weeksDTSQc: six months ago (before you changed to the medication you are using now)	8	Satisfaction with treatment (6 items)Perceived Hyperglycaemia (1 item) Perceived Hypoglycaemia (1 item)
Diabetes Treatment Satisfaction Questionnaire (DTSQ) change version (DTSQc)[32]					
Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS)[33]	To assess satisfaction with medical treatments for erectile dysfunction	Adult	4 weeks	11	Satisfaction with treatment (11 items)

Note: *Population, recall period, items and domains data sourced from ePROVIDE's PROQOLID Database[34].

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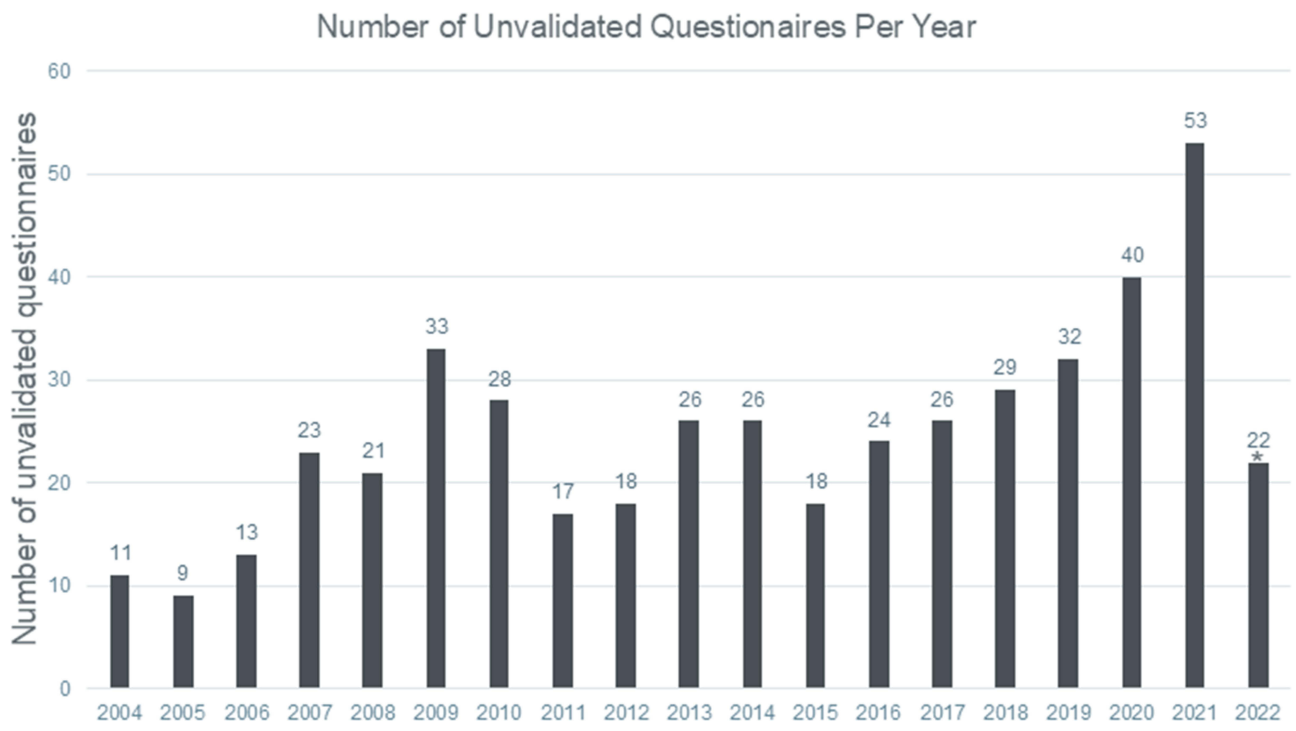

Figure 4 Unvalidated questionnaires identified by year.
Note: * The search was performed until June of 2022.

The EDITS is a validated 11-item questionnaire used to assess treatment satisfaction and the likelihood of treatment continuation in patients with erectile disfunction.[33] A condition from the genitourinary system that affects more than 50% of males aged 40–70 years.[36]

Therapeutic areas, Diseases, and Treatments where Treatment Satisfaction was Measured Each study was categorized into a therapeutic area using the World Health Organisation's International Classification of Diseases 11th revision (ICD-11).[24] Of the 1,398 studies included in our review, 329 (23.5%) were related to the therapeutic area of endocrine, nutritional, or metabolic diseases (Figure 8), with diabetes being the most studied condition (312 studies, 94.8%) (Figure 9A). Specifically, type II diabetes was the most prevalent form of diabetes mentioned (190; 60.9%). The second area where most treatment satisfaction instruments were incorporated was in the mental, behavioural or developmental diseases category (168 studies, 12.0%) (Figure 8). Schizophrenia (28 articles, 16.7%), drug addiction (26 articles, 15.5%) and depression (21 articles, 12.5%) were the most common diseases within this category. Regarding diseases of the nervous system (n=117; 8.4%), multiple sclerosis emerged as the most frequently studied condition (n=53; 45.3%), followed by migraine (n=21; 18.0%). The conditions related to sexual health and diseases of the skin completed the top five therapeutic areas with most treatment satisfaction instruments with 106 (7.6%) and 97 (7.0%) studies respectively. Surprisingly, diseases of the circulatory system or neoplasms categories were left out of the top 10 therapeutic areas with most treatment satisfaction instruments found in our search with 86 (6.2%) and 58 (4.2%) studies (Figure 8).

Treatment satisfaction instruments have been administrated to patients using oral (n=420, 44.6%), parenteral (n=365, 38.8%), topical (n=64 studies, 6.8%), and other routes of administration such as inhalation (n=30 studies, 3.2%) (Figure 9). Some studies compared several administration routes of the same drug to understand the level of satisfaction, adherence, and effectiveness of the treatment administered (n=46, 4.9%) (Figure 9).

The most common treatment therapies that utilized treatment satisfaction instruments included insulin (88 studies, 52.7%), sildenafil (33 studies, 19.8%), Diseases Modifying Therapies to treat multiple sclerosis (32 studies, 19.2%) and tadafil (14 studies, 8.4%) These types of treatment are included in the most common therapeutic areas except for sildenafil. In the case of insulin, DTSQ (49 studies, 55.7%) was the most common treatment satisfaction instrument used to evaluate therapy satisfaction in patients For Diseases Modifying Therapies, the TSQM (27 studies, 84.4%) was the

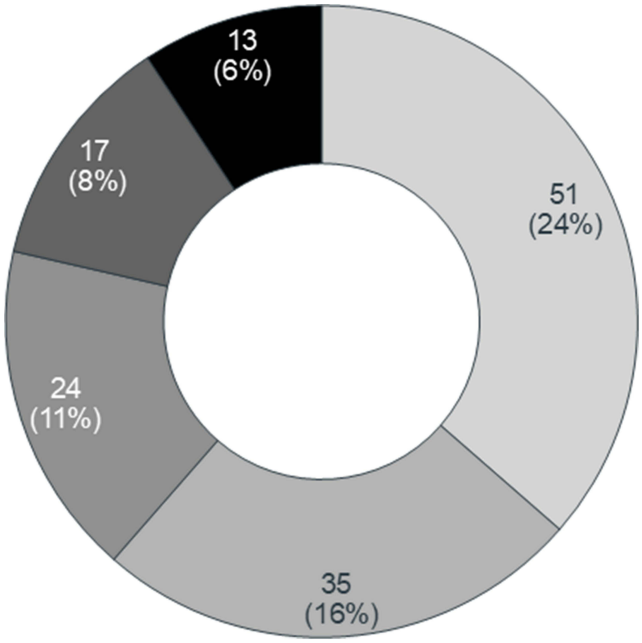

Figure 5 Principal therapeutic areas where TSQM was the most frequently used instrument to assess treatment satisfaction.
Note:

- 08- Diseases of the nervous system
- 14- Diseases of the skin
- 11- Diseases of the circulatory system
- 06- Mental, behavioral or developmental diseases
- 12- Diseases of the respiratory system

mostly used treatment satisfaction instrument within multiple sclerosis Regarding sildenafil, EDTIS (28 studies, 84.8%) was the most common treatment satisfaction instrument utilized in patient with erectile dysfunction Interestingly, the most widely used treatment satisfaction PRO instrument (the TSQM; see Figure 2) was not used in insulin or sidenafil studies where disease-specific instruments were preferred.

The nature and distribution of studies where treatment satisfaction was measured was collected. Seven hundred and forty-three studies (53.1%) were research funded by academic institutions, whilst 570 (40.8%) were sponsored by industry (pharmaceutical companies). Within the medical technology field, 34 studies (2.4%) were sponsored by academic and 51 (3.6%) within the medical product industry. We also explored the distribution of study designs where treatment satisfaction was measured. Out of the 1,398 studies, 778 (55.7%) pertained to interventional clinical trial studies that were designed to assess direct impacts of treatment or preventive measures on disease, whereas 600, 42.9%) corresponded to observational studies. We also found 20 studies (1.4%) describing the conceptual model, the development, and/or the validation of the treatment satisfaction instrument utilized.

Clinical trials are usually conducted in different phases. Most of the 778 interventional clinical trial studies utilizing a treatment satisfaction PRO instrument were Phase III with 214 publications (27.5%), followed by Phase IV with 81 (10.4%), Phase II with 48 (6.2%), pilot studies with 31 (4.0%) and Phase I with 4 (0.5%). Note that more than half of clinical trial studies did not specify their phase (Figure 10).

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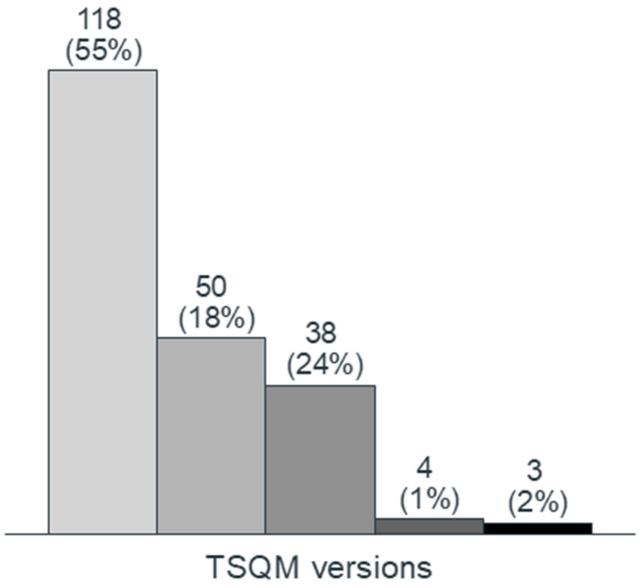

Figure 6 TSQM Frequency of Use Identified in This Review.

Notes:
TSQM-1.4
TSQM-9
TSQM-II
Not described
TSQM-1.4 or II

Abbreviation: TSQM, Treatment Staisfaction Questionnaire for Medication.

Discussion

Measuring patients' satisfaction with their medication has become of increasing interest over the past three decades,[25,26] since health authorities and payers progressively recognize the importance of patient perspectives and outcomes reported directly by patients in evaluating and approving pharmaceutical interventions, and ultimately, in health care decision making.[27] Finding the most appropriate treatment increases treatment satisfaction and consequently increases the quality of care and treatment outcomes.[28] Moreover, treatment satisfaction is related to adherence.[26] Data show that the more satisfied patients are with a treatment, the more likely they are to continue use as prescribed.

PRO data are an important complement to the clinical evidence in demonstrating the value of a treatment, particularly for interventions developed to treat chronic, disabling conditions where the intention is not necessarily to cure but rather to alleviate symptoms, facilitate function, or improve quality of life.[29–31] Therefore, treatment satisfaction PRO instruments have become a very useful tool for understanding the patient's perspective on their current treatment that can differentiate among alternative treatments, reflect on adherence and willingness to continue treatment in clinical trials and other studies.[25]

The objectives of this scoping review were to summarize, understand, and disseminate findings from a broad body of literature where treatment satisfaction PRO instruments were used in clinical research and academic studies. Of the final 1,398 studies included, the results of this review highlighted that the therapeutic areas where most treatment satisfaction instruments were utilized were endocrine, nutritional or metabolic diseases; followed by mental, behavioral or developmental diseases; as well as diseases of the nervous system. What is common to these diseases is their chronicity and the use of treatments over a long period of time. For endocrine, nutritional or metabolic diseases, the most common disease where treatment satisfaction was measured was diabetes type I and II. The outcome of diabetes treatment should not be evaluated only by Hb1A1c levels. The evaluation of psychological aspects of patients' experiences with treatment regimens, including treatment satisfaction, wellbeing and quality of life, are also important.[34] For mental diseases, treatment satisfaction was the most measured concept in behavioral or developmental diseases, schizophrenia, and diseases related to drug addiction and depression.[38] In these conditions, lower treatment satisfaction leads to high treatment failures, relapse rates and lack of symptoms control.[37] Poor treatment satisfaction has also been shown to result in poor retention and adherence to treatments.[39] The third therapeutic area where treatment satisfaction was commonly

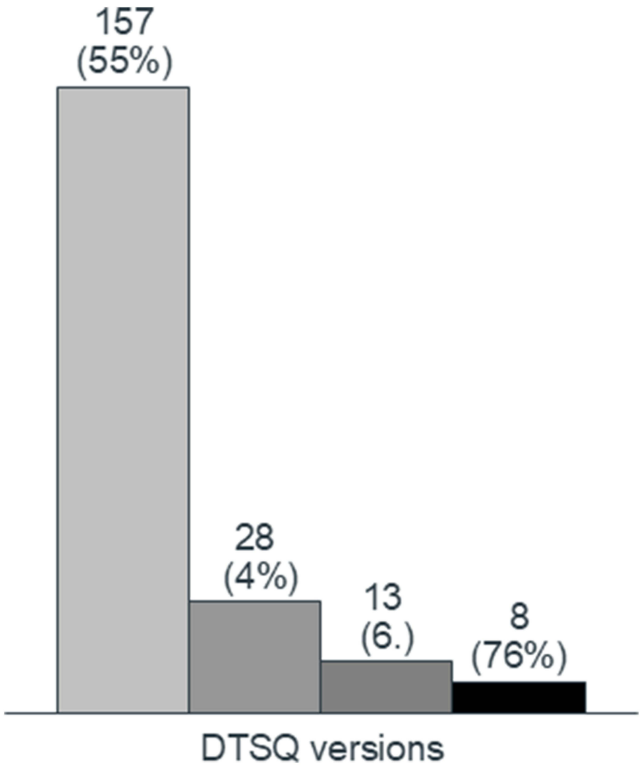

Figure 7 DTSQ Frequency of Use Identified in This Review.

Notes:

- Not described
- DTSQs
- DTSQs or DTSQc
- DTSQc

Abbreviations: DTSQ: Diabetetes Treatment Satisfaction Questionnaire DTSQs: status version of the Diabetes Treatment Satisfaction Questionnaire. DTSQc: change version of the Diabetes Treatment Satisfaction Questionnaire.

evaluated were diseases related to the nervous system, with multiple sclerosis being the most common and migraine the second most common. There are several publications that highlight the importance of measuring treatment satisfaction in these chronic diseases.[40–42] With approximately 50% of people with multiple sclerosis discontinuing therapy within 2 years, medication adherence and persistence are critical to optimizing therapeutic benefit.[42] Factors such as the administration route, treatment satisfaction, side effects and convenience of treatment have been shown to be drivers of elevated adherence in distinct types of multiple sclerosis patients.[42] Treatment satisfaction PRO instruments can reliably capture patient perceptions around these factors.

Analysis of the annual trends in the use of validated and unvalidated treatment satisfaction measures reveals important patterns in research practices over the past two decades. The number of studies employing validated instruments has generally increased, with notable peaks in 2018 and 2021. Similarly, the use of unvalidated questionnaires has also risen, reaching its highest point in 2021. It is important to note that the data for 2022 only includes studies published up to June, and therefore likely underestimates the true annual totals for both validated and unvalidated measures.

The persistent growth in both categories suggests that, while there is increasing recognition of the value of psychometrically robust instruments, many researchers continue to rely on self-developed or context-specific tools that lack formal validation. This dual trend highlights ongoing challenges in instrument selection and underscores the need for continued advocacy for the use of validated measures. Furthermore, the fluctuations observed in both graphs may reflect changes in publication rates, evolving research priorities, or the introduction of new instruments. Instrument choice is often driven by factors such as the availability of disease-specific tools, the need for rapid or context-specific assessment,

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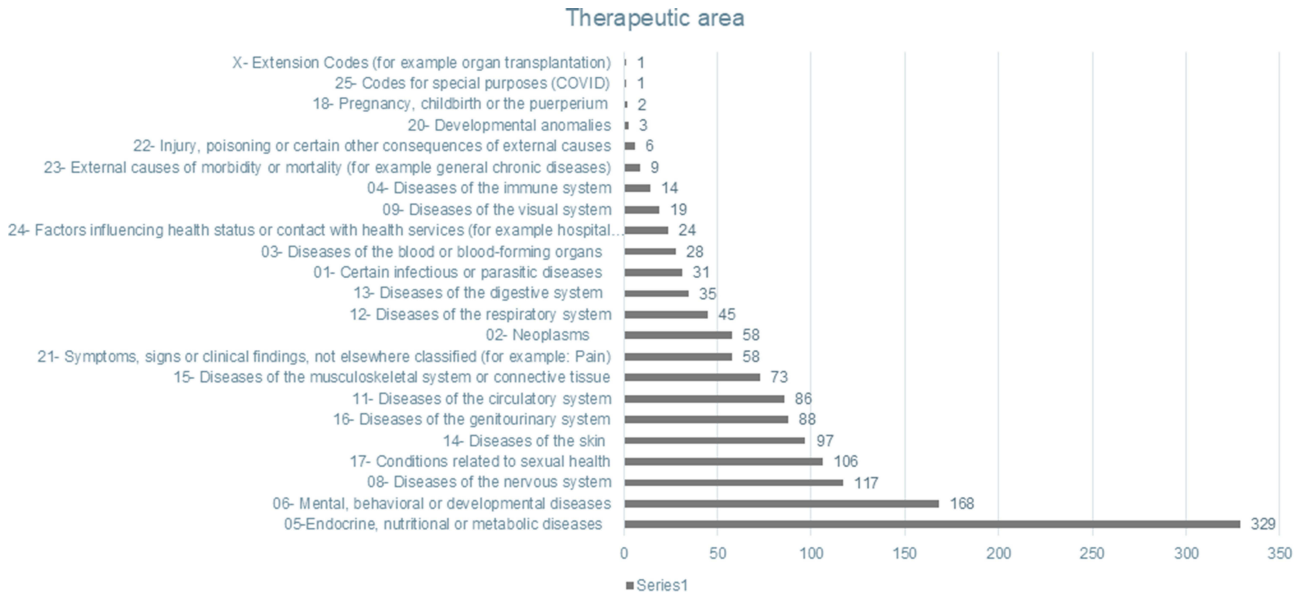

Figure 8 Treatment Satisfaction PRO Instrument publications by therapeutic area.
Notes: The text and number of each category in the Y axis correspond to the International Classification of Diseases, 11th Revision (ICD-11) of the World Health Organisation.[37].

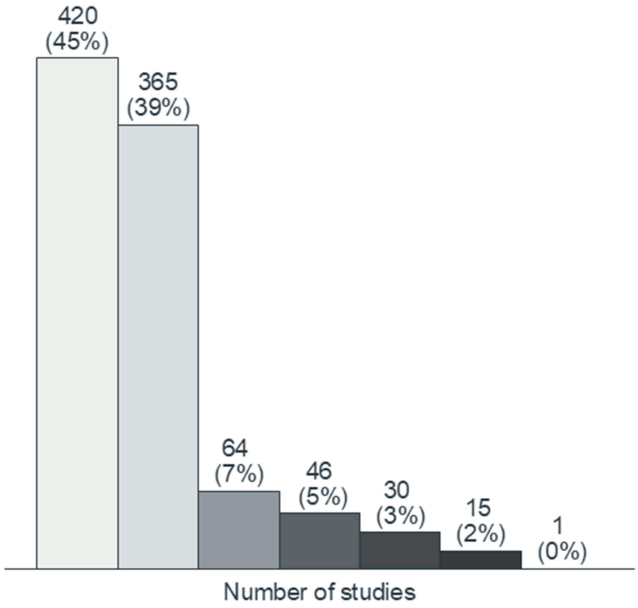

Figure 9 Routes of drug administration which treatment satisfaction PRO instruments have been applied.
Note:

and the perceived relevance of certain questionnaires to particular patient populations or study designs. In some cases, researchers may prioritize convenience or familiarity over psychometric rigor, especially in exploratory or pilot studies.

Overall, these findings emphasize the importance of promoting validated tools to ensure research quality and comparability, while also recognizing the practical constraints faced by investigators. Future efforts should focus on

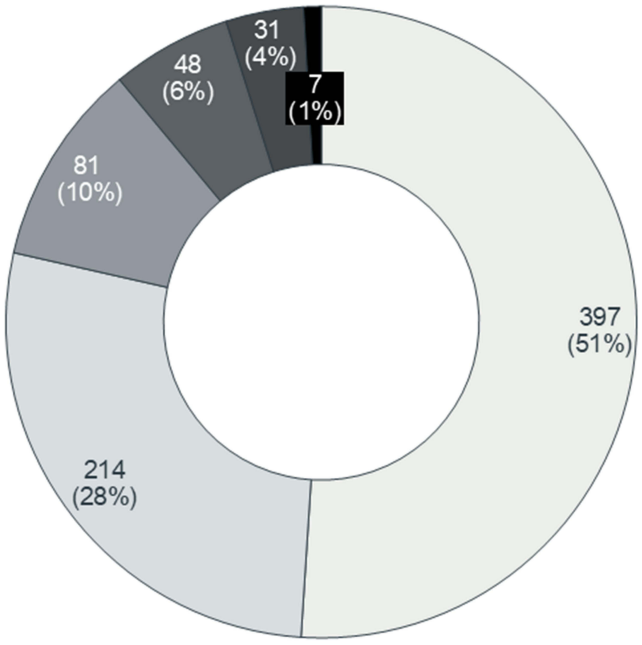

Figure 10 Phases of interventional clinical trial studies that included a treatment satisfaction PRO instrument.

Notes:

- Not phase specified
- Phase III
- Phase IV
- Phase II
- Pilot study
- Other

Abbreviation: PRO, Patient Reported Outcome.

facilitating access to validated instruments, supporting the development and validation of new measures, and encouraging transparent reporting of instrument selection and psychometric properties.

This scoping review has identified that a large body of research has used self-made treatment satisfaction instruments that are not psychometrically assessed. To be confident in research findings, outcome measures must exhibit good psychometric properties such as reliability, validity and ability to detect the change of the measure.[43] This is even more important when evaluating between-group differences. Randomized controlled trials (RCTs) using validated and reliable PRO instruments are more likely to show significant between-group difference than RCTs using non-validated measures.[44] The recent development of clear guidelines from regulators for the use of PRO instruments to support clinical trial evidence (for example the FDA Patient-Focused-Drug Development (PFDD) provides a clear direction on the importance of using validated and reliable PRO instruments.[8]

Additionally, when selecting the right PRO measure, researchers must choose between a generic or specific questionnaire, evaluating a range of clinical conditions (eg, TSQM), or a specific disease, population, and symptom (eg, DTSQ). Generic instruments are intended to be used in any disease population and allow comparisons between diseases or compare data with population normative values.[45] Whilst generic PRO measures enable researchers to compare outcomes across different diseases and symptom populations, specific PRO measures do not. Disease-specific questionnaires are developed to address those aspects of outcomes important for a particular patient population. Consequently, disease-specific instruments possess greater potential for showing differences between competing therapies. A criticism of disease-specific instruments is the lack of comparability across diseases. This is a particular issue for reimbursement authorities, who are required to assess the comparative benefits of treatment reimbursement across disease areas.[45] Given the benefits of generic instruments and the specificity of disease-specific ones, both generic and specific PROs can be used concurrently to combine their respective

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benefits.[46] In the current research, the TSQM, a generic instrument, was the most commonly used PRO measure to assess treatment satisfaction. The DTSQ, a disease-specific instrument, was the second most utilized measure.

The evaluation of treatment satisfaction for different modes of drug administration is a key element in drug development studies.[26] The results of this review show that treatment satisfaction instruments have mostly been used in oral and parenteral modes of administration. There is a correlation between different modes or frequency of drug administration and treatment satisfaction, as greater satisfaction and compliance is typically associated with lower regimen complexity or treatment burden.[26] In fact, prior research suggests that the main source of dissatisfaction with a treatment is the inconvenience of the administration regimen.[41] A generic measure like the TSQM could be used to assess differences in treatment satisfaction per modes of administration.[15] Alternatively, some measures have been developed to specifically assess treatment satisfaction between different modes of drug administration. An example is the Rituximab Administration satisfaction questionnaire (RASQ), developed to evaluate the treatment satisfaction of rituximab treatment, administered subcutaneously or intravenously.[47]

This review identified that treatment satisfaction instruments are used primarily in phase III trials, when clinical trials are typically conducted targeting submission to regulators, Health Technology Assessment (HTA) bodies and payers.[48] Measuring treatment satisfaction in phase III clinical trials is also an opportunity to provide evidence of the added value of new treatments as compared to those already on the market. This is particularly true for situations where there are several treatments with similar efficacy and safety profiles and where the patient experience, and in particular treatment satisfaction, is a valuable differentiator.

Strengths

This review assessed the most common treatment satisfaction instruments used in academia and in an industry setting for the last 18 years, including almost 1,400 articles to describe the treatment satisfaction instruments per context of use. Typically, such a large output would indicate a broad research question. However, one of the main objectives of the study supported such a large scope and the inclusion of all literature pertaining to treatment satisfaction in order to properly describe the different types of measures used and in which context. Such a large body of work is useful for this publication, but additional analyses could emerge for future work.

Limitations

Despite its strengths, this review has several limitations. First, the search was restricted to English-language publications, which may have excluded relevant studies published in other languages. Second, the exclusion of conference abstracts may have limited the scope to formally published instruments, potentially overlooking emerging tools. Third, the use of a scoping review methodology, while appropriate for mapping the literature, does not include formal critical appraisal or snowball searching, which may affect the completeness of the findings. Additionally, the literature search concluded in June 2022, and newer instruments may not be captured.

Conclusions

To our knowledge, this is the first time that a scoping literature review has been conducted to evaluate and characterize treatment satisfaction instruments that are frequently used in academic and industry research. Endocrine, nutritional, or metabolic diseases are the most common therapeutic areas where treatment satisfaction was measured, followed by mental and behavioral or developmental diseases. Additionally, most of the studies where treatment satisfaction is measured are conducted in academic research setting or in a phase III clinical trial.

The most surprising finding is that there is an abundance of studies where treatment satisfaction instruments are used without proper psychometric validation, which calls into question the validity and generalizability of their research findings.

The TSQM was identified as being the most frequently utilized validated generic instrument in all studies reviewed (both in industry and academia). The TSQM is used across all therapeutic areas, but neurology and dermatology were the most common. The TSQM-1.4 is the most used version across all studies reviewed. The second most frequently utilized treatment satisfaction instrument is a disease-specific instrument, the DTSQ, which is specific to treatment satisfaction in diabetes.

Treatment satisfaction is a useful outcome both in academic and industry research contexts for assessing the value of medications from the patient experience perspective. Valid, reliable, and sensitive-to-change measures must however be

used to minimize measurement error and for proper comparisons, conclusions, and generalizability to be drawn, and ultimately, to maximize the chances of impacting health care decision making.

Future Directions

In light of our findings, we recommend that future research prioritize the use of validated patient-reported outcome instruments to enhance the reliability and comparability of treatment satisfaction data. Researchers should be encouraged to transparently report instrument selection and psychometric properties, and to consider both generic and disease-specific tools as appropriate for their study context. As the field continues to evolve, ongoing efforts are needed to develop, validate, and disseminate new instruments that address emerging needs and populations. Regular updates to literature reviews will be essential to capture the adoption of newer tools and trends. Ultimately, fostering collaboration between researchers, clinicians, and regulatory bodies will help ensure that patient perspectives are robustly and consistently integrated into clinical decision-making and health policy.

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Disclosure

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