

# Satisfaction with Medication: An Overview of Conceptual, Methodologic, and Regulatory Issues

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## ABSTRACT

**Objective:** Patients' satisfaction with their medication or medical device has been of increasing interest over the past decade. This is reflective of the rise of the patient as consumer and the desire of pharmaceutical and device manufacturers to obtain feedback from the consumers about their products. Satisfaction with medication is more narrowly focused and should be distinguished from other aspects of satisfaction. The purpose of this article is to place the concept of patient satisfaction with medication in an appropriate theoretical context, to explore the challenges of performing this research, and to offer recommendations for the basis of satisfaction claims.

**Methods:** We reviewed the literature on satisfaction with medication or medical devices. We summarize and discuss the background, conceptual issues, and theoretical justification for studying satisfaction with medication. We offer examples of domains to be included and suggestions on how to develop a psychometrically sound satisfaction measure. We also address additional issues for consideration.

**Results:** Medication satisfaction is a type of patient-reported outcome, but is distinguished from other

patient-reported outcomes—specifically health-related quality of life (HRQL) and self-reports of symptoms. The Theory of Reasoned Action provides one theoretical justification for the concept. The heuristic value of this theory leads to implications regarding the relation between satisfaction and adherence. In addition, the theory is consistent with the need to focus on the patient's beliefs and values concerning the impact of taking his/her medication. Although the beliefs will differ according to the specific drug–disease combination, the beliefs can often be categorized in several domains of satisfaction: symptom relief/efficacy, side effects, ease and convenience, impact on HRQL, general satisfaction, and additional domains specific to the given research question.

**Conclusion:** Patient satisfaction instruments should be subjected to the same psychometrically rigorous standards and procedures as any other patient-reported outcome and should also be subject to the same regulatory standards as other patient-reported outcomes with respect to advertising and promotion.

**Keywords:** adherence, patient-reported outcomes, satisfaction, theory of reasoned action.

## Background

The past few decades have witnessed increasing interest in the issue of patient satisfaction with the medical care they receive [1–10]. This interest reflects the perspective that has developed over this time of the patient as an active consumer of health-care services rather than merely as a passive recipient of these services. Increased direct-to-consumer (DTC) advertising over the past decade, three-tier copays, and a dizzying array of information (and misinformation) sources reinforce the patient-as-consumer roles. And, like those responsible for pro-

viding many of life's goods and services, including automobile manufacturers, hotel chains, television networks, and so on, providers of health-care services have become increasingly interested in obtaining feedback about their product from the primary consumers of these products. In fact, assessment of aspects of patient satisfaction with health care is a component of the National Committee for Quality Assurance (NCQA) recommended procedures for assessing health plans [11,12].

It is quite natural, then, that concomitant with the rise of the patient as consumer, pharmaceutical and medical device manufacturers are asking questions such as: "Are our patients satisfied with our medication?"; "How satisfied are our patients compared to patients on our competitor's product?"; and so on. The demonstration of greater satisfac-

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tion with one product over another provides a competitive marketing advantage, provided that such claims are based in empirical data. Hence, over the past few years, there has been an increasing interest on the part of pharmaceutical firms in assessing patient satisfaction with their medications. The purpose of this article is to place the concept of patient satisfaction with medication in an appropriate theoretical context, to explore the challenges of performing research in patient satisfaction with medication, and to offer recommendations for assuring that satisfaction claims are based on the results of studies designed and conducted in accordance with principles used in other patient based assessments. For purposes of this article, “satisfaction with medication” will refer to satisfaction with medication and/or medical devices.

### Definitions and Distinctions

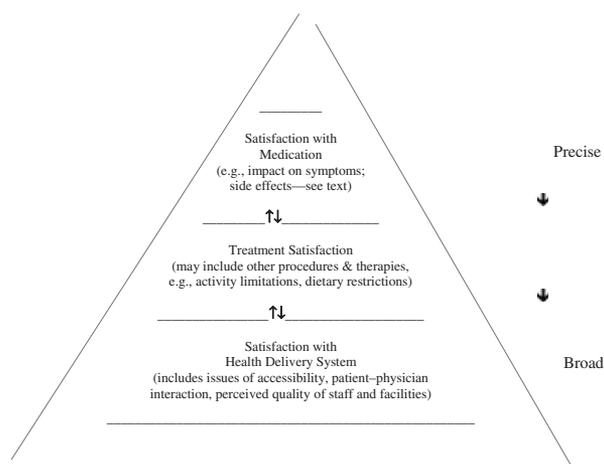
*Satisfaction with Medication Versus Satisfaction with other Aspects of Medical Care* We define satisfaction with medication as the patient’s evaluation of the process of taking the medication and the outcomes associated with the medication. This definition is similar to that of Weaver et al. [10], in that it emphasizes both process and results. We prefer to use the term “satisfaction with medication” to the more widely used term of treatment satisfaction, in that the former focuses on the specific issue of medication and the latter encompasses the entire treatment experience. It is useful to think of a satisfaction hierarchy (see Fig. 1). The broadest level of the hierarchy is satisfaction with health-care delivery, which has been the basis for much of the recent interest in treatment satisfaction [13–17]. Neverthe-

less, from the perspective of a researcher or practitioner who is interested in patient evaluation of a specific medication, assessment of patient satisfaction with the entire delivery of health care is much too broad. The latter will include a number of factors that go far beyond satisfaction with medication, such as access to appropriate medical staff on a timely basis, perceived quality and responsiveness of medical staff and quality of medical facilities, and the patient’s own personal experience with respect to the duration and severity of the disease and expectations for receiving efficacious and timely medical care.

The middle level of Figure 1 represents treatment satisfaction. Treatment satisfaction involves evaluation of more than just the patient’s satisfaction with the medication. It will include issues of physician–patient interaction, recommendations by the physician that go beyond the specific medication (e.g., dietary restrictions, behavioral changes), and concomitant therapies (e.g., physical rehabilitation). Assessment of treatment satisfaction as broadly defined here will result in a number of factors extraneous to the patient’s satisfaction with medication for a researcher who is specifically interested in the latter.

Finally, at the narrowest end of the hierarchy, we have satisfaction with medication. Although not denying the importance of the other aspects of satisfaction, satisfaction with medication is the appropriate target of inquiry for a number of purposes and should not be confused with the other levels of the hierarchy. As we will see in this article, satisfaction with medication is influenced by a variety of factors, all of which are subject to assessment. To the extent to which the treatment is focused entirely on the medication, treatment satisfaction will devolve to satisfaction with medication. Nevertheless, even in this case, there may be aspects of treatment satisfaction (e.g., physician–patient interactions, physician communication style) that will result in treatment satisfaction not being identical with satisfaction with medication.

Any level in Figure 1 can impact the other levels. As a first example, consider a patient who has been prescribed a new medication for a chronic, debilitating disease. Satisfaction with medication, the top level of the hierarchy in Figure 1, may positively dispose the patient toward the entire health delivery system (the bottom level of the hierarchy). Conversely, prescribing a drug that the patient believes is less efficacious because the preferred medication is not on the formulary can negatively impact satisfaction with the health delivery system. Similarly,



**Figure 1** Hierarchy of levels of health satisfaction.

a physician's communication style with the patient influences the patient's satisfaction with the health plan [18,19], as well as with the medication [20]. This is an example of the middle level of the Figure 1 influencing both the top and the bottom levels. Nevertheless, the central lesson of Figure 1 is that we need to match the level of satisfaction assessed in a given study with the level that is most appropriate for the study objective. Instruments such as the Patient Satisfaction Questionnaire [21], the Client Satisfaction Questionnaire [22], and the Service Quality Instrument (SERVQUAL) [23], while appropriate for assessing the bottom level of the hierarchy, are far too broadly focused to assess satisfaction with specific therapies, the target of the present review.

*Why Should We Measure Satisfaction with Medication?* Patient satisfaction is a legitimate patient-reported outcome to consider for inclusion in studies on medications for the following reasons:

First, we would expect satisfaction with medication to be related to patient adherence to prescription regimens. Although drug adherence is an important and complex medical issue [24–29], there has been little research that empirically demonstrates the link between medication satisfaction and adherence. This deficiency reflects the general lack of research involving patient satisfaction with medication—many of the studies that assess satisfaction along with adherence have focused on satisfaction with care, rather than satisfaction with medication. As implied by Figure 1, if our intent is to determine the relationship between adherence to a regimen for prescription of a medication, the appropriate level of assessment of satisfaction is at the level of satisfaction with medication, not satisfaction with care or satisfaction with health delivery. In addition, the lack of empirical support for the relation between adherence and satisfaction with medication also reflects measurement difficulty, both in measuring adherence and in adequately measuring satisfaction with medication. Typically, when satisfaction with medication has been measured, the assessment involves a single question assessing overall satisfaction. The study by Shikiar et al. [8] is one of the few studies to focus specifically on various aspects of dimension with satisfaction and to subsequently [30] explore its relation to adherence.

Second, detailed feedback about patient satisfaction can be used in improving products. For example, if it is found that lack of convenience of taking the medication is a key factor resulting in decreased

satisfaction, the drug might be reformulated in a way that results in a less frequent dosing requirement. If satisfaction is not measured, systematic efforts cannot be made to improve it.

And finally, all other things being equal, we would expect satisfaction to be related to patients' preferences—and requests for specific medications. In the case of a patient who has had the opportunity to have tried several different medications, the one with which he or she is most satisfied will likely be the drug of choice. For patients who have not yet had medication prescribed for their disease, the situation is a bit more complicated. Nonetheless, patients' expectations about being satisfied with a drug can be shaped by a variety of information sources, including DTC advertising.

*When Is Satisfaction with Medication Worthwhile to Assess?* Despite the enthusiasm for assessing satisfaction with medication, it is not always an appropriate endpoint. For example, in situations where a medication is clearly the most efficacious compound, there is usually no need to expend the effort to assess satisfaction with medication. Similarly, where the comparator in a clinical trial is a placebo, assessing satisfaction with medication as an endpoint in these trials might not be worth the effort in many cases, especially if the drug will be competing with existing medications. Another instance where satisfaction with medication may not be worth assessing is when the medication is only a small part of a comprehensive treatment plan. In such instances, patients may have a difficult time discerning the impact of the medication from the rest of the treatment regimen.

Consider assessing patient satisfaction with medication when:

- One medication offers offsetting advantages and disadvantages relative to another in terms of efficacy and side effects.
- Medications of approximate equal efficacy have competing modes of administration or other convenience factors (e.g., dosing schedules).
- Medications of approximate equal efficacy have different side effect profiles.
- The medication plays a central role in the treatment regimen.
- There are other unique situations where demonstration of satisfaction with a medication relative to a comparator is considered to offer a potential advantage with respect to adherence issues or in marketing.

*Satisfaction with Medication Versus other Patient-reported Outcomes* Satisfaction with medication is conceptually distinct from health-related quality of life (HRQL), symptom assessment, functional status, or any other patient-reported outcome that may be assessed. Central to the selection of a patient-reported outcome, should one be desired, is the research question: What is the desired outcome of the trial? If the hypothesis is that drug A will reduce pain symptoms by 20% more than drug B, then symptoms must be assessed. If an additional hypothesis is that patients will be more satisfied on drug A than B, then satisfaction with medication must also be assessed. Satisfaction with medication does not have to be assessed with other patient-reported outcomes. Nevertheless, it generally is.

HRQL pertains to the impact of health on a person's physical, psychological, and social/occupational functioning and well-being [31]. Typically, HRQL is based on the patient's own assessment of his/her status regarding these dimensions, using a wide variety of generic and/or disease-specific instruments (e.g., see Spilker [32] and McDowell and Newell [33] for descriptions). Increasingly, HRQL measures are being included as secondary or primary outcomes in clinical trials [34]. HRQL assessments typically result in a score for a patient on each of the domains used in the HRQL instrument (e.g., a "vitality" score of 70 on the SF-36 [35], a psychosocial score of 65 on the Sickness Impact Profile [36], an HAQ score of 1.75 [37]). Note that there is nothing inherently evaluative about the scores resulting from assessments of HRQL. Although most observers, including the patient him- or herself, would agree that more vitality is better than less vitality, or that more pain is worse than less pain, the respective scores do not indicate the patient's evaluation of the HRQL, but only their status on the respective dimension. Utility measures (e.g., the Health Utility Index, the EuroQoL) attempt to rectify this shortcoming by assessing the desirability or preference associated with the particular HRQL status. Nevertheless, neither a measure revealing the patient's HRQL status nor a utility score associated with that status reveal the patient's satisfaction with the medication vis-à-vis its role in creating that HRQL status for the patient. As discussed later in this article, one important component of medication satisfaction is the assessment of the extent to which the medication is perceived to impact HRQL, but that assessment is distinct from the actual HRQL outcomes themselves.

Self-reports of symptoms deal with a patient's assessment of the presence/absence or the severity of

symptoms, usually obtained via standardized symptom questionnaires. As with the case for assessing HRQL, self-reports of symptoms will typically result in a score for a patient on a given symptom or symptom category (e.g., a depression symptom score of 35 on the CES-D [38], a pain score of 1.5 on the Brief Pain Inventory [39]). As with the case for HRQL scores, although most observers would agree that less severe is better than more when it comes to symptoms, there is nothing inherently evaluative about these symptom scores. The symptom score is distinct from the patient's evaluation of the medication's impact on his/her symptoms.

Satisfaction with medication, on the other hand, deals specifically with the evaluative aspect of the patient's experience with the medication. In accord with our definition, that experience involves both the process and the outcomes associated with the medication. With respect to the outcomes associated with a medication (e.g., symptom reduction, changes in HRQL), the extent to which the patient perceives the medication as positively impacting valued outcomes should logically be related to the patient's evaluation of the medication—that is, his/her satisfaction with the medication. Note that under this conception of satisfaction, satisfaction with medication is influenced by the outcomes of treatment, especially HRQL and symptom status, but it is not identical to these constructs. Another way of thinking about the relationship among these patient-reported outcomes is that HRQL and self-reported symptoms represent patient reports of the patient's status on each of the constructs in question, whereas satisfaction takes into account the extent to which the patient values each of these status points, as well as other factors that enter into determining satisfaction, discussed later in this article.

Figure 2 demonstrates the conceptual relationship among the patient-reported outcomes discussed in this section. At the top of Figure 2, we assume treatment will include the medication of interest as a major component. If not, then satisfaction with medication would usually not be an outcome worth assessing. Treatment is designed to positively impact or prevent patients' symptoms. The extent of this impact can be measured by clinical examination or patient assessment of symptoms. A patient's satisfaction with medication will be determined, in part, by the extent to which the patient attributes the change in symptoms to the action of the medication. If the patient believes the medication has improved disease-related symptoms, then all other things being equal, that treatment medication should be positively evaluated. For

example, consider a patient with chronic lower back pain who has already tried physical therapy, weight loss, and standard OTC drugs. If the physician now prescribes a pain medication, and the pain symptoms are greatly improved, then the patient is likely to attribute the improved health status to the prescribed medication. If the patient had not previously tried physical therapy and weight reduction, and the physician recommends both as well as prescribing the pain medication and the pain symptoms decrease substantially as a result of the medication, the patient may not attribute the improvement entirely to the drug. Although it is conceptually simple to design controlled experiments to tease out the impact of the different aspects of the treatment, in practice these types of tightly controlled experiments will not usually take place for the sole purpose of determining patient satisfaction. Hence, our admonition that the medication should be a major component of the treatment if the goal is to determine satisfaction with medication as opposed to the more general treatment satisfaction.

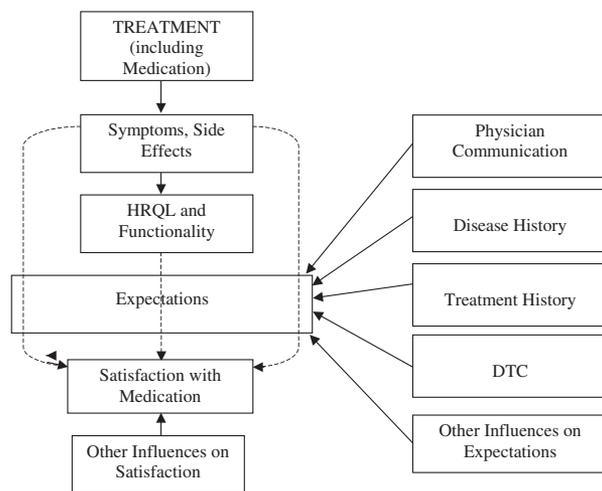
Note that the medication impacts not only disease symptoms, but may also result in side effects that the patient finds bothersome. Hence, to the extent that the patient attributes negatively valued side effects to the action of the drug, patient satisfaction with medication should decrease. Therefore, in assessing satisfaction with medication, it is important to determine the patient's satisfaction with the action of the drug on his or her symptoms and with the side effects of the drug. Ascertaining patients' satisfaction with the impact of the drug on symptoms and side effects is different from assess-

ing symptoms and side effects directly and requires a different set of questions.

Because symptoms and side effects owing to medication are affected by medication, they in turn influence HRQL and functional status. Wilson and Cleary [40] discuss the complex relationships among environmental and individual patient characteristics, symptom and functional status, and HRQL. Nevertheless, for the rather limited goal of assessing satisfaction with medication, we believe that assessment of environmental and many individual personality and motivational variables will result in far greater complexity than is warranted in many medication satisfaction studies. Nonetheless, if a medication has an impact on HRQL or functional status, it is important to assess the patient's satisfaction with this effect, even though it may occur indirectly through the drug's action on symptoms and side effects.

There are factors that may influence satisfaction with medication that have little or nothing to do with the perceived effect of the drug on symptoms, HRQL, or functional status. These factors include the ease and convenience with which a patient can adhere to their medication. For example, the mode of administration or medication storage requirements of a new medication may be more tolerable than previous treatments. Patients would then be more satisfied with this medication because it would be easier to use. Other factors include the medication's dosing schedule, the patient's confidence in his or her ability to take the medication properly, or the comfort level a patient feels with the amount of information received on the medication from the physician or other health-care provider. Although these factors may have negligible impact on the patient's well-being, they may very well be a determining factor in satisfaction in cases where the drug and its comparators have similar clinical efficacy.

Figure 2 also conveys the concept that the patient's judgment of satisfaction with medication is mediated by his or her expectations with respect to the impact of the medication on symptom relief, on side effects, and on HRQL and functionality. The importance of expectations is described in more detail in the next section.



**Figure 2** Depiction of relation among different patient-reported outcomes.

### Conceptual Issues: Theoretical Justification and Domains of Satisfaction

#### *Satisfaction as an Antecedent of Adherence: The Theory of Reasoned Action*

In their review of the patient compliance literature, Morris and Schulz [25] state: "More than 20 years

of research in the area of compliance has produced very little consistent information on the factors which can be correlated with noncompliant behavior. Most of the variables examined are inconsistently correlated with compliance and thus cannot be used to predict compliant behavior adequately.” Morris and Schulz [25,26] argue that the patient is an active participant in the decision to comply or not comply with a prescribed medical regimen and that to better understand and predict compliance, it is important to consider the patient’s perspective. Adherence to a given medical regimen may be related to an individual’s lifestyle, financial options, level of disease symptoms versus medication side effects, and other factors. Thus, an understanding of different aspects of a medication, such as clinical (e.g., symptom relief, side effects), HRQL, and financial, should be given attention in the assessment of treatment adherence.

There are several useful conceptual models to assist us in gaining insight into satisfaction with medication. We find models that are consistent with that of the admonition by Morris and Schultz [25] to treat patients as active participants and decision makers in the decision to take their medication [41] to be most useful for our purposes. In particular, we believe that the Theory of Reasoned Action (TRA) [42–44] is a particularly useful heuristic for understanding satisfaction with medication and adherence to treatment from the patient’s perspective, as well as for linking adherence to satisfaction. It should be noted that TRA has a long history of use in both health and nonmedical-care-related phenomena, including smoking [45], drinking [46], contraceptive use [47], exercise behavior [48], voting [49], and wearing seat belts [50]. There have also been some applications of TRA to the issue of medical compliance [51–53]. Although it is not necessary to invoke TRA to justify the assessment of patient satisfaction with medication, TRA leads to several important concepts that can be translated into research on satisfaction with medication.

The TRA was developed explicitly to address the issue of the relationship between attitudes and behaviors. Hence, to glean useful insights from TRA, we can consider satisfaction with medication to represent the patient’s “attitude” toward the medication or, more specifically, the patient’s attitude toward “taking the medication.” Both attitude and satisfaction are constructs that deal primarily with the evaluative aspects of a person’s perception of an object; hence, the substitution of one construct for another for purposes of gleaning possible insights should not be considered too far of a stretch with respect to

either construct. According to TRA, attitude toward the behavior of taking one’s medication is determined by two elements: the person’s beliefs about the outcomes of performing the behavior, weighted by the evaluation of each of these outcomes [43]. Thus, a person who believes that mostly positively valued outcomes (e.g., cessation of symptoms, no side-effects of drug, positive impact on lifestyle) will result from engaging in the behavior of taking the medication in the prescribed fashion will have a positive attitude toward their medication. Conversely, a person who believes that more negative outcomes (e.g., painful side effects, only modest reduction in symptoms, a drug administration mode such as subcutaneous injection that severely crimps one’s lifestyle) result from taking the medication will have a less positive attitude toward taking their medication.

It is important to keep in mind that the beliefs under consideration are very specific to the act of taking the medication (i.e., “If I take this drug for my disease, then I will have . . .”). In this sense, they serve as expectations about taking the drug—in fact, TRA is an expectancy-value model. In this way, TRA helps us to link expectations about a drug to satisfaction. To the extent that one expects—or believes—that positive outcomes will continue to result from taking the medication, the more satisfied that person should be. Should expectations not be matched or exceeded—for example, the extent of symptom relief was not as great or the side effects were worse than expected—then we would expect satisfaction with the medication to suffer. It is this sense, then, that expectations are seen to mediate judgments of satisfaction, as shown in Figure 2.

Note that a person’s expectations about the outcomes of taking a medication can be formed and influenced by a myriad of factors, as shown in the right side of Figure 2. A person’s experience with the specific drug or with the class of drugs will often be the greatest influence on these beliefs (“This migraine medication has resulted in relief of pain symptoms before; it will do it again.”). But for beliefs about a drug the patient has not taken before, there will be other factors, such as communication from the physician (“My doctor indicated that this drug will work better than aspirin in relieving my headaches.”), from other people (“This drug has worked really well for my spouse in relieving his/her pain symptoms.”), from advertising (“They claim to have relieved headaches in four of five patients.”), from experiences with medications in general (“Drugs never seem to work for me.”), and so on. Note that these beliefs about the impact of taking the drug are expectations that are subject to

change as new information is received and processed by the patient. In addition, disease and treatment history will have an influence on forming expectations, as described later in the article.

With respect to the relationship of satisfaction to adherence, the TRA model states that the best predictor of behavior (i.e., adherence) is the intention to engage in that behavior. The attitude toward taking the medication—satisfaction—is only one of the elements that are predictive of intention. The second determinant of behavioral intention is the subjective norm that a person has about engaging in the behavior. The subjective norm is determined by two components—the person’s normative belief as to whether important referent individuals (e.g., primary physician, spouse, friends) want the person to adhere to their prescription regimen, weighted by the person’s motivation to comply with each of these referent individuals.

What are some of the implications of this model for research in satisfaction with medication? We believe the most important insight provided by TRA is the recognition that satisfaction with medication is based on the beliefs of the patient about the likely outcomes of taking the medications and the patient’s evaluations of these outcomes. Most research in TRA starts with ascertaining salient beliefs “from the subject’s perspective.” Therefore, TRA guides us to assure that we capture all salient aspects of impacts of taking the medication as viewed by the patient. Hence, it is important that great care is taken in assuring that the medication-related outcomes that the patient is asked to evaluate contain no major errors of omission. In the extreme, this would lead to each patient generating his or her own list of salient beliefs and outcomes associated with taking a drug, as well as the value placed on each of these, resulting in satisfaction being determined in a completely idiosyncratic manner. Nevertheless, as in most research in patient-reported outcomes, there are measurable domains of medication-related outcomes that are common to most patients and for most drugs, as discussed later in this article.

A second implication of TRA is that although the behavior of taking the medication can be predicted by the patient’s intention to take the medication, this relationship is less than perfect. TRA assumes that the patient is a rational decision maker; the patient actively decides whether or not to rigorously adhere to the prescription regimen. Nevertheless, not all behavior stems directly from conscious reasoning. For example, patients sometimes forget to take their medication—this is not a conscious deci-

sion on their part. Similarly, the notion of reasoned action may be problematic for some psychiatric illnesses and, indeed, compliance with psychotropic drugs is generally poor [54–57]. Hence, TRA shows us that although assessment of patient satisfaction with medication can help to better understand prescription adherence, it will not always fully explain it (i.e., assessment of satisfaction is necessary but not sufficient for understanding patient adherence).

A third implication of the TRA model focuses more on the issue of adherence than on the patient satisfaction. According to the TRA, the normative component involving motivation to comply with others is another potential predictor of adherence. This helps us to place into perspective the literature on the relation between physician communication styles and patient adherence [20]. Specifically, from the perspective of TRA, it is likely that the physician would almost always be a salient referent individual; friends, spouse, etc., are likely to be other salient referent individuals. It could well be that, in addition to influencing a patient’s expectations, as shown in Figure 2, physician communication styles may influence the patient’s motivation to comply and impact adherence through that route. Note that this is completely independent of satisfaction with medication.

Finally, inherent in the TRA model is the focus on matching the behavior of interest to the level of specificity of the underlying beliefs and values that form the basis of inquiry. If the specific behavior of interest is taking one’s medication, then the level of inquiry should be with respect to the beliefs (i.e., expectations) about the outcomes associated with taking the medication and the value placed on those outcomes. This is consistent with Figure 1. If our interest is in a specific medication, we should focus our inquiry on satisfaction with that medication and not on the more general satisfaction with the treatment and its context or on the health system in general.

#### *Domains of Satisfaction*

As described above, TRA leads us to the importance of understanding important outcomes of medication from the perspective of the patient. The outcomes in any particular study involving satisfaction with medication research should be disease and medication specific. Nevertheless, for many research applications, these specific outcomes will fall into one of the following domains:

*Symptom Relief/Efficacy* Patients are taking medications to relieve symptoms and to achieve cure of

disease, if possible. Therefore, one major domain of satisfaction involves the extent to which the medication is efficacious and provides symptom relief. Although it is possible to inquire about overall symptom relief and/or efficacy, the more precise assessment tools will inquire about satisfaction with relief of specific symptoms (e.g., itching and tearing for allergy medications, ear pain for otitis externa medications [8]). In addition, the questionnaire will often assess satisfaction with the time until symptom relief (i.e., onset of action, extent of effect, and duration of effect). The specific symptoms and aspects of symptom relief that are actually included in the satisfaction questionnaire must be based on patient input. This is discussed in more detail later.

For most diseases and medications, we would expect efficacy—the degree to which the drug results in cure and/or symptom relief—to be the most important determinant of satisfaction with medication. Nevertheless, satisfaction research is often invoked when there are trade-offs involved between competing drugs (e.g., one drug may be quicker acting but has a less favorable side effect profile). Or one drug may result in quicker onset of relief, but another drug may result in greater duration of relief. Or one drug may have a much more convenient dosing schedule or mode of administration than a comparator. These are the very types of situations in which a manufacturer might wish to assess patient satisfaction studies. It is much less likely that satisfaction research would be invoked when these types of trade-offs are not involved.

*Side Effects* For some drugs and for some patients, the cure might be seen as “worse than the disease.” Satisfaction with the side effects of a medication and degree of satisfaction/dissatisfaction with these side effects should be assessed in the questionnaire. The specific side effects about which satisfaction data are obtained should be based on the known side effects of the drug and also based on patient input. The issue of the impact of side effects on satisfaction with medication is likely to be most salient when comparing drugs of approximate equivalent clinical efficacy, but with different side effect profiles. In addition, as discussed later, the saliency of side effects can change over the course of the prescription (e.g., side effects early on during the course of treatment may be less important than side-effects later in the treatment).

*Ease and Convenience* Frequently, newer formulations of drugs will compete on the basis of ease and convenience to the consumer. Aspects of ease and convenience include dosing schedule; mode of

administration (e.g., pill, liquid, injection, patch, inhaler), restrictions associated with the medications (e.g., with meals, avoidance of certain foods), and product-specific designs (e.g., portability of certain devices, operation of devices). As with side effects, the saliency of ease and convenience factors is likely to be greatest when comparing medications of approximately equal clinical efficacy.

*Impact on HRQL* From a patient’s perspective, one of the key reasons for treating an illness and seeking symptom relief through medication is to return to a normal (i.e., predisease) state of HRQL or, in the case of chronic conditions, to attenuate the impact of the indication on HRQL. Hence, in addition to assessing the impact of a treatment on a patient’s HRQL, we can also assess the patient’s satisfaction with that impact. In fact, Shikier et al. [8] found that the single best item correlating with overall satisfaction with a medication for otitis externa was an item dealing with satisfaction with time to return to normal activities.

As in the case with the other domains of satisfaction, it is important that the HRQL domains about which satisfaction of the impacts of medication are to be obtained should be specific to the disease–drug combination (e.g., it may not be worth the effort to ask about bodily pain if neither the disease nor the medication involves bodily pain) and also be based upon salient HRQL dimensions from the patient’s perspective.

*Overall or General Satisfaction* In addition to the specific domains about which satisfaction might be obtained, it is frequently useful to include a few questions dealing with overall satisfaction. Examples of questions dealing with overall satisfaction include: “How satisfied are you with your medication?”; “How likely are you to recommend this medication to a friend who had the same disease?”; and “Would you ask your doctor to prescribe this medication in the future if you suffer from this disease again?” Having several items that assess overall satisfaction allows the researcher to compare this overall satisfaction with satisfaction with symptom relief, with side effects, with impacts on HRQL, with ease and convenience, etc. Analyses involving the different domains of satisfaction allow the researcher to understand the key drivers underlying satisfaction with the particular drug.

*Additional Domains* Any given patient satisfaction research program may result in program-specific domains that are relevant to the specific disease, drug, and/or comparator. For example, in some sit-

uations involving a new device, questions might be asked about the patient's confidence in using the device. In other instances, satisfaction with the information provided about the drug—by the package insert, the physician, the pharmacist, and/or the nurse—might be deemed important to ascertain, or ease of storage of the drug or device might be salient in some instances. In their review of the satisfaction literature, Weaver and colleagues [10] list 17 different topic areas that had been used in at least two studies.

### **Developing Psychometrically Sound Satisfaction Instruments**

#### *Item Generation*

Generating a satisfaction instrument entails gathering information from different sources. One source of information is the published literature on the disease and its treatment, including the clinical trial literature. Patient involvement is essential to develop an initial item list and assist with refinements of the questionnaire. Using any one or more of patient elicitation techniques (e.g., focus groups, structured interviews, open-ended interviews), the researcher should ascertain the most salient aspects of taking the medication from the patient perspective. Physicians who have broad experience in treating the disease and use of medications for the disease will be able to identify and/or clarify issues raised by patients. Finally, it is good practice to pilot test the draft instrument with a group of patients then query them as to their interpretations of each item. This “cognitive debriefing” will result in deletions, additions, and modifications to the draft instrument.

#### *Framing the Questions*

Streiner and Norman [58] describe biases common to most questionnaires, as well as strategies for minimizing its impact on the responses given to the questionnaire. In addition, several researchers have discussed the prevalence of acquiescent response bias (ARB) or social desirability response set (SDRS) within satisfaction-with-care studies [14,59].

#### *Psychometric Analyses*

The psychometric properties of the instrument should be established, including its reliability, validity, and sensitivity, depending on the actual research design. Standards and guidelines exist for evaluating reliability and validity of various patient-assessed instruments [60–63].

### **Additional Issues for Consideration**

#### *Potential Transitory Nature of Satisfaction*

The beliefs and values underlying satisfaction may change over time. When this occurs owing to adaptation to an illness, it is referred to as “response shift.” Response shift may also occur owing to a patient's change in internal standard of measurement or a personal redefinition of satisfaction [64,65]. For example, over the course of the treatment regimen, as symptoms of a disease subside, a drug's side effects or lifestyle limitations may become more prominent and the actual disease symptoms may become less important. To the extent this results in changes in satisfaction with the medication, this might help explain a decrease in adherence over time. Therefore, appropriate measurement of satisfaction with medication requires long-term and/or repeated observations. Additionally, it may be necessary to actually measure whether a patient's beliefs or values have changed over time, actually taking into account the response shift [64,65].

Another aspect of the transitory nature of satisfaction is that expectations about a medication are formed in part by disease and treatment history. Dawson et al. [66] recently explored the paradox of patients expressing satisfaction with inadequate pain management. They demonstrated that satisfaction was related to the patient's expectations about pain and its inevitability, and they point toward improving patient–provider relationships to help shape patient expectations about pain management. Of course, the physician is not the only source of information that may shape patients' expectations. Increased DTC advertising over the past decade has likely changed consumer expectations about the efficacy of many medications. Finally, the relationship between expectations and satisfaction has been demonstrated in the realm of satisfaction with medical care [67–69]; as more research is performed in the area of satisfaction with medication, we would expect similar findings to appear.

#### *Patient History and Other Characteristics*

Related to the notion of expectations is the difference between patients with long-term chronic illnesses who have tried a variety of therapies versus first-time medication users. The former might have very different expectations about a new drug than the latter, and so might be much more satisfied with an incremental improvement in outcomes, whereas the latter might be disappointed in a small improve-

ment. In performing satisfaction research, it is important to take into account patients' backgrounds, especially disease history. These differences might be handled statistically, but if they are not assessed, they cannot be taken into account in any analyses.

### **Patient Satisfaction Claims: Regulatory Implications**

Because patient satisfaction is a patient reported outcome, it would stand to reason that the requirements for making claims on other patient-reported claims would have relevance to satisfaction with medication. Leidy et al. [31] discussed in detail recommendations for evaluating the validity of quality of life claims for labeling and promotion. In short, they recommended:

- Assurance that all relevant domains are included—this translates to the content validity evidence for the instrument. Having patient feedback as an integral part of instrument development is very important in establishing the relevancy and content-coverage of domains of satisfaction.
- A well-documented rationale for including the domains—for example, it should be clear why satisfaction with ease and convenience with respect to a medication under study was included in the study.
- Evidence of instrument reliability and validity—thorough and appropriate psychometric analyses will provide the requisite evidence.
- Clear objective and hypotheses—the satisfaction claim should not be the result of a “fishing expedition.” Studies should be based on the expected advantage of one drug over an appropriate comparator, and the statistical hypotheses and delineation of primary and secondary outcomes should reflect these expectations.
- Adequate sample size—the study should be appropriately powered. In fact, the FDA will frequently want to see the results from more than a single, well-constructed study.
- Careful implementation—the studies developed to assess differences in satisfaction should undergo the same rigor as other clinical studies that will be used to make clinical claims.
- Complete disclosure of all results—in accord with the statistical plan, all outcome measures, both primary and secondary, should be reported.

### **Summary and Conclusions**

Patient satisfaction with medication is a potentially important patient-reported outcome. There is reason to believe that it is an important factor linked to adherence with medications, which has been repeatedly a major concern in health care [27,28,70–72]. Satisfaction has been all too often taken lightly as an outcome measure. When it is collected in clinical trials, it has often been as a single, untested item. Nevertheless, just as the inclusion of HRQL in clinical trials and other medication research has resulted in a more scientific, methodologic approach to its assessment over the past two decades, if patient satisfaction with medication is to be treated as the important outcome measure that we believe it is in many situations, then the field should be subject to similar, rigorous methodologic standards.

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