

# The Role of Health-Related Quality-of-Life Data in Pharmacy Benefit Decisions

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**ABSTRACT** To better understand the role of health-related quality-of-life (HRQOL) information in the formulary management process, focus groups were conducted with pharmacy benefit decision-makers. Participants reported that HRQOL information can be useful when other more

important factors (e.g., efficacy, cost) are equal. Participants believed pharmacy benefit decision makers are not trained to interpret HRQOL data and that relevant and timely HRQOL data are generally unavailable. Thus, HRQOL information is currently of limited use in formulary management.

The pattern of illness in the U.S. has shifted from mostly acute disease to one in which chronic conditions predominate. Although there are many diseases that can shorten life expectancy, it is more likely that a disease will have adverse health consequences that result in dysfunction and decreased well-being. Hence, patient self-reports of functioning and well-being, or health-related quality of life (HRQOL), are increasingly viewed as important measures of therapeutic outcome. Sanders and colleagues found that the reporting of quality-of-life therapeutic endpoints in randomized controlled trials increased more than 650% between 1980 and 1997.<sup>1</sup>

As described by Badia and Herdman, the relative importance of HRQOL information depends on the type of condition (i.e., chronic or acute) and the type of treatment (i.e., preventive, curative, or palliative).<sup>2</sup> In chronic conditions (e.g., osteoarthritis, angina, Parkinson's disease), HRQOL might be a primary measure of therapeutic efficacy, whereas in acute conditions (e.g., community-acquired pneumonia, urinary tract infections), the primary goal is usually to cure the disease (i.e., infection eradication). Commonly measured dimensions of HRQOL include physical functioning, psychological/emotional functioning, social/role functioning, and perception of well-being.

The pharmaceutical industry has been the principal driving force behind the recent expansion in the number and type of HRQOL instruments available to clinicians and researchers.<sup>3</sup> Therapeutic areas receiving increased attention from the pharmaceutical industry include arthritis, asthma, cancer, diabetes, end-stage renal disease, HIV, hypertension, migraine headaches, and other chronic diseases. Information based on patient-reported perceptions of the impact of pharmaceuticals on HRQOL are beginning to be included in product labeling

and promotional materials.<sup>4-6</sup> This is likely to occur with increasing frequency as pharmaceutical firms look for ways to demonstrate value and differentiate their products from competing therapies.

Information regarding the impact of pharmacotherapy on HRQOL can provide additional data for making medication-use policy and formulary decisions.<sup>4,7</sup> The use of formularies among managed care plans has been slowly increasing as more patients have access to pharmaceuticals as part of their basic health benefits.<sup>8</sup> Numerous clinicians, researchers, and clinical practice organizations have recommended that HRQOL data be considered in formulary development.<sup>9-12</sup>

However, the literature suggests that HRQOL data are not commonly included in the pharmaceutical formulary management process.<sup>8,13,14</sup> The goal of this preliminary research was to investigate the role of HRQOL data in pharmaceutical coverage decisions within managed health care plans. The specific objectives were to assess, in a focus-group format, decision-makers' perceptions regarding: 1) the relative importance and value of HRQOL data in the formulary management process and 2) the quality of HRQOL data available in the published literature and promotional materials.

## METHODS

To fulfill the research objectives, two focus groups with five participants each were planned. Potential participants were identified, based on their job titles, from among pre-registrants of a conference sponsored by the University of Arizona's Center for Health Outcomes and PharmacoEconomic Research. They were contacted by telephone to determine interest in participation and eligibility. Specific inclusion criteria required that they: 1) be 18 years of age or older; 2) be in a position in which they make pharmaceutical benefit decisions; 3) be able to successfully communicate in English in a group setting; and 4) have signed written informed consent to participate. This project was conducted under the auspices of the University of Arizona's Human Subjects Committee. The participants were provided with an honorarium.

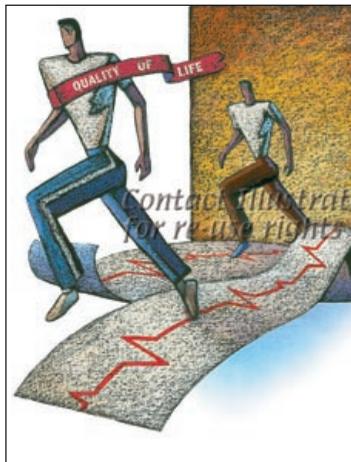
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Illustration by John Evans, 2002.



The two focus group sessions were identical and divided into four parts. During the first part, participants were given an introduction to the topic. Next, the participants were asked to rate the importance of various factors/inputs (Table 1) in their organizations' formulary management. Then, the participants were asked to read an abstract of a published randomized clinical trial

(RCT) in which HRQOL was a measured outcome of the intervention. Facilitated discussions were held in the final part of the focus group, during which participants were asked about their 1) conceptualization of HRQOL; 2) perceptions of the usefulness of the HRQOL data presented in the abstract; and 3) views on the quality of HRQOL data that was generally available in the literature or promotional materials. In addition, participants were prompted to discuss their perceptions of the value of HRQOL data in the formulary management. The focus group discussions continued until no new information was obtained. The focus groups were audiotaped and transcribed and a content analysis of the transcriptions was performed.<sup>15,16</sup>

### RESULTS

To obtain the target of 10 focus group participants, 29 prospective participants from the conference pre-registrant list were identified and contacted. Although eight men and three women met the inclusion criteria and agreed to participate, three of them were unable to attend, leaving a total of eight (i.e., six men and two women) focus group participants. These participants were on P&T committees that made pharmaceutical benefit decisions for over 500,000 enrolled lives.

Participants described HRQOL as an evaluative tool that includes the patient's acceptance and tolerance of a medication as well as the convenience associated with the use of a medication. Furthermore, they described HRQOL as a measure of patients' involvement in activities of daily living and physical functioning. They also perceived it to be implicit that all pharmacotherapy is designed to improve HRQOL (e.g., "the goal of drug therapy is to allow patients to live their lives to the fullest"). Table 2 provides the importance ratings for the drug coverage decision-making factors on a scale from 1 ("not important") to 5 ("very important"). Of the eight factors, participants rated "efficacy of the drug" and "consumer demand for the drug" the most and least important factors in drug coverage decision-making, respectively. "Health-related quality-of-life effects of the drug" was rated at approximately the midpoint (i.e., 3.2) of the importance scale.

**Table 1 Factors in the Drug Coverage Decision**

Efficacy of the drug
Cost of the drug
Consumer demand for the drug
Physician demand for the drug
Health-related quality-of-life effects of the drug
Cost-effectiveness of the drug
Safety of the drug
Rebate arrangements affecting the drug

**Table 2 Importance\* of Specific Factors in Drug Coverage Decisions**

Factor	Mean Rating	Range
Efficacy of the drug	4.9	4-5
Cost-effectiveness of the drug	4.4	4-5
Cost of the drug	4.0	3-5
Safety of the drug	4.0	2-5
Physician demand for the drug	3.4	2-4
Health-related quality-of-life effects of the drug	3.2	2-4
Rebate arrangements affecting the drug	2.9	1-5
Consumer demand for the drug	2.4	2-3

\*On a scale of 1 to 5 with 1 being "not important" and 5 being "very important"

Four dominant themes emerged from the analysis of the discussions: 1) although the quality of HRQOL data in the literature or in promotional material is perceived to be good, the data are not routinely applicable to the formulary decision-making process; 2) formulary decision-makers are not trained to interpret HRQOL data; 3) HRQOL data is valuable only when other more important factors are equal; and 4) the usefulness of HRQOL data can be enhanced, but it will take a concerted effort on the part of health care professionals.

### Applicability of HRQOL Data

Participants were in agreement that HRQOL data appearing in scientific/clinical literature and promotional material based on RCTs could be of good quality, but that data from effectiveness studies that were performed in a managed care setting would be preferable. Participants did not perceive that HRQOL information based on effectiveness trials was readily available ("you don't generally see effectiveness trials with HRQOL as an endpoint"). Participants' overall perceptions of HRQOL data from RCTs were that the data were: 1) incomplete, because not all comparable drugs were tested ("they pick and choose the drugs they want to compare so that theirs will look better"), and based on short durations of follow-up ("our patients are with us longer than a six-month follow-up") and 2) not applicable, because the subjects in RCTs were not similar to their managed care patient populations ("they pick and choose their subjects; we have to care for all of our sub-

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scribers”). In addition, participants perceived HRQOL data from post-marketing studies as lacking timeliness (“Information on drugs changes every three months; most of these trials are a couple of years old.” “[We] have to wait for phase IV trial results and they aren’t ready until at least a year after the drug is released”).

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**Participants described themselves and their formulary decision-making colleagues as unsophisticated in the understanding and interpretation of HRQOL data—as one participant said, “our P&T committee has no HRQOL ‘expert’ to help us interpret the data.”**

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### Interpretation of HRQOL Data

Participants described themselves and their formulary decision-making colleagues as unsophisticated in the understanding and interpretation of HRQOL data—as one participant said, “our P&T committee has no HRQOL ‘expert’ to help us interpret the data.” Participants described P&T committee members (e.g., physicians and pharmacists) as untrained in relating HRQOL data to clinical significance (“physicians on P&T committees rely on their personal experience to make decisions”). Some participants verbalized their perception that larger organizations (e.g., Kaiser, the Blues, etc.) had staff trained in HRQOL interpretation. Participants from large organizations did not corroborate this perception.

### Value of HRQOL Data

Gauging the importance of data to formulary decision-makers on a scale from 1 to 5, participants, on average, rated data regarding the HRQOL effects of a medication at the midpoint. Although no tests of statistical significance were performed, this rating was numerically lower than average ratings for data on the medication’s efficacy, cost, cost-effectiveness, physician demand, or safety. Only data on consumer demand and on rebate arrangements of the medication were rated lower in importance than HRQOL data (“Other factors besides HRQOL weigh more heavily”). Participants were in agreement that when it came to making formulary decisions, safety, efficacy, and cost were the primary factors in their decisions (“Only when other more important factors [costs and efficacy] are equal do we consider HRQOL”).

Participants did not perceive a demand from consumers or third-party payers to include HRQOL in the formulary decision-making process (“Payers don’t see the value in it [HRQOL data].” “Baby boomers want it [HRQOL data] included but employers don’t see the value”). Participants were unsure of any health plan that required submission of HRQOL data as part of the dossier for formulary decisions.

Participants were in agreement that appeal mechanisms are in place so that decisions regarding the use of non-formulary, HRQOL-enhancing medications can be made at the patient level. Participants wondered what value HRQOL data will provide in the future as managed care organizations shift from closed formularies to multi-tiered co-pays (“its value may be only for high-profile drugs”).

### Enhancing the Usefulness of HRQOL Data

Participants agreed that to enhance the usefulness of HRQOL data in the formulary management, employer groups and health care consumers must first be convinced of the value of HRQOL data. They also stated that health care professionals need to be trained in the use and interpretation of HRQOL data before it will be widely accepted as a factor in formulary decision-making (“Health care professionals need to be educated on the value of this data [HRQOL] from the start of their training”).

To increase the use of HRQOL data in the formulary decision-making process, participants recommended that: 1) HRQOL data need to be made available in a more timely manner (“data needs to be available when decisions are being made”); 2) HRQOL data from effectiveness studies, as opposed to RCTs, would be more accepted by decision makers (“Data from studies in naturalistic settings is more relevant to me than data from RCTs.” “Sample sizes of the studies need to be large”); 3) a standardized system of reporting HRQOL data needs to be established (“Every study uses a different [HRQOL] instrument; it’s hard to compare one study to the next”); and 4) presentation of HRQOL data needs to be improved (“HRQOL scores can be confusing; the data needs to be presented more visually”).

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**Participants were in agreement that when it came to making formulary decisions, safety, efficacy, and cost were the primary factors in their decisions.**

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## DISCUSSION

These results are exploratory and are limited by the small number of participants and managed care organizations represented. No attempt was made to obtain a random or representative sample of managed care decision-makers, so the findings cannot be generalized beyond the study participants. However, a number of the findings are consistent with results reported by other investigators.

Focus group participants reported that only when other more important factors (i.e., acquisition cost, safety and efficacy) were equal was HRQOL information of value in the formulary management process. This finding was not surprising because other authors have reported that decision-makers

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placed less value on HRQOL data than other data in the decision-making process.<sup>17,13,8,14</sup> Even if all the proposed steps were taken to enhance the usefulness of HRQOL data in formulary/pharmacy benefit decision-making, it is unlikely that HRQOL data would move up appreciably in relative importance in this context.

Participants reported that they were, in general, untrained in the analysis and interpretation of HRQOL data. HRQOL data might not be used to formulate policy decisions because the consequences and impact of a medication on patients' self-reported HRQOL is not readily understood or appreciated by them. Although survey data indicate that decision-makers are familiar with pharmacoeconomic analyses, only a small percentage reported that they had completed training (e.g., certification) in pharmacoeconomics beyond individual continuing education programs.<sup>17</sup> It is likely that even fewer of them have an adequate grasp of HRQOL assessment and its application.

Most HRQOL data were generally unavailable when the formulary decisions were being made and were not applicable to the managed care patient population for which the decisions were being made, according to participants. In addition, there was concern that HRQOL studies might be designed (e.g., in the selection of comparators) by sponsors to reflect most favorably upon their products. The fact that participants perceived HRQOL data from RCTs to be of lesser value was somewhat puzzling because they did not report that safety and efficacy data from RCTs was not applicable to their patient populations. However, these findings might reflect the respondents' relative comfort level with their ability to evaluate different types of RCT data (efficacy vs. HRQOL) and/or their recognition that most RCTs are designed to evaluate clinical efficacy as the primary endpoint and that HRQOL, if measured, would be secondary.

Participants believed that, to enhance the usefulness of HRQOL data in health care decisions, consumers and purchasers/payers must be better informed about the role of HRQOL data in demonstrating the overall value of medications. In addition, participants agreed that health care professionals must be trained in the interpretation and application of HRQOL data. These findings support the position of other authors who have asserted that the education of health care consumers and the training of health care professionals in HRQOL assessment must be improved before HRQOL data is widely accepted in the formulary management process.<sup>7,18</sup>

### CONCLUSIONS

Although HRQOL information is seen as increasingly important in documenting therapeutic outcomes, it does not appear to be a significant factor in formulary/pharmacy benefit decision-making at this time. This might be caused by the lack of rele-

vance and/or value attributed to it by decision-makers. Patients might be the more receptive consumers of HRQOL information, a concept that has not been lost on the producers of direct-to-consumer advertisements (DTCAs) for prescription medications. Most of the current DTCAs are presenting an implicit or explicit HRQOL message. Although it is hard to obtain precise data on the actual demand created by DTCAs of this type, there is no doubt that managed care organizations are dealing with the effect of medication-related HRQOL information, one way or another. ■

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