



POLICY PRINCIPLES: HEALTH CARE VALUE ASSESSMENT

BACKGROUND

The U.S. health care system is experiencing a shift in how it delivers and pays for care—moving from a model that is based on volume or a simple transaction of services to one based on value. However, “value” is not one-size-fits-all; it varies based on an individual's personal circumstances and life stage or across diseases and conditions; can span clinical and economic to quality-of-life outcomes; and can change over time.

WOMEN AS A SOCIETAL DRIVING FORCE

- Women comprise [more than half \(51%\)](#) of the U.S. population.
- In the United States, women make more than 80% of health care spending decisions.
- Women provide the majority of caregiving.
 - More than [75% of all caregivers](#) are female.
 - Female caregivers may spend as much as [50% more time](#) providing care than men,
 - Millennial women (aged [22-39](#)) comprise [more than one-third](#) of all multigenerational caregivers, which could result in “[caregiver squeeze](#),” affecting social and economic outcomes.

Determining what constitutes value is referred to as value assessment. [Value frameworks](#), which are continually being developed and tested, incorporate an assessment of evidence from clinical and economic data to inform decision-making about health care interventions for a range of audiences, including patients, health care providers, and entities that pay for health care, such as insurance companies and federal agencies. They are increasingly used in medication review processes and formulary decisions as well as to determine coverage.

Women—with diverse needs as patients, caregivers, and often as the chief health decision maker of the family—must be accounted for within health care value assessments.

The Society for Women's Health Research (SWHR), which has worked during its more than 30-year history to address women's unique health needs, supports a patient-centered approach to value assessment. We are committed to ensuring that frameworks are appropriately designed and used to meet women's needs, account for patient population diversity, and have the infrastructure and analytic capacity to evaluate data that matter to women. Health care interventions have the potential to reduce disparities in the United States; this value to society should be recognized and incentivized.

The Policy Principles provided herein build upon SWHR's 2019 “[Policy Principles: Health Care Value Assessment](#).” By revisiting the 2019 Principles, SWHR reflected on the current health care value assessment landscape and identified additional opportunities to promote patient-centered value and incorporate factors that are relevant for women in the ongoing improvement of their health and quality of life.

SWHR VALUE ASSESSMENT PRINCIPLES

- I. **Value assessments should consider and account for differences among patient populations and subgroups.** Population differences, including sex and gender, should be considered and accounted for in value frameworks to inform what is or is not known about variation in response to different treatments. Value assessments that acknowledge patient heterogeneity will be better positioned toward providing value to all patients.
 - a. Due to historical underrepresentation in clinical trials, research outcomes from predominately male cohorts have [driven the creation](#) of clinical guidelines that are not sex-specific. Yet, biological and physiological differences and hormonal fluctuations [have been shown to play a role](#) in the rate of drug absorption, distribution, metabolism, and elimination, resulting in different drug responses in women and men.
 - i. [Sex](#) refers to the classification of living things according to reproductive organs and functions assigned by chromosomal complement.
 - ii. [Gender](#) refers to the social, cultural, and environmental influences on the biological factors of women or men. Gender is rooted in biology and shaped by environment and experience.
 - b. Factors, including comorbidities, age, genetics, and life stages (e.g., pregnancy) can affect drug response. As a result, the value of a given treatment may vary across subpopulations or could change over time, such as in aging populations when new comorbidities arise.
 - i. [Studies have shown](#) that multimorbidity and the number of chronic illnesses increase with aging and that, as people age, the number of medications they use increases.
 - ii. [Reviews](#) and [studies](#) have shown that there are differences in drug disposition among different racial and ethnic populations.
 - iii. For some patients, such as those with autoimmune diseases and conditions, an optimal treatment or management regimen may involve a combination of therapies, further demonstrating the importance of considering different needs across a diversity of patient populations.
 - c. Due to the historical underrepresentation of groups, including [pregnant and lactating populations](#) and [persons with disabilities](#) in clinical trials, scientific evidence regarding these populations is often lacking. Value assessment frameworks must consider, account for, and accurately communicate what is known and unknown about these populations and avoid taking a “one-size-fits-all” or “one-size-fits-most” mentality for assessing value.
 - d. Value is context specific. Research is increasingly pointing to how social determinants of health (SDOH) affect health and quality-of-life outcomes and risks. Identifying ways to gather and assess SDOH data could provide tremendous insight into optimizing care.

VALUE ASSESSMENTS' ROLE IN ADVANCING HEALTH EQUITY

Value assessments, by their very nature, should help improve health care access and advance health equity. If value assessments appropriately consider diverse populations and accurately reflect the varying needs of those populations, they can help drive improvements in research and research methods, account for diverse needs in real-world clinical practice, and inform policy decisions, including decisions around the allocation of health care resources, drug pricing, and improving participation in clinical trials. Further, value assessments should make every effort to avoid exacerbating health disparities. For instance, value assessors should consider whether factors, such as Quality Adjusted Life Years (QALYs), could discriminate against certain populations as well as ensure that value is being examined across multiple metrics.

- II. **Value assessments should acknowledge the full spectrum of treatment options for a given medical condition.** Consideration should be given to patient response, patient preferences, and the types of medical interventions currently on the market.
 - a. Patient subpopulations can differ in their response to a given therapy (i.e., heterogeneity of treatment effect). Therefore, value assessments for new therapies should take into consideration factors, such as patients who cannot tolerate currently available therapies, are contraindicated for these therapies, have heterogeneous responses to these therapies, or for whom these therapies are ineffective or whose conditions have progressed .
 - b. Value assessments should consider all available evidence-based options within the health care system, rather than focus exclusively on medications or one type of medical intervention. Some options may include interventions not regulated by the U.S. Food and Drug Administration (FDA), such as evidence-based behavioral therapies and lifestyle interventions.
 - c. When there are limited treatment options for a given disease or condition, value assessments need to account for the importance of providing patients as much choice as possible when it comes to establishing a treatment plan. Choice alone could be a valuable outcome for certain populations.
- III. **Value assessment frameworks, in addition to measuring clinical outcomes, should account for what matters most to patients, caregivers, and society.** Value measurements should include a broad array of factors to provide a comprehensive snapshot of a treatment's true value, and, they should reflect a whole-person care approach.
 - a. Importantly, value framework assessments should account for the fact that values are dynamic and change over time as patients' individual circumstances and experience of illness and treatment evolve throughout the course of disease. Some factors that could impact one's current value construct include:
 - i. Shifts in prognosis
 - ii. Severity of illness
 - iii. Comorbidities (e.g., obesity)
 - iv. Available treatment/palliative options
 - v. Caregiver availability
 - vi. Life stages and events (e.g., pregnancy, breastfeeding, menopause)

- b. There are several burden of illness factors that are important to—and may be disproportionately experienced by—women. These include, but are not limited to:
- i. Ability to work and workplace productivity
 - Presenteeism
 - Absenteeism
 - Employment disability
 - ii. Quality of life
 - Physical, social, and economic well-being
 - Pain or discomfort
 - Adverse side effects
 - iii. Levels of disease burden and progression, including risk of disability
 - iv. Comorbid conditions or concomitant medications
 - v. Caregiver burden
 - Difficulty, stress, or negative experiences resulting from providing care
 - Physical, emotional, mental, and financial costs associated with caregiving
 - vi. Limitations in treatment
 - No treatments available for a particular condition, disease, or symptoms
 - Limited treatment options (i.e., there have been few innovations in the disease states, the products on the market are contraindicated for a subset or subsets of patients, or available therapy does not meet the patient's preferences)
 - vii. Duration of care (short-term versus long-term)
 - viii. Delivery of care
 - Telemedicine
 - ix. Barriers to access
 - Ability to attend and ease of access to appointments
 - Interactions with health care providers
 - Continuity of care and communication between specialists and primary care providers
 - x. Financial and ancillary costs
 - Health care costs, including general health care costs, out-of-pocket costs, and costs of treatment side effects
 - Time costs
 - Transportation costs
- c. Value assessors must remember that patient values vary and change across patient populations. At a societal level, patient values may be shaped by social, religious, and cultural factors. At an individual level, [treatment-based values are influenced](#) by age, sex and gender, education, family and friends, attitude toward work and career, and personal finances, among other factors.

- IV. **Value assessments should take both the short- and long-term costs and benefits of a given therapy into consideration.** Focusing only on short-term outcomes may overlook important clinical and economic benefits that may become evident over a longer period of time. Further, incorporating long-term outcomes will allow for value assessments to better account for the full value of a therapy or intervention, particularly as additional evidence continues to emerge post-approval.
- V. **Value assessments should contain a range of high-quality and patient-centered sources of evidence.** To account for different population experiences and patient outcomes, value assessments should include a variety of different sources of evidence.
- a. Real-world evidence (RWE), which is derived from data collected during routine health care practice, such as electronic health records, claims and billing files, or product and disease registries, should be considered in value models. RWE is often collected after a new therapy is already on the market and being used by patients. Therefore, RWE can provide insights beyond controlled clinical trial data into the impact of treatments on a diversity of patient populations.
 - b. Patient-reported outcomes and patient preference studies are also important for capturing the lived experiences and preferences from women. These measures can be especially useful in assessments that occur earlier, when there may be a dearth of other data available.
 - c. Although not typically collected as a part of clinical trials, value assessments should seek to account for caregiver outcomes and the costs of informal caregiving. For caregivers—the [majority of whom](#) are women—caregiving responsibilities can affect their physical and mental health as well as their ability to work. Therefore, gauging the impact of interventions from a societal perspective will require caregiving-related data.
 - d. Value assessments should acknowledge and state clearly where there may be a lack of data available, when perspectives are missing, and where there are limitations. Value assessors should also make every effort to identify and include sources—whether quantitative or qualitative—to fill these real or perceived gaps; the assumption should not be that the data or the impact to patients and caregivers doesn't exist.
 - i. Those with rare diseases, for example, may be willing to tolerate a higher amount of risk to achieve their treatment goals and may have a different view of risk than someone who is not living with that particular condition. If frameworks do not directly account for the perspectives of those living with the condition, that needs to be addressed within the framework.
- VI. **Value assessments should account for relevant data that could help assess health and economic outcomes.** Data should provide insight into trends and patterns in health and economic outcomes over time and across different patient populations.
- a. Value assessments should evaluate the impact that utilization management (UM) policies, such as step therapy and prior authorization, and insurance policies, such as non-medical switching, have on patients' health outcomes and on health care system costs.

- VII. **Value assessment organizations should provide ample opportunities for stakeholder engagement to ensure their input is both acknowledged and meaningfully incorporated into assessments.**
- a. Proposed assessment topics, processes, and timelines should be announced in advance and allow for participation by stakeholders, especially those whose resources may be limited.
 - b. Sufficient time and multiple rounds of review should be provided for stakeholders, including patients and patient advocacy organizations, to review materials and submit public comments in various stages throughout the assessment process. Timeframes for stakeholder input on value assessment reviews should be commensurate with established and customary timeframes for other stakeholder review timeframes (e.g., federal government public comment periods are typically not less than 30 days and frequently a minimum of 60 days).
 - c. Stakeholders who have direct, lived experience with, or expertise on, a particular illness and its burden should be appropriately represented on value assessment panels and committees tasked with making determinations about a treatment's value. These stakeholders may include, but are not limited to:
 - i. Patients who are diagnosed with the disease or condition under review (in addition to identifying patients across a diversity of populations, panels may wish to consider ensuring that diverse patient journeys are represented, bringing together perspectives of both newly diagnosed patients as well as patients farther along in their treatment journeys).
 - ii. Health care professionals who actively treat patients with the disease or condition under review.
 - iii. Caregivers who assist patients with care needs for the disease or condition under review.
 - d. Assessments should be subject to regular review. Mechanisms ought to be in place that allow for stakeholders to request a timely review of an assessment to account for new innovations and technologies or changes in the evidence base.

- VIII. **Value assessment processes, methodologies, and results should be transparent to all stakeholders.** Transparency should entail both transparency for patients, ensuring they understand each aspect of the framework development process, and for stakeholders who may wish to review and/or replicate results. While progress has been made in some respects, such as sharing input related to processes among key stakeholders, every effort should be made to ensure transparency surrounding model sources and methods, such as risk equations.
- a. Explanation of assessment criteria, methodologies, and assumptions should be understandable to all stakeholders, including patients.
 - b. Detailed information about how stakeholder input was considered, addressed, or incorporated into the assessment should be clearly and publicly communicated.
 - c. The models, data, and methods used should be made publicly available and subject to review to allow for research findings to be analyzed and the results replicated by others.

IX. **The intended use of value assessment frameworks—and by whom they are intended to be used—should be clearly articulated.** To avoid misuse, assessments should clearly state their intended audience(s) as well as which type of health care decision-making they aim to support.

- a. Value assessments should not be used to prevent patients and their physicians from making evidence-based decisions that are tailored to the specific needs of individual patients.

X. **Value assessment frameworks should be living documents that reflect a system of continuous learning.** Value frameworks should be validated and tested prior to and after development to guarantee frameworks' accuracy and reproducibility and to ensure that they do not harm patients.

Further, these frameworks should be regularly reviewed and updated to account for changes in the evidence base or for changes in medical or technological innovation. Confirming that assessments are current and account for new innovation or an evolving evidence base will better position them to support patient care.

CONSIDERING HEALTH CARE UTILIZATION IN THE CONTEXT OF COVID-19

When considering future opportunities in health care value assessment, there may be important lessons learned and questions raised from the COVID-19 pandemic, including that of health care utilization. While a robust and timely response to the public health emergency was warranted, the prioritization of COVID-19 placed other health care needs on the back burner. People experienced delays in seeing their health care providers and in receiving surgeries or other treatment, and annual routine screenings were neglected. When it comes to health care value assessments, how might we account for these large-scale, unplanned shifts in the health care system—when health care resources and attentions aren't being allocated equitably? How might these changes, which can affect health outcomes, impact value and one's perception of value?

About SWHR

The Society for Women's Health Research (SWHR) is a national nonprofit and thought leader dedicated to promoting research on biological sex differences in disease and improving women's health through science, policy, and education. Founded in 1990 by a group of physicians, medical researchers, and health advocates, SWHR is making women's health mainstream by addressing unmet needs and research gaps in women's health. Thanks to SWHR's efforts, women are now routinely included in most major medical research studies and more scientists are considering sex as a biological variable in their research. Visit www.swhr.org for more information.