The Value of Transformative Therapies: An Interview with Bill Guyer

How one developer and medical educator views the shifting landscape of value frameworks.

Value & Outcomes Spotlight had the good fortune to sit down with Bill Guyer, PharmD, senior vice president of medical affairs at Gilead Sciences in Foster City, CA, USA. In his position, he oversees all therapeutic areas for approved and near-term products including: HIV, viral hepatitis, nonalcoholic steatohepatitis, hematology/oncology and inflammation for Gilead around the world. Bill is responsible for the evidence generation from the company's Global HEOR/Health Technology Assessment function. Additionally, Bill has oversight of the medical affairs function, the group at Gilead that develops and delivers medical education to healthcare practitioners, payers, patients and policy makers, as well as developing and implementing Phase 3b/4 studies for all the company's approved products. Bill also serves as secretary on the board of the Gilead Foundation, which focuses on expanding access to HIV and hepatitis education, outreach, prevention and health services. We recently spoke with Bill about how innovative technology – and curative therapies – are changing the way we think about value models in healthcare.

***VOS:* As we introduce new innovative technologies—for example cell therapy or curative therapy—is the existing health technology framework still valid?**

Bill Guyer: Current value frameworks and assessment methodology for evaluating healthcare technology have largely gone unchanged over the past 30 years, yet there have been tremendous leaps forward medically and scientifically for patients. Healthcare technology has evolved with breakthrough technologies such as cell therapy, as well as our ability to collect and analyze data, from digitized clinical trial data to real world data, that demonstrate the benefits of these breakthroughs for patients, economies, and society at large.

Value frameworks and health technology assessments would benefit from more comprehensive metrics that capture the full impact of transformative therapies. For example, appendectomies for appendicitis and direct-acting antivirals for hepatitis C provide clear-cut cures for life-threatening conditions, with clearly measurable impact on patient health. Curing an infectious disease such as hepatitis C, however, also has compounding effects, including larger public health benefits and related cost savings to healthcare systems, which should also be captured in any value assessment.

At the same time, there is a need for clearer definitions of cures, curative therapies, and products with long durations of response. Often, there may be a difference of opinion as to whether a therapy is curative before long-term follow-up is available and, in some cases, these therapies may be approved before long-term durability is known. For example, CAR Ts may be potentially curative for a subset of patients with relapsed/refractory large B-cell lymphoma based on two-year follow-up data, although additional longer term follow-up data are required to confirm. Frameworks must be designed to address this uncertainty and rapidly integrate new data, including real-world evidence, as it becomes available. This will ultimately help broaden patient access, which is, of course, the long-term goal.

For all these reasons, as health technology advances in both scope and in diversity, the older, one-size-fits-all models will need to keep pace to maximize value to patients and society.

Our current healthcare reimbursement model does not support that type of innovative, curative therapy. In your opinion what needs to be changed?

Innovation is not just about science – we must also be innovative in how we deliver and pay for medicines. Current reimbursement systems, particularly in the United States, provide little incentive for payers to recognize the full value of cures and other transformative therapies. For example, curing a life-long condition may deliver extraordinary savings in long-term healthcare costs. Yet those savings will be realized by multiple insurers over a patient's lifetime – not just the insurer that covered the one-time cure.

There's no simple solution to this challenge, but I'm encouraged that many stakeholders, both public and private, are working to develop new approaches. For example, for some therapies and conditions certain models may allow payers to address urgent medical needs while amortizing costs across multiple years. I believe there is growing consensus about the need for new models that provide access to cures while incentivizing future scientific innovation, and I am optimistic that we will see new solutions emerge in the coming years.

As we look at the evolution we are seeing in healthcare, how do we evolve to incorporate patient-centric outcomes in value assessment, rather than simply looking at health and economic outcomes?

Traditional HTA and value framework methodologies do not capture some of the most important patient outcomes, including reduction in uncertainty, insurance value of preventing conditions, such as HIV or HCV transmission, reduced severity of disease, and increased hope for the future. These important elements of patient benefit are harder to measure, but reflect how individuals, families, and society think of value.

As patients become more empowered with their healthcare choices, it's critical that we embrace patient voice in determining the relevant outcomes in clinical trial design (for example PROs to measure depression and fatigue with HCV) and the value assessment that will factor in the impact of such reduction. Patient-reported outcome measures are essential to capture the full value of transformative therapies. I hope that they will become increasingly commonplace in all healthcare settings.