Health Technology Assessment for Molecular Diagnostics: An Interview with Susan Garfield, DrPh

on behalf of the ISPOR Medical Devices and Diagnostics Special Interest Group

Value & Outcomes Spotlight had the opportunity to catch up with Susan Garfield, DrPh, on the recent article, "Health Technology Assessment for Molecular Diagnostics: Practices, Challenges, and Recommendations from the Medical Devices and Diagnostics Special Interest Group," to appear in the July/August 2016 issue of *Value in Health*. Our conversation on this intriguing subject follows.

Garfield S, PolisenaJ, Spinner D, et al. Health Technology Assessment for Molecular Diagnostics: Practices, Challenges, and Recommendations from the Medical Devices and Diagnostics Special Interest Group. Value Health *2016;19: 577-587.*

Additional information:
You can access, "Health Technology Assessment for Molecular Diagnostics: Practices, Challenges and Recommendations from the Medical Devices and Diagnostics Special Interest Group," and other articles in this issue of Value in Health *at: http://www.ispor.org/valueinhealth_index.asp.*

To learn more about the Medical Devices and Diagnostics Special Interest Group, go to: http://www.ispor.org/HTa-Molecular-Diagnostics-MDD.asp

***Value & Outcomes Spotlight*:** What was it about this issue that caused it to become a priority item for the Special Interest Group?

Garfield: The group is comprised of industry members, academics, HTA participants, and payers. Together we saw a developing system that was not optimally aligned with the market needs and the complexity of the technologies coming to market. The report provides context through several case studies of tests that have recently gone through HTA in different settings. These examples demonstrate the heterogeneity in approach and requirements observed. The SIG felt current diagnostic HTA processes could be greatly improved by aligning methods, providing greater transparency on process and requirements, and having clear links between HTA and reimbursement outcomes. The results of which would be both improved access to valuable molecular diagnostics for patients and greater predictability for investors.

VOS: Who is the audience for this report, and how will they benefit?

Garfield: The audience is all people developing or evaluating molecular diagnostics, including those at established HTA groups and those developing new approaches for molecular diagnostics specifically. They will benefit from seeing examples from different groups and having actionable recommendations to adapt or build new approaches. Additional work needs to be done to consider the implications of innovative diagnostic technologies to these recommendations, like next generation sequencing and hybrid diagnostic/algorithm approaches.

VOS: What was the greatest difficulty in comparing HTAs across multiple molecular diagnostics in multiple nations?

Garfield: HTAs do not always share the same goals in their evaluations and use different methods to reach conclusions. Each country/setting has their own clinical, economic and cultural context that impacts how they consider the value of diagnostic innovations, and the implications for HTA results. For example, some groups have very clear linkages between their decisions and reimbursement/access outcomes in the country or for a specific payer. In others, there are no clear linkages to any specific outcome or impact of the review. Some HTAs include economic evaluations and/or quality of life considerations while others consider clinical impact only. In addition, for molecular diagnostics there is no standard efficacy measure across HTAs with analytic validity, clinical utility, sensitivity, and specificity all used in varying ways as metrics of impact. Finally, not all tests are evaluated across HTAs. As a result, there are few examples where a single test's HTA process and outcome can be considered across all relevant HTA organizations. Together, these factors make evaluation of HTA processes globally challenging.

VOS: What do you see as the most urgent challenge with regard to the use of HTAs for molecular diagnostics?

Garfield: MDx are becoming an increasingly important part of treatment selection, patient monitoring, and diagnosis. Testing methods are increasingly complex, and tests are being used as single markers, panels, and within larger sequencing contents. The methods to evaluate how and when different tests should be incorporated into standard practice need to evolve to keep pace with the technological and clinical innovation occurring. In addition, HTA is often a gateway for access and therefore needs to be set up to encourage innovation in test development, expeditious pathways to get products from the bench to the patient, and a reasonable evaluation of value. ■