

Q&A

Getting “Personal” With Personalized Medicine: An Interview With Kathryn A. Phillips, PhD

Value & Outcomes Spotlight had the opportunity to sit down with Kathryn A. Phillips, PhD, to discuss personalized medicine and its role in today's world of health economics and outcomes research (HEOR). Kathryn is a professor at the University of California at San Francisco, where she is a health services researcher and health economist and leader in the application of new technologies to improve healthcare, and is the founding director of the Center for Translational and Policy Research on Personalized Medicine (TRANSPERS) in the School of Pharmacy at the University of California, San Francisco (UCSF). She is also a professor of health economics and health services research in the Department of Clinical Pharmacy at UCSF, with additional appointments in the UCSF Philip R. Lee Institute for Health Policy Studies and UCSF

Helen Diller Family Comprehensive Cancer Center. Kathryn is an active member of ISPOR; she is a current member of the Society's Personalized/Precision Medicine Special Interest Group and a member of the Value in Health Editorial Advisory Board, in which she has served as guest editor on ViH's themed section on Value to Decision Makers of Evaluations of Personalized/Precision Medicine: Applications to Other Emerging Technologies in January 2017, which assessed the value and implications of personalized/precision medicine and the “lessons learned” for other emerging technologies. In 2018, she served as a guest editor on the themed section on Measuring the Economic Value of Multigene Tests and Clinical Sequencing. She currently is serving as a guest editor on a themed section on implementation of evaluation approaches.

Value & Outcomes Spotlight: Is personalized/precision medicine still a “hot” topic that has important implications for HEOR?



Phillips: Yes absolutely! Although some have noted that progress in implementing precision medicine has not been as fast as predicted, its importance and impact continue to grow. Precision medicine has been referred to as “medicine's Wild West”, given that 10 new genetic tests enter the market each day in the United States.¹ Expenditures on genetic testing are also growing, with the highest expenditures for prenatal tests among commercial payers.¹ And much of the growth is for multigene tests.

We are seeing similar growth globally, so it is not only limited to the United States. The global clinical next-generation sequencing market was \$2.2 billion in 2015 and is forecast to reach \$7.7 billion by 2020, which is a compound annual growth rate of 28%.²

The continuing interest and excitement about precision medicine, however, must be tempered by the realization that genetics is only one contributor to disease and disease risk. We learn about new genetic associations every day, but it is going to take a long time to understand the role of genetics more completely and how that compares to other etiological factors. We should all keep eating healthy and exercising!

What are the biggest challenges to appropriate implementation of precision medicine, and where are we in terms of finding solutions?

It has been said, “The biggest challenge to implementation for precision medicine now is not the science but the economics.” It has also been said, “The three biggest barriers to precision medicine are reimbursement, reimbursement, reimbursement.”

There's a big role for HEOR!

I founded the UCSF Center for Translational and Policy Research on Personalized Medicine (TRANSPERS) in 2008 to develop objective evidence on the appropriate and efficient implementation of precision medicine. At the time, there was excitement about these new technologies but very little focus on their translation into clinical care and health policy. I am happy to say that there are now other centers and initiatives underway.

One ongoing initiative that I'm very excited about is the Global Economics and Evaluation of Clinical Sequencing Working Group (GEECS), which consists of leading global economists who are working together to develop economic evaluation frameworks and approaches for assessing next-generation sequencing. GEECS published a special theme section in the September 2018 issue of *Value in Health* that focused on assessing the value of NGS-based clinical testing.³⁻⁸ This series of expert articles pushed the envelope by highlighting the challenges and by suggesting innovative solutions to move the value assessment process forward for precision medicine. The papers incorporate a wide range of perspectives and topics and use both systematic reviews and case studies—but they all focus on the overarching issue of proposing new methodologies to assess the value of NGS-based technologies in clinical care. GEECS is now developing additional papers that delve more deeply into the challenges of implementing appropriate evaluation methods and approaches.

I also continue to be excited by our work on understanding payer coverage policies. Since 2007, we have led a Payer Advisory Council that includes senior executives from the largest private health plans as well as other thought leaders, which enables us to have a deep understanding of payers' decision making for coverage policies. For example, we are finishing analyses of 14 in-depth interviews with payers on how they view coverage of whole exome sequencing in the prenatal and pediatric settings.

So stay tuned!

What are some important developments in this field that are relevant to HEOR?

There are many! One important topic is the increasing use of real-world evidence and the challenges faced by payers in using such evidence for coverage policies. Our group just completed a study that developed 14 recommendations for how to facilitate the ability of payers to use real-world evidence rather than only randomized clinical trials (RCTs) for coverage decisions, which is critical given that precision medicine is often not appropriately studied by RCTs.

Another fascinating development is the evolution of the lab industry. We recently published a paper in *JAMA* on the growth of "hybrid labs" that provide low-cost testing with medical-grade results, which we believe is changing how genetic testing is and will be done in the United States.⁹ We also have a paper under review on the growth of lab benefit managers (LBMs), which has substantial implications for precision medicine—particularly that some payers are now contracting with LBMs to develop and write their coverage policies and thus, the focus can no longer just be on payers as the coverage decision makers.

Lastly, HEOR needs to prepare for the next frontiers of "precision health" and artificial intelligence. There are many definitions and permutations of these topics, but there is no doubt that the integration of data to facilitate overall individual well-being and the use of big data and machine learning will have important impacts on economics and implementation. •

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ADDITIONAL INFORMATION

ISPOR has a Personalized/Precision Medicine Special Interest Group focusing on topics such as leveraging RWE to address uncertainty in cell and gene therapy, and, in cross collaboration with the Medical Device and Diagnostic Special Interest Group, exploring unique methodological and value demonstration considerations associated with next generation testing.

For more information on these topics, go to <http://www.ispor.org/member-groups/special-interest-groups>.