

ISPOR 2018

TOP 10 HEOR TRENDS



ISPOR 2018 TOP 10 HEOR TRENDS

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TOP 10 HEOR TRENDS

1

DRUG PRICING AND SPENDING

Conversations on how to manage drug prices are intensifying, with a particular focus on ensuring that drug prices reflect the value of treatment.



2

INNOVATIVE AND CURATIVE THERAPIES

As drug discovery and healthcare move toward more personalized medical treatment, novel therapies will continue to be developed.



3

ACCELERATED DRUG APPROVALS

Regulatory efforts continue to speed the approval of new drugs that conquer unmet medical needs and get much-needed therapies to patients, yet in making them widely available, reimbursement is equally important.



4

UNIVERSAL HEALTH COVERAGE

Globally, a growing commitment to universal health coverage is elevating the role of HEOR.



5

AGING POPULATION

The world is getting older. By 2050, the number of people over 65 is expected to reach 1.5 billion. It is crucial that healthcare spending be managed to deliver outcomes most desired by our aging population.



6

mHEALTH

There is rising optimism about the potential of mHealth (mobile health) to cost-effectively improve patient care.



7

DIAGNOSTICS

With the launch of more advanced—and even more costly—therapies, the need for jointly developed diagnostics to ensure the right patients are benefiting from them has grown even more essential.



8

BIOSIMILARS

Biosimilars have the potential to give patients a wide variety of treatment options—and to provide savings to the entire healthcare system.



9

PREVENTIVE MEDICINE

Health economic evaluation is particularly important for preventive medicine that improves healthcare worldwide.



10

DISRUPTIVE INNOVATORS

In the past decade, scientific innovations in cell and gene research have been creating new therapies that pose novel challenges to those involved in health technology assessment and healthcare decision making.



EXECUTIVE SUMMARY

INTEREST IN THE FIELD OF HEALTH ECONOMICS and outcomes research (HEOR) has grown exponentially as governments and other payers grapple with how to provide the best possible health outcomes at affordable costs. As HEOR continues to grow in importance and play an ever greater role in helping to inform healthcare decisions, now is the time to delve into the top trends that the Society's members see having the most influence over the coming year. As the leading global professional society in the field, ISPOR is uniquely positioned to leverage the thought leadership of its member experts and provide direction on where the field of HEOR is heading in what is a rapidly changing healthcare marketplace. The ISPOR 2018 Top 10 HEOR Trends is the inaugural publication for this initiative.

The trends are many and complex, but this report will distill the top 10 that the Society members identified as having the most impact during 2018. ISPOR members will continue to explore these trends and many others throughout the year at conferences and through the Society's working groups, councils, and roundtables all over the world.

ISPOR's Health Science Policy Council played an integral role in the development of the Top 10 HEOR Trends initiative. The council serves as an advisory body to the Society's board of directors and helps guide ISPOR's focus on key research issues in HEOR.

Methodology for this initiative included a comprehensive exploration and collation of potential trends for consideration; careful review and vetting of the topics by the council; in-depth surveys of ISPOR's thought leaders to provide feedback and rankings of the topics; and final discussion and selection of the top 10 trends by the council at the Society's 20th Annual European Congress in November 2017.

The topic that topped the 2018 list of HEOR trends was the highly debated issue of drug pricing. Innovative and curative therapies came in a close second, perhaps not surprisingly, as balancing incentives for research with pricing of these novel, breakthrough therapies is integrally connected. Third on the list is accelerated/expedited drug approvals and the evidentiary needs required for reimbursement.

2018 Top 10 HEOR Trends

1. **Drug pricing and spending**
2. **Innovative and curative therapies**
3. **Accelerated drug approvals**
4. **Universal health coverage**
5. **Aging population**
6. **mHealth**
7. **Diagnostics**
8. **Biosimilars**
9. **Preventive medicine**
10. **Disruptive innovators**

ISPOR members are actively engaged in many of these topics, as might be expected. These topics have been the focus of numerous publications and conference presentations, as well as some of the Society's task forces and special interest groups. We expect to see continued, and probably heightened, work in these areas in 2018 and invite interested readers to follow ISPOR's work at www.ispor.org.

1



DRUG PRICING AND SPENDING BALANCING VALUE AND COST

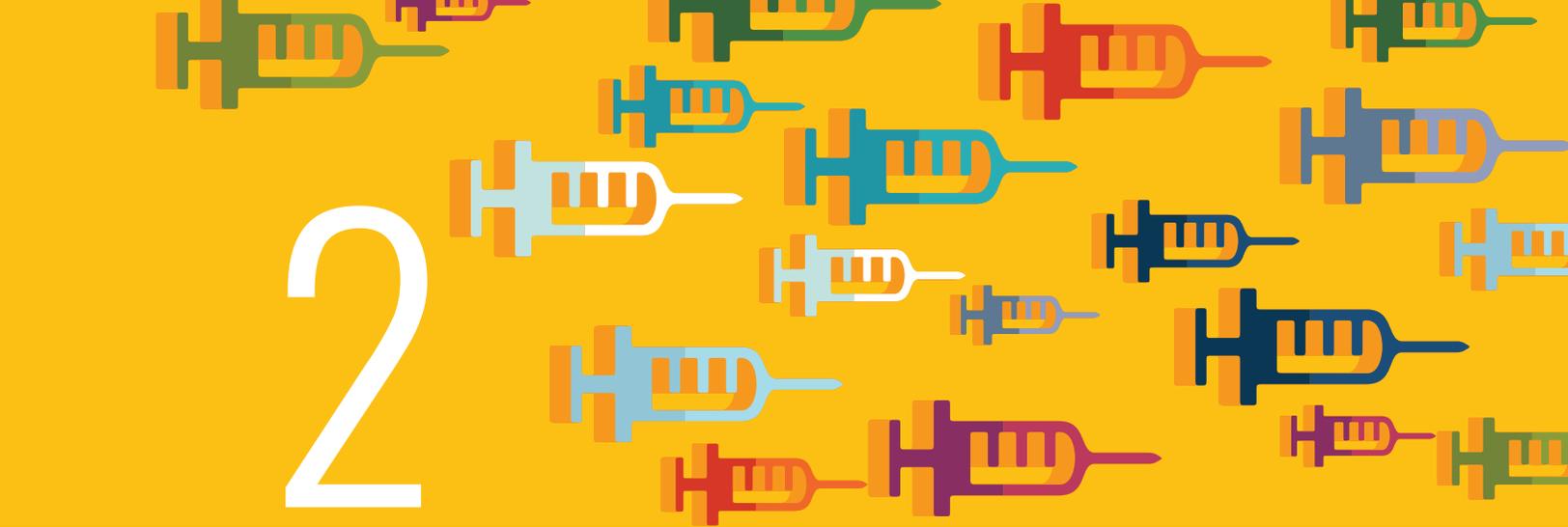
A topic of broad interest that continues to garner attention is drug pricing. The issues include affordability of drugs at the individual patient level and recent increases in overall drug and healthcare spending. In all types of systems, however, discussions about ways to manage drug prices are intensifying, with a particular focus on calibrating drug prices with the value received from treatment.

Determining the value of specific drug treatments at the societal, health plan, and patient levels remains a fundamental consideration underlying value-based pricing.

Various approaches to value-based pricing are being explored. For example, in the last decade there has been steady discussion of performance-based (or outcomes-based) risk-sharing agreements. Put simply (although details can get very complex), under such agreements, how much the manufacturer is paid depends on whether, or how well, the drug works. As experience with these approaches accumulates and the data systems needed to make them operational mature, such solutions can bring greater efficiency to drug spending. Additionally, some organizations have suggested indication-specific pricing as a possible way of controlling costs. Indication-specific pricing would allow more flexibility to adjust pricing to value when a drug has both a high-value and a low-value indication for a given drug dosage.

Determination of the value of specific drug treatments at the societal, health plan, and patient levels remains a fundamental consideration underlying value-based pricing. A variety of “value assessment frameworks” have been put forward in recent years¹⁻⁵; the report of an ISPOR Special Task Force on this topic, entitled “A Health Economics Approach to US Value Assessment Frameworks,” will be published in the February 2018 issue of *Value in Health*. Among other things, it sets forth a research agenda for better measurement of certain elements of value not normally captured in cost-effectiveness analysis and related approaches.

To deal with the manifold issues underlying drug pricing and spending, an equally diverse set of approaches may be necessary; some are actively being pursued. In 2018, we should expect to see an extended set of research, process, and policy efforts in this area.



2

INNOVATIVE AND CURATIVE THERAPIES TRANSFORMATIVE TREATMENTS ADD TO BUDGET PRESSURES

A number of truly innovative and curative therapies have entered the market, from hepatitis C to oncology drugs and beyond. Many of these therapies are transforming treatment—and the lives of patients—in a number of disease states. As drug discovery and healthcare move toward more personalized medical treatment, as well as toward curative therapies for chronic and genetic diseases, novel treatments will continue to be brought forward.

While these innovations provide more and better treatment options for patients, on a per-patient basis they tend to be expensive, both to develop and to use, potentially creating systemic budgetary pressures that may threaten the sustainability of innovation of this type.

Driving the costs of specialty drugs—for cancer, orphan diseases, and other indications—are a host of factors. These drugs are often complicated to manufacture, distribute, dispense, and administer. They may require unusual resource-intensive handling or dispensing procedures; have complicated dosing regimens; have minimal generic substitutions available; and have smaller patient populations, which means the fixed costs of development and manufacturing are spread among fewer patients. They may also require related

diagnostics, monitoring, and additional services and increased focused clinical management; require risk evaluation and mitigation strategies; have adherence issues that impact outcomes; entail complicated billing with increased prior authorizations; and have limited distribution networks. Reconciling these cost drivers with value and near-term affordability concerns can create major challenges.

As medical, genetic, and pharmacologic sciences improve, our hopes for major cures (and concerns about increasing costs) are more and more likely to be realized. With the help of creative thinking and collaboration of payers, health technology assessors, manufacturers, policymakers, patient groups, health economists, and outcomes researchers, encouraging innovation that meets significant unmet medical needs, while mitigating its economic pressures, may be a realistic goal.

With creative thinking and collaboration, innovation that meets significant unmet medical needs while mitigating its economic pressures may be a realistic goal.

3



ACCELERATED DRUG APPROVALS EVIDENCE NEEDS FOR REIMBURSEMENT

In recent years, there have been a number of regulatory efforts to expedite approval of new drugs or new indications of drugs largely in cases of significant unmet medical need. Somewhere in the passionate arguments of those who want research on medicines to go to market faster and those who warn that speed comes at the expense of safety lies an elusive balance.

In 2012, the US Food and Drug Administration introduced the new “accelerated approval” pathway, as well as the “breakthrough product” designation (an alternative to the existing “fast track” designation).⁶ In 2014, the European Medical Agency began a pilot project to investigate “adaptive pathways”⁷ as a complement to its conditional approval process and more recently established other expedited approval mechanisms. In Japan, the Sakigake (or “forerunner”) fast-track development and review system was announced in 2014 and launched in 2015.⁸

While such faster approval processes are an important step for getting much-needed drugs to patients more quickly, another important step in making drugs widely available is reimbursement. Payers, and the health technology assessment bodies which often inform them, generally want to see evidence of value based on clinical outcomes, which may not be included in the more limited data on which the expedited approval

was granted. The resulting tension between expedited approval and rapid reimbursement is an evolving situation that is generating different approaches across countries, as well as public concern about actual availability and pricing of these new products.

The patient and clinical demands for early access to breakthrough therapies seem unlikely to diminish, but questions about how to establish initial pricing and reimbursement remain. To help address these concerns, we expect to see further use of outcomes-based risk-sharing agreements and coverage with evidence developments schemes. We also expect to see more research on the reliability of surrogate markers for prediction of both clinical and economic outcomes, and on the appropriate use of real-world evidence and methods to simulate clinical trial results based on real-world data. ISPOR has published a number of good practices task force reports in these areas, all of which are freely available on our website.⁹

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4



UNIVERSAL HEALTH COVERAGE WHO SETS THE STAGE

Implementation of universal health coverage involves significant decisions around the nature of funding, covered benefits, creation of needed healthcare resources, governing authority, and more—all of which can vary from country to country.

Universal health coverage (UHC), also known as universal healthcare, began taking root in Europe following World War II with the establishment of national health insurance systems in a number of countries. UHC is the norm in Europe and many other countries, but the United States and many developing countries have been slower to adopt it.

In recent years, the World Health Organization (WHO) has been a major proponent of extending UHC globally, following up on a World Health Assembly resolution on a sustainable health financing structure and universal coverage that was passed in 2011.¹⁰ Implementation of UHC involves significant decisions around the nature of funding (eg, single payer or mixed), covered benefits, creation of needed healthcare resources, governing authority, and more—all of which can vary from country to country. These decisions are guided by each country's culture and ethics, as well as its political and economic system and situation, and are informed by health economics and outcomes research relevant to its own

system. In 2014, the World Health Assembly passed a resolution on health intervention and technology assessment in support of UHC, and WHO launched initiatives to implement the resolution with member states.¹⁰ Given such commitments, UHC is likely to progress in 2018.

ISPOR supports the scientific and educational basis for health technology assessments, particularly with its focus on health economics and outcomes research methodology. With 84 regional chapters, ISPOR and its members around the world are involved in research that can contribute to more informed UHC decision making at the country level.¹¹

5



AGING POPULATION CONTROLLING RISING COSTS WHILE MAINTAINING QUALITY

The world's population is getting older. According to the World Health Organization's (WHO) 2010 report, "Global Health and Aging," an estimated 524 million people (about 8% of the world's population) were aged 65 years or older. By 2050, this number is expected to nearly triple to about 1.5 billion, representing 16% of the world's population.

Improved measurement and use of individual patient preferences can help ensure that healthcare services are used to pursue outcomes that bring the most value to older patients.

Although more-developed countries have the oldest population profiles, the majority of older people and the most rapidly aging populations are in less-developed countries. Between 2010 and 2050, the number of older people in less-developed countries is projected to increase more than 250%, compared with a 71% increase in developed countries. According to WHO, population aging is likely to influence healthcare spending patterns in developed and developing countries in the decades to come.¹² Given these pressures, it is crucial that this spending is managed to deliver the outcomes most desired by patients and society.

There are a number of ways that health economics and outcomes research can contribute to more effective

healthcare spending as the population ages. Improved measurement and use of individual patient preferences can help ensure that healthcare services are employed pursuing outcomes that bring the most value to patients; this may apply especially to end-of-life care. And while economic evaluation of specific services will continue to be important, more systematic evaluation of clinical care pathways can provide insight into the most efficient ways to integrate healthcare services. Perhaps most critically, by helping to identify treatments and behaviors that prevent or mitigate the most prevalent chronic diseases (such as diabetes), we can enable healthier (and less-costly) aging.

6



mHEALTH

FITBITS, HEALTH APPS, AND THE RISE OF REAL-WORLD DATA

From Fitbits to apps like MyFitnessPal, to blood glucose monitors that attach to a smart phone and send readings directly to the patient’s health record, to national programs of telehealth and other countrywide telemedicine initiatives, optimism continues to rise about the potential of mHealth (mobile health) to improve patient care in a cost-effective manner. As with most emerging technologies, however, evaluation and refinement can help ensure that mHealth achieves this potential.

The widespread availability of mHealth has begun to generate enormous amounts of real-world data that can be used for the evaluation of mHealth and of more traditional healthcare. These data can be rich and unique, but can also present some challenges. They tend to be less systematic than other data sources, may or may not be easily integrated with other healthcare data for analytic purposes, and can easily be influenced by selective patient use of mHealth, meaning that results may not be generalizable to all patients. Learning how to make better use of real-world data is crucial to sound evaluation in this area. For all these reasons, ISPOR and the International Society for Pharmacoepidemiology

established a special joint task force on [Real-World Evidence in Healthcare Decision Making Initiative](#) to improve standards and practice for the conduct and reporting of real-world data studies.^{13,14}

As with drugs and other healthcare products and services, evidence about the effectiveness, safety, and cost-effectiveness of mHealth is likely to be desired by clinicians, patients, and payers as they consider adoption and reimbursement of these new technologies. As a result, evaluation of mHealth is a rapidly growing focal point for those involved in health economics and outcomes research.

Learning how to make better use of mHealth-based data is crucial to sound evaluation of real-world evidence.

7



DIAGNOSTICS

THE POTENTIAL FOR COMPANION AND COMPLEMENTARY DIAGNOSTICS

With the launch of more-advanced therapies, especially in the area of oncology, the need for jointly developed diagnostics to ensure that the right patients are benefiting from these drugs has grown even more acute. Properly prescribed and used companion diagnostics foster accurate diagnosis, early treatment, less invasive care, faster recovery, fewer relapses, disease prevention or slower progression, fewer complications, and more informed consumers.

The global companion diagnostics market is projected to reach \$6.51 billion by 2022 from \$2.61 billion in 2017, at a compound annual growth rate of 20.1%.¹⁵ While diagnostics represent just 2% of healthcare costs, they influence 70% of healthcare decisions, and there are \$900 million in estimated total avoidable healthcare costs per year related to lack of appropriate diagnostics use.¹⁶

When determining reimbursement of a diagnostic, the evidence of value established for one stakeholder is not always enough to satisfy another. By examining the relationship between the full set of benefits and overall costs resulting from diagnostic use, health economics and outcomes research has a significant role in informing their utilization and reimbursement. Payers often prefer data-based results and are most interested in short-term benefits and direct cost considerations,

which may or may not lead to timely and comprehensive value-based decisions for a diagnostic.

ISPOR's Medical Devices and Diagnostics Special Interest Group¹⁷ has been actively considering issues related to health economics and outcomes research and health technology assessment (HTA) for devices and diagnostics. It has recently published work discussing practices, challenges, and recommendations for HTA of molecular diagnostics, finding that "the few HTA programs that have molecular diagnostic-specific methods do not provide clear parameters of acceptability related to clinical and analytic performance, clinical utility, and economic impact."¹⁸ ISPOR also has been offering a short course entitled "Introduction to the Economic Analysis of Diagnostics" at its major conferences. The diagnostics area continues to be of growing interest both to ISPOR members and to the healthcare community at large.

HEOR plays a significant role in informing decisions about the use and reimbursement of diagnostics.



8

BIOSIMILARS DETERMINING THEIR VALUE

Just as the development and marketing of biosimilars has not been on the same timeline around the world, the estimation of their value also cannot be considered in the same way across countries.

The use of biosimilars is expected to generate between €11.8 billion and €33.4 billion in savings between 2007 and 2020.

Regulatory requirements for biosimilars in the European Union, United States, Latin America, and Asia-Pacific regions are similar and yet slightly different.^{19,20} The European Medicines Agency took the lead on developing an approval process for biosimilars, introducing an abbreviated registration process in 2005 to 2006. According to the *Generic and Biosimilars Initiative Journal*, the use of biosimilars is expected to result in overall savings from €11.8 billion and €33.4 billion between 2007 and 2020, with the largest savings expected for France, Germany, and the United Kingdom.²¹

Biosimilars have the potential not only to provide cost savings to the healthcare system but also to give patients a wider set of treatment options. However, costs of switching, potential differences between the original and the biosimilar, pricing considerations around the appropriate discounts for both original and biosimilar products, and the potential for utilization by more patients given lower biosimilar prices (although not as low in absolute terms as small molecule generics) must also be taken into account. As a result, careful evaluation, management, and cost-effectiveness considerations in this category are expanding areas of focus.

9



PREVENTIVE MEDICINE

THE PROMISE OF IMPROVING HEALTH THROUGH PREVENTION OF DISEASE

Back in 2005, the World Health Organization (WHO) estimated that 35 million people would die of chronic diseases such as diabetes, heart disease, chronic respiratory diseases, and tuberculosis. Only 20% of these deaths occur in high-income countries, while 80% occur in low- and middle-income countries where most of the world's population lives.

The cost is not only in lives. For example, WHO estimates that China will forgo \$558 billion in national income over 10 years as a result of premature deaths from heart disease, stroke, and diabetes. WHO says the global response to chronic disease is inadequate.²²

Health economic evaluation is particularly important for preventive medicine. Costs are typically incurred in the short-term to a large population; benefits accrue in the longer term to a smaller population because not all those at risk would have ultimately experienced the disease. Evaluating risk levels and targeting interventions appropriately can be key considerations for cost-effective disease prevention. Disease

transmission and herd immunity considerations affect evaluation of communicable diseases like tuberculosis. Also, patients can be less willing to pay for medicine or tolerate side effects when they are not yet suffering from a disease. Other behavioral and patient preference factors can come into play as well, particularly when chronic diseases are partly a result of lifestyle choices. Ultimately, in addressing preventive care, changing patient behavior must be part of the equation. ISPOR members are engaging in research that follows, and will help to improve, the best methods and strategies for evaluating disease prevention, including the value of patient-centered behavior change programs.

Evaluating risk levels and targeting interventions appropriately can be key considerations for cost-effective disease prevention.

10

DISRUPTIVE INNOVATORS

CRISPR, CART T-CELL THERAPIES, AND THE VALUE OF NEW SCIENCE

This is not your parents' biotechnology. During the past decade, scientific innovations in cell and gene research have been creating new therapies that will make monoclonal antibodies look as sophisticated and efficient as early generation small molecule drugs. They are tremendously exciting in the scientific and medical sense and pose some new challenges to those involved in health technology assessment and healthcare decision making.

One of the techniques—promising as well as controversial—is CRISPR. The acronym, which stands for clustered regularly interspaced short palindromic repeats, is a genome-editing technology. CRISPR offers tremendous potential to produce therapies that can edit disease-causing genetic mutations. Another innovative technology is the class of immunotherapies known as CART T-cell therapies. CART T-cell therapies are a type of adoptive cell transfer in which patients' own immune cells are collected and used to treat their cancer.

Products created by techniques such as CRISPR and CART-T bring value to healthcare in two ways. First, they create immediate benefits for those patients who are treated for the initial indications of these products; these benefits are routinely accounted for in health economic evaluation. Secondly, they create "scientific spillovers" (ie, new scientific knowledge that can be applied to development of other new therapies), the commercial benefits of which often cannot be fully realized by those creating these spillovers, despite patents and other intellectual property protections.²³

In an economic sense, it is important not to under-reward these fundamental advances in order to maintain the research incentives for such important breakthroughs. Not all incentives are monetary, to be certain, and it is expected that society at large will realize much of the benefit of new therapies. The value of scientific spillovers is typically not captured in economic evaluations of new products, creating concerns that non-commercial incentives (such as government funding of research) may not be sufficient to encourage these key advances. However, this value is not straightforward to measure, particularly for disruptive therapies because all of their applications may not be immediately foreseen. Group-based deliberative processes, such as multiple criteria decision analysis,²⁴ are being considered increasingly as a way to make decisions about new technologies, especially when their costs and/or benefits extend beyond those that are well-measured by standard economic evaluation.

Group-based deliberative processes, such as multiple criteria decision analysis, are increasingly considered in decisions about important new technologies.

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DEVELOPMENT OF THE ISPOR 2018 TOP 10 HEOR TRENDS

ISPOR—THE PROFESSIONAL SOCIETY FOR HEALTH ECONOMICS AND OUTCOMES RESEARCH (HEOR)—is an international, multistakeholder scientific and educational nonprofit organization that is recognized globally as the authority in HEOR and its use in decision making to improve health. ISPOR is the leading source for scientific conferences, peer-reviewed and MEDLINE®-indexed publications, good practices guidance, education, collaboration, and tools/resources in the field. As the leading professional society in HEOR, ISPOR is uniquely positioned to provide direction on trends in the field. ISPOR's Health Science Policy Council, in conjunction with the Society's Chief Science Officer Richard J. Willke, PhD, has led efforts in developing a list of the 2018 Top 10 HEOR Trends.

ISPOR's Health Science Policy Council

The ISPOR Health Science Policy Council was established as an advisory council to the Board of Directors in 2004 to ensure that the Society is addressing key research issues in outcomes research. Membership in the Health Science Policy Council is composed of invited members, including ISPOR past presidents, Avedis Donabedian Lifetime Achievement Award honorees, and other key thought leaders from the ISPOR membership base. In addition to its involvement in the HEOR trends initiative, the Health Science Policy Council also serves as an advisory body for the Society through horizon scanning efforts and critical review and oversight of proposals for ISPOR's Good Practice Task Forces.

In 2017, the Health Science Policy Council was reorganized to include 3 key committees—the Policy Outlook Committee, the Science Research Committee, and the Task Force Review Committee. These committees are co-chaired by Health Sciences Policy Council members and include representatives from other ISPOR groups, including the Institutional Council, Student Chapter Faculty Advisors Council, Health Technology Assessment Council, Patient Council, Education Council, Latin America Consortium, Asia Consortium, Central and Eastern Europe Consortium, Africa Network, Arabic Network, the Co-Editors-in Chief of *Value in Health*, as well as the ISPOR Chief Science Officer.

Methodology

The methodology for development of the 2018 Top 10 HEOR Trends included:

Topic Exploration

Comprehensive exploration to generate a “long list” of potential topics was conducted by examining HEOR-related topics at a variety of industry conferences (including ISPOR conferences and other industry events), articles in scientific journals, research/industry blogs, and articles in trade publications.

Review and Vetting

ISPOR's Health Science Policy Council (including its committees) reviewed and vetted the “long list” at their council meeting at the ISPOR Annual International Meeting held in May 2017 in Boston, Massachusetts, United States, to generate a “short list” of more than 40 potential HEOR trends for consideration.

Thought Leader Survey

A survey of ISPOR thought leaders was conducted to rate the topics curated by the Health Science Policy Council.

Finalization

The Health Science Policy Council and its committees reviewed and finalized selections for the Top 10 list based on the survey results from their meeting at the ISPOR Annual European Congress held November 2017 in Glasgow, Scotland, United Kingdom.

ACKNOWLEDGMENTS

The Society would like to thank all of the members of the Health Science Policy Council and its committees for their thought leadership and advisory role in guiding the development of the 2018 Top 10 HEOR Trends publication.

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