Health Technology Assessment and Private Payers' Coverage of Personalized Medicine

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Abstract

Purpose: Health technology assessment (HTA) plays an increasing role in translating emerging technologies into clinical practice and policy. Private payers are important users of HTA whose decisions impact adoption and use of new technologies. We examine the current use of HTA by private payers in coverage decisions for personalized medicine, a field that is increasingly impacting oncology practice.

Study Design: Literature review and semistructured interviews.

Methods: We reviewed seven HTA organizations used by private payers in decision making and explored how HTA is used by major US private payers (n = 11) for coverage of personalized medicine.

Results: All payers used HTA in coverage decisions, but the number of HTA organizations used by an individual payer ranged from one (n = 1) to all seven (n = 1), with the majority of payers (n = 8) using three or more. Payers relied more extensively on HTAs for reviews of personalized medicine (64%) than for other technologies. Most payers (82%) equally valued expertise of reviewers and rigor of evaluation as HTA strengths, whereas genomic-specific methodology was less important. Key reported shortcomings were limited availability of reviews (73%) and limited inclusion of nonclinical factors (91%), such as cost-effectiveness or adoption of technology in clinical practice.

Conclusion: Payers use a range of HTAs in their coverage decisions related to personalized medicine, but the current state of HTA to comprehensively guide those decisions is limited. HTA organizations should address current gaps to improve their relevance to payers and clinicians. Current HTA shortcomings may also inform the national HTA agenda.

Introduction

Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technology to inform health care decision makers in health policy or practice.[1] The role of HTA in health care decisions in the United States is expected to increase with proliferation of new medical technologies and the implementation of health care reform.[2,3]

Private payers, which insure approximately two thirds of the US population,[4] are important users of HTA. Understanding how they make coverage decisions regarding new technologies is critical, given that it identifies the information needed for decisions and helps clinicians understand payer policies and their impact on clinical practice.[5] This article examines how private payers use HTA in coverage and reimbursement decisions related to personalized medicine. We focus on personalized medicine—the use of genetics or genomics to guide health care decisions—because the rapid pace of development and lack of evidence in this field are particularly challenging to both payers and clinicians.[6,7] We also expand the findings of other studies[8,9] by further examining the role, strengths, and shortcomings of external HTA in private payers' decisions related to personalized medicine.

This topic is particularly relevant in oncology, in which significant growth of personalized medicine is occurring.[10] There are more than 100 genetic tests in oncology, of which at least 38 new tests have been introduced since 2006.[11] Coverage decisions are critical factors in patient access to these technologies and their use in oncology practice.[12,13]

Methods

Definitions and HTA Inclusion Criteria

According to the International Network of Agencies for Health Technology Assessment, HTA is the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its primary purpose is to inform technology-related policy making in health care. HTA is conducted by interdisciplinary groups that use explicit analytic frameworks and draw from a variety of methods.[1]

Here we refer to the entities conducting HTA as HTA organizations, and we refer to the output of HTA as HTA reviews. We included as HTA organizations the US entities that conduct or propose to conduct systematic evaluation of personalized medicine that could be used in coverage decisions by US payers. We excluded professional medical societies, because not all of them conduct systematic evidence evaluations in development of guidelines.[14]

Study Data and Methods

The study was conducted under a protocol approved by the institutional review board of the University of California, San Francisco. We conducted a literature review and semistructured interviews with private payers to examine how they used HTA in coverage decisions for personalized medicine.

First, between June and July 2009, we conducted a literature review to identify which HTA organizations to include. We searched the PubMed database, Google, HTA organizations'

Web sites, and private payer Web sites. An initial list of HTA organizations was forwarded to several experts, who provided input.

Second, between August and October 2009, we conducted semistructured hour-long interviews with senior executives (n = 17) who were directly involved in coverage decisions at eleven US private health plans. These included six of the seven largest national plans, based on membership, and five smaller regional plans with membership numbers ranging from 1.6 million to more than 5 million. The eleven plans together covered more than 125 million members.[15] We provided interview questions to the payers before the interviews. Verbal consent was obtained in the beginning of each interview.

We asked the interviewees:

- what external HTAs their organizations used in decisions related to personalized medicine;
- how external HTAs were used in the decision process; and
- what they perceived as strengths and shortcomings of the HTAs in informing their decisions related to personalized medicine.

Results are described based on the number of payers versus the number of interviewees. We found similar results among interviewees at the same plan.

Results

HTA Organizations Identified and Described

On the basis of a literature review and input from experts, we identified seven examples of HTA organizations that might inform private payer coverage decisions related to personalized medicine:

- Blue Cross Blue Shield Technology Evaluation Center (BCBS TEC)[16]
- Emergency Care Research Institute (ECRI)[17]
- Evaluation of Genomic Applications in Practice and Prevention (EGAPP)[18]
- Hayes[19]
- Institute for Clinical and Economic Research (ICER)[20]
- United States Preventive Services Task Force (USPSTF)[21]
- UpToDate[22]

Six HTA organizations (BCBS TEC, ECRI, EGAPP, Hayes, USPSTF, and UpToDate) had developed genomic technology reviews by the time of our study, and the seventh (ICER) was planning to conduct a genomic technology assessment.

The seven HTA organizations included two private companies, two independent panels developed by the government, one academic center, and two nonprofit organizations (Table 1). Four organizations made HTA reviews publically available; others charged a fee. The HTA organizations ranged in years of existence (from the 40-year-old ECRI to the 3-year-old ICER) and in the number of genetic reviews they produced (fewer than 15 by BCBS TEC, EGAPP, and USPSTF; more than 15 by ECRI; and more than 100 by Hayes and UpToDate).

HTA organizations varied in focus. Only one of them focused solely on genomics (EGAPP), and another (USPSTF) included only genomic technologies related to preventive services. Other organizations focused on assessing procedures by using novel technologies, imaging tests, and drugs and biologics. At least three HTA organizations also assessed laboratory tests and behavioral services (ECRI, Hayes, and UpToDate).

All seven HTA organizations conducted rigorous evidence assessment and contained description of the systematic evidence review. However, the HTAs answered differently formulated overarching research questions. USPSTF and EGAPP answered whether a technology should be used in clinical practice; ECRI and UpToDate provided a comprehensive topic review; BCBS TEC and Hayes evaluated evidence on the basis of their respective predefined criteria; ICER was concerned with comparative value of a technology. The majority (n = 5) provided evidence ranking, but only three (EGAPP, UpToDate, and USPSTF) provided recommendations for clinical use.

Payers' Perceptions of the Strengths and Shortcomings of HTA Reviews

All interviewed payers reported conducting internal technology assessment and using external HTA in their coverage decision making for personalized medicine. Payers valued the following strengths of the HTA reviews as related to decisions regarding personalized medicine (Table 2): expertise and credibility of reviewers (100%); rigor of scientific evidence evaluation (82%); whether HTA methodology was specific to genomics (73%); independence from external influences (73%). Payers valued evaluation rigor as highly as the HTA reviewer expertise. The majority (64%) considered genomic-specific methodology less important than other HTA strengths.

The reported shortcomings of external HTAs were related to review availability (73%) and to the inclusion of nonclinical factors (91%; Table 2). Availability shortcomings included the small number of genetic reviews (64%), a lack of timeliness

Take-Away Points

Our study explored how private payers use health technology assessment (HTA) in coverage decisions related to personalized medicine, including oncology.

- Both large and smaller payers used HTA more extensively for personalized medicine than for other technologies and preferred using multiple HTAs.
- A lack of HTA availability and timelines and insufficient inclusion of nonclinical factors limit their relevance in coverage decisions.

Our findings may inform:

- efforts to improve HTA relevance to private payers, particularly for oncology.
- the national HTA agenda, which may benefit from considering private payers' needs related to emerging technologies and how they intersect with patient and provider issues.

Table 1. Description of the HTA Organizations and Their Respective Reviews

HTA Organization	Organization Type	Year Formed	Overarching Question(s) Addressed by HTA and Distinguishing Features	Is Evidence Ranked or Recommendation Provided	HTA Review Availability	Range of Technologies Assessed	Capacity of Personalized Medicine Reviews (total No. of reviews issued)
BCBS TEC	Association of private payers	1985	Does a technology meet 5 criteria? Judged by regulatory status, evidence quality, net health benefit, better than alternatives, benefits in the real world	No evidence ranking or recommendations are provided.	Public	Procedures using novel technologies; imaging tests; biologics and novel therapies (eg, vaccines); genetic testing	Lower volume (< 15 genomic reviews)[16]
ECRI	Private nonprofit	1969	Clinical effectiveness evaluation was based on key questions specific to topic. 360-degree technology overview	No recommendations are provided.	Fee-based	Behavioral interventions; procedures using novel technologies; genetic tests; laboratory tests; novel treatments; imaging tests; home care technologies	Higher volume (> 15 reports on genomics)[17]
EGAPP	Independent panel assembled by CDC	2004	Should a genomic technology be used in clinical practice? Specific focus on genomic technologies	Evidence is ranked, and recommendations for clinical practice are provided.	Public	Genetic technologies	Low volume (< 10 genomic reviews)[18]
Hayes	Private	1996	What is the strength of evidence for a specific technology? Assesses strength and direction (positive/negative) of evidence	Evidence is ranked A-D. No recommendations are provided.	Fee-based	Drugs and biologics; laboratory tests; imaging diagnostics; genetic tests; behavioral interventions; procedures using novel technologies; alternative medicine	High volume (> 100 reviews of genomics)[19]
ICER	Academic	2006	What is the comparative value of a technology (clinical effectiveness and cost-effectiveness)?	Evidence is ranked. No recommendations are provided.	Public	Imaging diagnostics; procedures using novel technologies; comparison of treatment options	In planning[20]
UpToDate	Private	1992	Clinical topic review, including relevant genomic and other technologies	Recommendations for clinical practice are provided.	Fee-based	Broad range of technologies and services for a specific disease, including procedures; diagnostic tests; treatments and health services	High volume (> 100 reports, including genetics)[22]
USPSTF	Independent panel assembled by AHRQ	1984	Should a preventive service be used in clinical practice? Specific focus on preventive services	Evidence is ranked, and recommendations are provided.	Public	Preventive and screening services and technologies	Low volume (< 10 genomic reviews)[21]

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; BCBS TEC, Blue Cross Blue Shield Technology Evaluation Center; CDC, Centers for Disease Control; ECRI, Emergency Care Research Institute; EGAPP, Evaluation of Genomic Applications in Practice and Prevention; HTA, health technology assessment; ICER, Institute for Clinical and Economic Review; USPSTF, United States Preventive Services Task Force.

Table 2. Strengths and Shortcomings of HTA Reviews

Strength/Shortcoming	Payers Noting as Strength or Shortcoming (n = 11; %)	Illustrative Payer Comment
Strength		
Expertise and credibility of reviewers	100	"The structure of evaluation is as important as the people doing it and how good they are. The field is so new that you want the most experienced and credible people to do it."
Rigor of scientific evidence review	82	"I think they all do a thoughtful, careful job in their evaluations of science and are pretty thorough organizations in their approaches."
Whether the methodology is specific to genomics	73	"The methodology here is a very important and evolving question. We are going to need a different framework to really understand those sorts of tests that get at a very different concept of the underlying disease state and how they are being incorporated into care."
Independence from external influence	36	"You mostly want a group that is outside of the political pressures of the day—whether these are political pressures from insurers or from physicians, manufactures, or patient advocacy groups. They really focus on the science, and to me, that's where it has to start."
Shortcoming		
Availability of reviews		
Capacity of HTA organizations (too few reviews are issued on personalized medicine)	64	"These reviews are extremely cumbersome, and their frameworks are not usable for the growing number of tests; they are choking." "Some reports take up to a year […] then we note that multiple groups are working on the same topics.[…] Is there a way to organize that from the national level and get a greater quantity and a better turnaround time? But there are no incentives, and that model remains elusive."
Reviews are not timely	55	"We usually have to start on that path [evaluating a technology] way before any reviews are out, and we have to look at those evidentiary documents before to try to do our own review and get our own sense." "These groups wait for evidence before they do a review, and then they take a long time to develop a review. I get calls from a provider wanting to know if we're going to cover X, and 'I will tell you in two years when there is enough evidence' is not the answer they're expecting. They want a yes or no. That forces us to do something now when there are evidence gaps or the reviews are not available."
Reviews from fee-for-service organizations are too costly	45	"The work burden involved in putting together these reviews is enormous. I have to tell you that the cost of it is that I don't think any payer is going to be willing to pay over the long haul, looking at the growing number of genetic tests."
Review does not adequately incorporate nonclinical factors		
Cost-effectiveness	82	"We don't use cost-effectiveness in decisions today, but in the future state, it's critical that we do that and get some agreement on how we measure the value and cost-effectiveness. The groundwork needs to be lain, but it's not there today."
Adoption and acceptance of a technology in clinical care	45	"Their one big weakness is they deliberately limit themselves to the science; they're very careful about that, but they tend to ignore entirely what I call the market factors. We need to know if a technology has become a common practice and whether we want it or not—this is a part of our decision." "We often get situations when preliminary evidence looks pretty good but there is no power to the study yet, and we make a decision based on giving the benefit of the doubt to a member. So we need to know the situation of patient and provider demand for the test as part of the decision."
Expert opinion and clinical judgment is not sufficiently taken into account	36	"Basic flaw is: on one hand, let's have evidence and the proof; on the other hand, there are some technologies that show great promise with reduced morbidity that may take 10 years to get the evidence for. Do you not utilize those technologies until you have all the evidence? […] Like clinical judgment doesn't get used in these reviews. That is a missing piece, because I think we do withhold things that may be important to people."
Care delivery barriers to adoption (eg, lack of infrastructure, logistical challenges, disincentives)	27	"Another missing thing is that there are some practical, logistic things that come up too. For example, only in a few of those warfarin studies did anybody mention that it takes a while to send the blood off and have it analyzed and to get the results back. So it basically puts off initiation of therapy by several days. And there are downsides to that, and I don't think anybody actually talked about it."
Local regulations and factors	27	"One of the biggest gaps in these reviews is they do not consider the local environment—both academic and clinical—or the politics that have to do both with legislators and the community."

Abbreviation: HTA, health technology assessment.

relative to payer coverage decisions (55%), and the increasing costs of fee-for-service reviews (45%). Fifty-five percent of payers claimed a heavier reliance on Hayes and/or ECRI, because they issued a higher number of reviews, albeit for a fee. The cost concerns were reported by both payers who used the fee-for-service HTAs and who stated that the fees were becoming prohibitive, and by payers who considered using them.

Ten of the eleven payers noted that, although all HTA reviews included evaluation of clinical evidence, few of them incorporated other factors that might be important in coverage decisions. Payers listed a spectrum of these factors: cost-effectiveness (82%), current level of adoption in clinical care (45%), incorporation of expert opinion (36%), barriers to adoption in care delivery such as a lack of infrastructure or logistical challenges (27%), and local regulations (eg, state coverage mandates; 27%). Interviewees noted that these factors played a role in their coverage decisions, especially regarding technologies with limited evidence and including many personalized medicine tests. All payers stated that cost-effectiveness was currently not a factor in their coverage decisions; however, at least seven of them believed that it would be a factor in the future as health care reform unfolds.

Table 3. What HTAs Are Used and How

	Individual Payer											
HTA Used	**1 (nat)**	**2 (nat)**	**3 (nat)**	**4 (nat)**	**5 (nat)**	**6 (reg)**	**7 (reg)**	**8 (reg)**	**9 (nat)**	**10 (reg)**	**11 (reg)**	**No. of Payers (n = 11)**
BCBS TEC	x	x	x	x	x	x	x	x	x		x	10
USPSTF	x	x	x	x	x	x	x	x	x			9
ICER	x	x	x	x		x	x					6
Hayes	x	x	x	x	x					x		6
EGAPP	x	x	x	x				x				5
ECRI	x	x			x					x		4
UpToDate	x		x									2
Total No. of HTAs used per payer	7	6	6	5	4	3	3	3	2	2	1	

Abbreviations: BCBS TEC, Blue Cross Blue Shield Technology Evaluation Center; ECRI, Emergency Care Research Institute; EGAPP, Evaluation of Genomic Applications in Practice and Prevention; HTA, health technology assessment; ICER, Institute for Clinical and Economic Research; nat, large national payer; reg, smaller regional payer; USPSTF, United States Preventive Services Task Force.

How HTA Organizations Are Used by Private Payers in Decisions Related to Personalized Medicine

All interviewed payers reported using at least one external HTA organization in their coverage decision making related to personalized medicine (Table 3). The number of HTA organizations used by individual payers ranged from one (n = 1) to all seven (n = 1); the majority of payers (n = 8) used three or more different HTA organizations. Large payers reported using more HTA organizations than smaller payers used. HTA reviews from BCBS TEC and USPSTF were reported as being used by most payers (91% and 82%, respectively), whereas ECRI and UpToDate were used by the least number of payers (36% and 45%, respectively). Fifty-five percent of payers stated that using multiple HTAs and comparing them helped them construct a complete evidence profile for a technology, because they had found no one source that was able to provide complete evaluation for genomics. They experienced a higher need for using reviews from multiple HTA organizations for genomics than for other technologies. The majority of payers (91%) found HTA reviews beneficial to their coverage decision making related to personalized medicine and used them for one or more of the following purposes:

- to help internal reviewers with question formulation and methodology (91%);
- to validate internal evidence analyses (36%); and/or
- to demonstrate credibility of decisions to providers and patients (36%).

At least five payers reported that they would like to use HTA reviews for question formulation more often, but because HTAs were not available in a timely manner, payers' internal evaluations were often completed before an external HTA was issued.

All payers found systematic evidence analyses by external HTAs useful, but their opinions differed on the usefulness of other HTA review components. Many payers found evidence ranking (45%) and HTA recommendations (55%) helpful. However, others found ranking confusing, preferred to use their own ranking methods, or deemed external recommendations not relevant to their decisions.

Discussion

Private Payers Rely on External HTA in Coverage Decisions for Personalized Medicine, but HTA Shortcomings Limit the Use

Our study explored how private payers used HTA in coverage decisions related to personalized medicine. We found that they used HTA extensively and relied on multiple HTAs for evaluation of personalized medicine more than for other technologies. HTA shortcomings in support of private payer decisions were lack of availability of reviews on personalized medicine and high costs of subscription-based HTAs as well as insufficient inclusion of nonclinical factors, such as cost-effectiveness and adoption of technology in clinical practice. This and other studies highlighted the necessity of both developing solutions that improve the usefulness of HTA to decision makers and providing findings that suggest specific areas to be addressed by solutions.

Our study confirmed the findings by Deverka[8] and Faulkner[9] that private payers use HTA in coverage decisions on personalized medicine. We also found that, in our cohort of private payers, HTA may play a more essential role in decisions related to personalized medicine than on other technologies. We also discovered that both large payers (known to have robust internal HTA processes[8,23]) and smaller payers relied on HTA and used multiple HTA reviews for evaluation of personalized medicine. Future solutions to HTA issues should address the needs of both large and smaller payers.

Lack of availability and relevance of HTA to payers have been discussed in other literature as they relate to personalized medicine[9] and in the broader context.[3,24] Our findings highlight a dichotomy between the lack in availability and the redundancy of genetic reviews. Table 4 illustrates these issues for gene expression profile test Onco*type* DX (Genomic Health, Redwood City, CA). The relevant EGAPP review was issued after five major payers decided to cover Onco*type* DX, which rendered this review irrelevant to those payers who preferred using EGAPP. Conversely, BCBS TEC, Hayes, and ECRI all assessed Onco*type* DX within the same time period, which

Table 4. Health Technology Assessment and Payer Decisions: Example of Gene Expression Profile Test for Breast Cancer

Oncotype DX (Genomic Health, Redwood City, CA)
Oncotype DX becomes available in January 2004.[25]
Five major national payers* granted coverage to Oncotype DX between mid-2005 and late 2007.[25]
EGAPP published a report on gene expression profile tests, including Oncotype DX, in January 2008. The report took approximately 1 year to complete.[18]
EGAPP published recommendations on gene expression profile tests in breast cancer in January 2009.[26]
BCBS TEC, Hayes, and ECRI each issued several reports between mid-2005 and 2008.[16,17,19,27,28]†

Abbreviations: BCBS TEC, Blue Cross Blue Shield Technology Evaluation Center; ECRI, Emergency Care Research Institute; EGAPP, Evaluation of Genomic Applications in Practice and Prevention.

* The five payers are participants of the study described in this article.

† Timelines of the BCBS TEC, Hayes, and ECRI reports are approximate as a result of a lack of public availability of report history.

raises the question of the benefit of this redundancy to HTA users. In addition to lack of availability, we found that the costs of high-volume, subscription-based HTAs were limitations and a significant concern for payers. Payers expected they would not be able to afford these HTAs, given the inevitability of additional proliferations of genomics. Future solutions should consider the balance between using multiple reviews for comprehensiveness and avoiding redundant reviews to improve capacity while addressing the affordability of HTA reviews.

Other literature discussed the role of nonclinical factors in coverage decisions by private payers[25,29,30] and the inclusion of these factors in HTA.[24,31] For example, Teutsch et al[31] discussed how EGAPP includes contextual factors such as cost-effectiveness, current use, and feasibility of use. Neumann et al[32] considered how cost-effectiveness might be incorporated in health care decisions and in HTA. Conti et al[33] discussed the inclusion of cost-effectiveness in the evaluation of personalized medicine. Our findings suggest several additional nonclinical factors that are essential to private payer decisions and that payers want to incorporate in HTA. Additional studies might explore solutions for how to integrate evaluation of both clinical evidence and nonclinical factors in HTA.

Implications and Opportunities in Oncology

Current shortcomings in HTA of personalized medicine may be particularly relevant in oncology, given the growing number of genomics that guide the use of potentially lifesaving therapies. In addition to HTA organizations, oncology medical societies also conduct genomics evaluations. Private payers take into account not only HTA but also guidelines by medical societies, notably those by the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network.[8,9,29,34]

Our findings may be relevant to those societies that conduct systematic evaluations of cancer genomics. For example, ASCO experiences challenges similar to those of HTA, such as lack of timeliness of reviews relative to user needs.[14,35] It may be beneficial to cross-pollinate lessons learned and potential solutions among HTA and guideline societies. ASCO, for instance, is implementing a "more aggressive approach to guideline updating" by conducting annual assessments of new evidence. It has also established a process of endorsing other societies' guidelines to improve access to evidence-based recommendations for its members.[14] Such solutions may be beneficial to consider in the HTA context as well.

Considerations for Health Care Policy Development and HTA Organizations

Recognizing the increasing importance and current shortcomings of HTA, experts have called for more significant investment in HTA and for development of solutions, such as the establishment of a centralized HTA body.[2,4,36] Our own and others' research on the use of HTA by private payers may inform development of such solutions. For example, using multiple HTAs appears to be beneficial for private payer decision making for novel technologies, such as personalized medicine, in which both the evidence and the methods to evaluate it are still evolving. Therefore it may be beneficial to include multiple HTA organizations, especially those focusing on emerging technologies, in the national technology assessment agenda. However, the inclusion of multiple HTA reviews may be discussed in the context of another question: whether standardization or heterogeneity across HTA approaches would be more beneficial. If it is feasible to standardize the HTAs to provide a comprehensive assessment that meets decision-making needs, the use of multiple reviews may be unnecessary. Otherwise, a variety of HTA reviews may need to be a part of a solution with potentially higher costs to the users. Solution development may be informed by future research that provided a detailed account of review redundancy, agreement or disagreement across HTAs on specific topics, and whether the reviews are current.

A dialogue between the HTA organizations and payers is expected to improve evidence development, technology evaluation, and decision making.[8,24] Our study highlighted a need for dialogue and potential coordination among HTA organizations, which may improve their overall capacity for reviews of emerging technologies that are challenging for payers and providers. Although such efforts may encounter barriers,[3,37] the discussion could provide insights at both the health care policy and the HTA organization levels.

In conclusion, private payers use a range of HTAs to inform their coverage decisions regarding personalized medicine, but the current state of HTA to comprehensively guide those decisions is limited. HTA organizations should address current gaps to improve their relevance to payers and clinicians. Current HTA shortcomings may also inform the national HTA agenda.

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