Barriers to Paying for Personalized Medicine from the Perspective of Payers, Providers, and Patients

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ABSTRACT

Personalized medicine uses genomics and genetic testing to develop treatments specific to individual patients. Personalized medicine has recently emerged as a counterpoint to evidence-based practice which uses standardized protocols to treat patients. Despite the potential for positive patient outcomes from personalized medicine, it is currently mostly restricted to a few areas of practice, such as prenatal testing and targeted cancer therapies. Financial barriers are often singled-out as an obstacle for fully implementing personalized medicine, specifically provider reimbursement. This paper synthesizes research on the current state of personalized medicine reimbursement. The perspectives of payers, providers, and patients are addressed individually. Recommendations for removing financial barriers to personalized medicine implementation are also presented.

Keywords: Personalized medicine, genomics, genetic testing, reimbursement, systematic review

INTRODUCTION

Personalized medicine uses genomics to develop treatments specific to individual patients and has recently emerged as a counterpoint to evidence-based practice which uses standardized protocols to direct treatment decisions (Scheuner, Sieverding, & Shekelle 2008). Despite the potential to improve patient outcomes, the delivery of personalized medicine in current practice is mostly restricted to prenatal testing and targeted cancer therapies. Providers have singled-out reimbursement as an obstacle for fully implementing personalized medicine in practice (Manolio, Chisholm, Ozenberger, et al. 2013). Since most studies on genomic medicine focus on the efficacy of the treatment and often do not address the specifics of payment, current research does not address the factors necessary for successful reimbursement of personalized medicine. This paper synthesizes research on the current state of personalized medicine reimbursement by examining empirical studies that involve payment for services. Perspectives are addressed from all stakeholders: payers, providers, and patients. Recommendations for addressing barriers to reimbursement are also presented.

There are many incentives for insurance companies to reimburse personalized medicine, such as reducing the amount spent on treating normally high-cost conditions. Genetic research has shown that people with certain gene structures are predisposed to reacting to certain medicines and procedures. For instance, genomics may be able to tell if a cancer patient needs chemotherapy in addition to surgery. Faulkner (2011) noted that "single-marker diagnostics often have an acquisition cost of less than US $400 per patient. From the payer perspective, it is often considered a reasonable investment to determine whether a medicine with annual costs of $20,000 to $100,000 is likely to benefit a particular individual" (p.1163). Avoiding chemotherapy could lead to lower costs of treatment for all parties involved, not to mention preventing patients from exposure to unnecessary toxins and their effects.

Patients encounter many barriers to fully realizing the potential of individualized medicine. Currently, insurance only covers specific testing for certain disorders if there is sufficient reason to believe a person may have a genetic disorder. Patients cannot directly order most genetic tests themselves even when they are willing to pay out-of-pocket, instead needing a physician to order the test. Therefore, the utilization of personalized services relies on demand from both providers and patients.

In the area of population health, the major incentive to increase funding for genomic research and services is pursuing preventative care. Personalized medicine can be used to identify people at high risk for a genetic condition. However, the genetic information necessary to recognize potential conditions are often not available or not captured by providers. For example, patients' family or past medical history from electronic health records (EHRs) could be used to identify those at high risk of preventable genetic conditions.

Growth of personalized medicine continues to be remarkably slow despite the potential for improvements to patient outcomes and slowing costs through prevention of potentially severe illnesses. Reimbursement is often mentioned as an obstacle for fully implementing personalized medicine, but very few specifics have been offered to help address this issue. This review seeks to fill this gap by answering two questions:

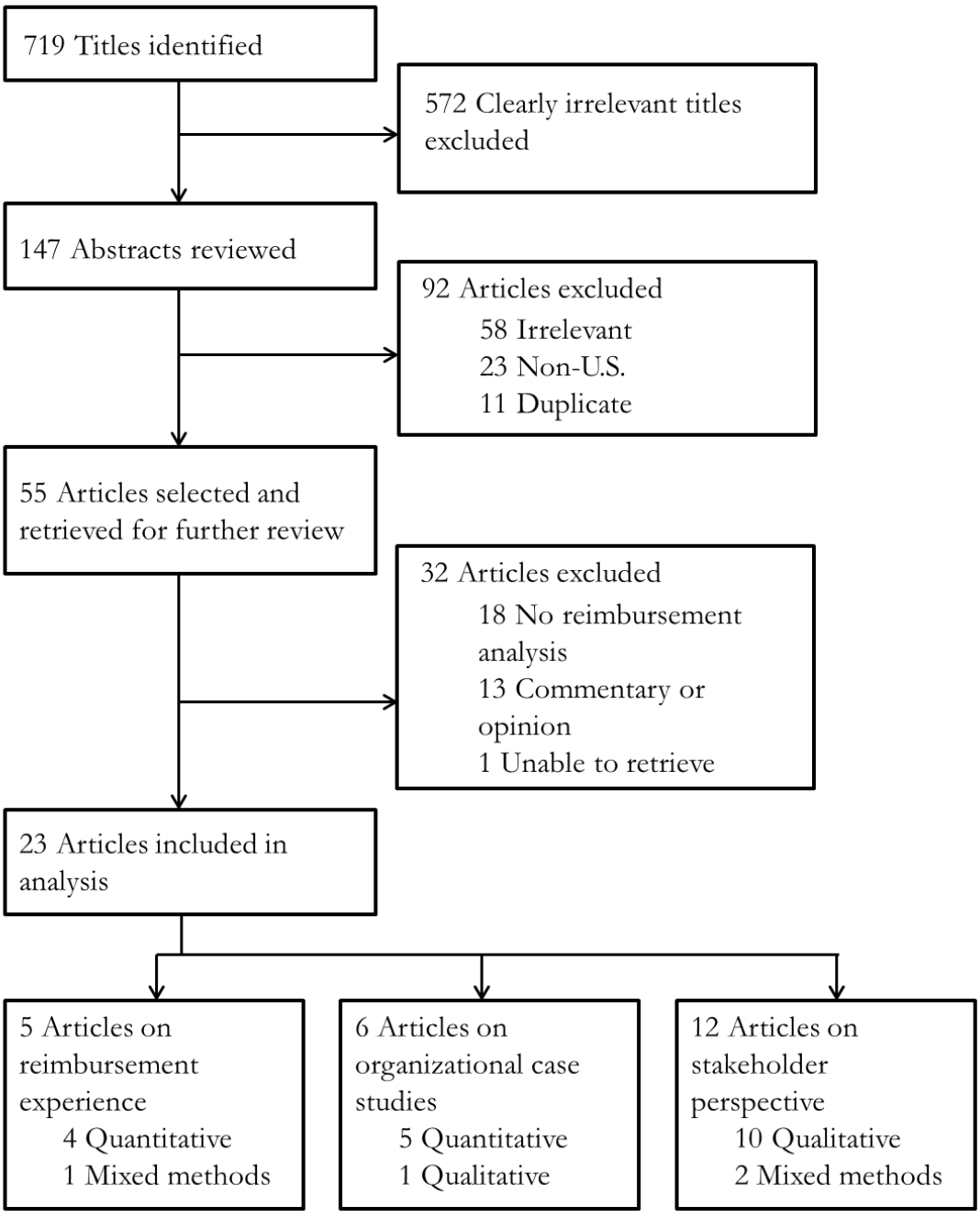
1. What is the current state of reimbursement of personalized medicine?
2. What needs to happen to increase the reimbursement of personalized medicine?

The first question uses empirical evidence to synthesize provider and organizational experiences with reimbursement. The second question is addressed from the point of view of payers, providers, and patients.

METHODS

PubMED/MEDLINE and JSTOR were searched using the following keyword combinations: *genomics* or *genetics* and *reimbursement, payer, payment*. Articles from January 2008 to June 2014 were included in the search. This choice was guided by the passage of Genetic Information Nondiscrimination Act (GINA) in 2008, which provides protection from genetic discrimination in health insurance and employment situations. Prior to GINA, the choice for utilizing personalized medicine might have been constrained by uncertainty over privacy and so these papers would be inappropriate to include in this paper. To exclude thought pieces and op-eds, only articles with an empirical component related to reimbursement of genetic services were reviewed, including quantitative, qualitative, and mixed method research designs. Articles relating to non-U.S. health care organizations were excluded due to lack of comparability of health care financing in other countries. A total of 719 article abstracts were reviewed and 23 fit the criteria. Most of the non-reviewed articles were excluded because they were irrelevant (e.g., genetically-modified food research), were commentaries or opinion-based, or were duplicate references (Figure 1).

Figure 1. Literature Flow



RESULTS

Articles fell into three general categories: experience with reimbursement, organizational case studies, and stakeholder perspectives. Provider experience with reimbursement articles all contained quantitative analysis, while the organizational case studies were often qualitative (e.g., interviews and

panel discussion). These two categories of articles were relevant to the first research question of this paper, which asks what specific factors are related to the current state of reimbursing personalized medicine. Articles relating to the perspective of payers, providers, and patients were considered mostly for the second research question, which asks what needs to be done from all stakeholder perspectives to increase reimbursement for genomic medicine. A summary of the relevant findings is provided by category in Table 1.

Table 1. Literature Summary Matrix

Lead Author, Year	Personalized Medicine Topic	Data Collection	Selected Reimbursement-Related Findings
Experience with Reimbursement			
Cohen, 2012	Pharmacogenomics	Survey & Administrative records	Companion diagnostic tests are not reimbursed consistently because payers want more comparative effectiveness research (CER). Medicare patients face fewer barriers to accessing personalized drug therapy when delivered through Part B, contrasting with reimbursement issues for self-administered (Part D).
Gustafson, 2011	Genetic Counseling	Administrative records	Using a newly-available CPT code (96040) for reimbursement of genetic services resulted in successful reimbursement 63% of the time. Reasons for denying reimbursement were coding concerns (37%), policy limitations (24%), bundling of services (33%), and preauthorization problems (8%).
Harrison, 2010	Genetic Counseling	Survey	The majority (69%) of genetic counselors surveyed used genetic services CPT codes for reimbursement, mostly billing under a physician's name. Reasons for not using CPT codes to bill include lack of credentials for the counselors and perception that alternative reimbursement strategies would result in higher payments. In place of payer reimbursement, providers covered the cost of genetic services using grant funding and using other types of CPT codes.

Riggs, 2013	Genetic Testing	Survey	Chromosomal microarray tests were ordered only 18% of the time when providers felt it was warranted. Two-thirds of respondents cited "lack of insurance coverage" as the major reason for not ordering the test, followed by the cost of testing. Of the 131 providers surveyed, 72% reported denials from payers. Reasons for denial included the "experimental" nature of the test, genetic testing exclusions, test deemed unnecessary, or efficacy of test questioned.
Weaver, 2010	Genetic foods	Survey & review	Coverage of medically necessary foods for people with genetic disorders varies by state, with 61% of states providing or guaranteeing medical foods for newborns and 82% providing formulas. Coverage is often restricted to children and newborns.
Organizational Case Studies			
Allison, 2008	Pharmacogenomics	Interviews	Drug companies that identify biomarkers face large sunk costs in R&D to provide proof of efficacy. Payers want to base reimbursement on how well testing works for individual patients.
Duke, 2009	Genetic surveillance	Panel discussion	Surveillance of stillbirths, which are often associated with genetic anomalies, requires resources for data collection, training, and other long-term considerations. As a public health initiative, reimbursement of services will likely be tax-funded.
Engel, 2012	Cancer risk management	Interviews	For the high risk breast and ovarian cancer program, insurance companies usually reimbursed for the initial consultation and follow-up visits. Insurance covered some costs, such as clinic visits and ultrasound costs, but overall only about 59% of clinic costs were covered for the comprehensive program. Cost-savings due to avoided high-cost cancer treatments were estimated to far exceed unreimbursed care.
Meckley, 2009	Genetic Services	Case studies	The likelihood of reimbursement of personalized therapies is stronger for randomized control trials (RCTs) than for observational sources of evidence. All six case studies were estimated to result in cost savings.
Seegmiller, 2013	Genetic Testing	Survey	Standard ordering protocols for genetic testing of bone marrow conditions resulted in more efficient reimbursement of testing. If used nationally, the authors estimate millions could be saved over traditional testing due to less over-testing and more efficient testing.

Wang, 2011	Genetic Services	Research review	Reimbursement for BRCA genetic services were more comprehensive for private payers compared with public payers. Family history of cancer was the most common predictor of coverage.
Stakeholder Perspectives			
Christianson, 2012	Genetic Testing	Focus groups	Even if individuals are at increased risk of cancer due to family history, providers may not pursue genetic testing due to questionable effectiveness of certain screening tests (specifically testing for prostate and ovarian cancers), lack of reimbursement for follow-up counseling, and lack of coverage of tests.
Dingel, 2012	Genetic Research	Interviews	Stakeholders fear public funding of genetic services will divert resources from other types of treatments that have proven to be effective.
Engstrom, 2011	Genetic Testing	Panel discussion & survey	The high cost of genetic testing was identified by 53% of providers as a deterrent to utilization. However, evidence supporting the need for a test was identified by 75% of respondents as the biggest impediment to ordering tests.
Epstein, 2009	Pharmacogenomics	Panel discussion	Seven main reimbursement issues were identified from payers: needing more cost-effective analyses, the poor predictive value of tests, more information is needed on long-term cost offsets, the risk reduction from tests should be considered relative to usual care, there is fear of bad press for covering certain tests, needing more individualized research (instead of hypothetical cases), and enhanced US FDA labeling of genetic products.
Esmail, 2013	Genetic Research	Panel discussion	Funding for genetic research should be prioritized by the level of benefit to the population, with more expensive genetic services given relatively lower priority.
Faulkner, 2011	Pharmacogenomics	Panel discussion	Value-based pricing is important for payers to maximize the benefit of paying for certain diagnostic tests.
Guzauskas, 2013	Genetic Services	Panel discussion & survey	Decision-analytic models used in other industries are desired for evaluating genetic services, due to the uncertainty of the value of many genetic services.
Noe, 2008	Cancer risk management	Research review	The main barrier to melanoma screening was lack of time, followed by patient reluctance and lack of reimbursement.

Powell, 2010	Genetic Testing	Web forum & interviews	Patients and providers cite inconsistent reimbursement as an impediment to genetic testing. High prices decreased the utilization of services due to patient unwillingness.
Sayres, 2012	Genetic Testing	Interviews & survey	Funding from all available resources is needed for research. Patient education is an important part of ordering test because patients may not want the test if they are uninformed about the value.
Watson, 2009	Genetic Testing	Survey	New genetic screening and test for adverse reaction to HIV drugs was perceived as being valuable to providers, but anticipated lack of reimbursement was cited as a reason for not utilizing the services. An educational program offered to providers from the genetic testing company decreased the percent of providers who feared lack of reimbursement from 69% to 60%.
Weldon, 2012	Genetic Services	Interviews	Barriers and perceptions of testing vary among providers, advocates, and patients. The main barriers to using genetic tests include the fear that the test may reduce later drug or procedure reimbursement, the time providers counsel patients on test decisions are not reimbursed, supportive and genetic services are not reimbursed, and the out-of-pocket expenses for patients were too high.

Current State of Reimbursement

Reimbursement of personalized medicine is inconsistent, however a few common factors were identified from the five articles related to provider experience. Four of the articles involved primary data collection through surveys and two analyzed administrative records to summarize billing and utilization trends. In general, perceived lack of potential reimbursement often prevented the use of genetic services altogether. This is despite evidence from one study that found the majority of claims for genetic counseling (62%) were at least partially reimbursed (Weaver, Johnson, Singh, et al. 2010). Three of the five articles found that unclear definitions of what constitutes genetic services were an impediment to utilization and reimbursement of these services. Three articles also found that lack of insurance coverage prevented providers from ordering genetic

services, even when the provider found them to be warranted. Only one of the five articles cited a lack of clinical utility as the major barrier to employing and seeking reimbursement for genetic services.

The six organizational case study articles employed five data collection strategies: survey, panel discussion, case studies, literature review, and interviews. Three of the articles performed some type of cost-benefit analysis and found that the genetic services were estimated to result in net savings, with one of those reporting that more evidence of effectiveness was nonetheless necessary for expanded reimbursement of genetic services. Two of the six articles specified that payers required more evidence of individual effectiveness. One perspective was that payers need better information on individual outcomes in order to base reimbursement on the likelihood of effectiveness (i.e., drugs with a low chance of effectiveness will not be covered or will only be covered with high patient cost-sharing). The article relating to stillbirth surveillance programs and related genetic disorders found that lack of resources prevents, and will likely continue to prevent, the implementation of these programs due to the need for government funding. Finally, mirroring the provider experience theme of definitional issues, the literature review on BRCA genetic services found that payers usually did not have specific eligibility criteria for reimbursement. Without defined eligibility criteria, providers often do not pursue genetic services because they perceive the treatment will not be covered.

Stakeholder Perspectives on Increasing Reimbursement of Personalized Medicine

The bulk of the reviewed articles were related to stakeholder perspectives on what is necessary to increase reimbursement and utilization of personalized medicine. Five of the twelve articles employed panel discussions, four involved interviews, four conducted surveys, one performed a research review, and one was a focus group. Four specific categories were identified to help increase reimbursement of genetic services, one directly related to reimbursement and the other three related

to increasing the demand for services. Many of these ideas were shared among the three stakeholders (Figure 2). First, reimbursement must cover not only genetic tests, but also for provider time to explain the objectives and value to patients. Indirectly, demand for services could increase in three ways: more evidence of effectiveness, a decrease in patient cost-sharing for tests and services, and more resources for patient education.

Comprehensive reimbursement of providers. Eight of the twelve stakeholder perspective articles highlighted the need to make utilization of genetic services worthwhile to the provider. Not only do tests need to be covered by payers, but the time it takes providers to explain and counsel the patient should also be reimbursed. In fact, Noe (2008) found that the main barrier to melanoma screening for providers was lack of time. Additionally, providers want incentives for engaging in research and innovation. A lack of resources was especially significant to public health providers who rely on government funding for genetic services.

Evidence of effectiveness. Nine of the articles found that the clinical utility of many genetic services is often not understood by payers or providers. Payers want more evidence of effectiveness, such as more comparative effective research (CER) and randomized control trials, before services will be consistently covered. Providers were often unconvinced from existing effectiveness research due to the poor predictive value of certain tests. Many of the papers found that questionable evidence of effectiveness was the biggest factor in preventing utilization of preventative services, trumping financial concerns.

Lower patient cost-sharing. Four articles found that high patient costs prevented utilization of genetic services. Both providers and patients desired greater coverage of services to reduce patient cost-sharing. For patients to consent to using genetic services, they must be willing to pay their share of the price. This category is directly related to the previous category of the need for more effectiveness evidence—for patients to be willing to pay a high price for genetic services, they must

also believe that it is worthwhile. Since providers are the gatekeepers to these services, they too must be convinced of the value.

Better patient education. Four articles found that both patients and providers want better educational resources for patients concerning the costs and benefits of genetic services. As noted, genetic services can be costly for patients and having access to information is necessary to help make the decision on whether the service is worthwhile. Providers want patients to be informed about the pros and cons of genetic services so they can make a well-informed decision together about the right course of action. Presumably, better access to educational resources would also lessen the amount of time providers had to spend explaining the information to patients.

Figure 2. Stakeholder Perspectives on Increasing Utilization of Personalized Medicine

Payer	Provider	Patient
More evidence of effectiveness		
	Comprehensive reimbursement for all genetic services	
	Lower patient cost-sharing	
	More patient education	

DISCUSSION

Currently, reimbursement of personalized medicine remains limited due to a number of factors. The empirical research and organizational case studies suggest the need for better definitions of genetic services to guide understanding of coverage and to address inconsistent payment. However, the introduction of standardized CPT billing codes may help improve the payment process. Nonetheless, a common sentiment was that the clinical utility of many genetic services is still in question. Given the high cost of some genetic services, utilization of personalized medicine is often simply avoided.

Reimbursement of personalized medicine can only happen if genetic services are utilized. The results of this review suggest three ways to increase utilization of genetic services, specifically, more research on effectiveness, a decrease in patient cost-sharing for tests and services, and more resources for patient education. More effectiveness research is sought by providers and payers who are both seemingly willing to support increased utilization of personalized medicine, but feel the evidence is not yet strong enough. Both patients and providers feel that patient cost-sharing for most genetic services is often prohibitively high, disincentivizing patient interest. Finally, better resources for patient education about the benefits of genetic services could spur interest and potentially increase patient demand, while also making providers jobs easier.

Conclusion

This paper sheds light on the current state of reimbursement of personalized medicine. Given its nascent stage, personalized medicine is surrounded by inconsistencies and confusion, especially related to the effectiveness of many services and the definitions of insurance coverage. Four specific categories were outlined to help guide an increase in the reimbursement of genetic services, focusing on ways to increase utilization and patient demand.

Personalized medicine has the potential to change the way health care is delivered by individualizing and improving the diagnosis and treatment of many conditions. Additionally, downstream expenditures could decrease if genetic testing and screenings help prevent diseases that are normally high-cost. However, more research and resources are needed before payers, providers, and patients will be convinced of the value of many genetic services.

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