INNOVATIONS in pharmacy lip

Volume 7 | Number 2 Article 8

7-1-2016

Greater Expectations for Pharmaceutical Value: Better Care, Healthier People, Smarter Spending

Jon C. Schommer
University of Minnesota - Twin Cities, schom010@umn.edu

Brian Isetts
University of Minnesota - Twin Cities, isett001@umn.edu

Greater Expectations for Pharmaceutical Value: Better Care, Healthier People, Smarter Spending

Jon C. Schommer, PhD: Editor and
Brian J. Isetts, PhD: Guest Commentator
University of Minnesota College of Pharmacy

VALUE-BASED HEALTH CARE PAYMENT

When it comes to improving the way health care providers are paid, value and care coordination are being rewarded – rather than volume and care duplication [1]. The U.S. Department of Health and Human Services is testing and expanding new health care payment models with the goals of improving health care quality and reducing its cost [1]. The 'Payment Taxonomy Framework' [1] describes progression across four categories of payment:

Category 1:	fee-for-service with no link of payment to quality
Category 2:	fee-for-service with a link of payment to quality
Category 3:	alternative payment models built on fee-for-service architecture
Category 4:	population-based payment

Value-based purchasing includes payments made in Categories 2 through 4. Moving from Category 1 to Category 4 involves two shifts: (1) increasing accountability for both quality and total cost of care and (2) a greater focus on population health management as opposed to payment for specific products and services [1-3].

Health care organizations have been making the shift toward increased collaboration, outcome-based payment, and new benefit design. This is changing the way entities pay for health care and how health care is delivered [4]. Value-based contracting models represent an evolution in clinical and payment methodologies aimed at creating quality and cost outcomes, fostering greater accountability, and taking advantage of innovations in medical technology [3,4]. These contract models align incentives across providers, members, employers, and payers to improve clinical outcomes and the patient experience along with improving cost efficiency [3-5].

Many health care markets already have physician and hospital performance-based contracts, or capitation arrangements. In response to health care reforms at national and state levels, there also has been growth in accountable care organizations (ACOs), with payment and care delivery models that tie provider reimbursements to quality metrics and reductions in the total cost of care for an assigned population of patients.

VALUE-BASED PHARMACEUTICAL PAYMENT

The same pressure that is being applied to health-systems, providers, and patient care programs is likely for value-based assessment of pharmaceuticals. Questions about (1) improving the patient experience of care, (2) improving the health of populations, and (3) reducing the per capita cost of health care (the Triple Aim) are relevant in the pharmaceutical domain [6].

In order to meet value-based care goals from the use of pharmaceuticals, patients themselves are responsible for engaging in behaviors, participating in self-monitoring, and providing information. In addition, patient variability needs to be taken into account which includes such things as genes, environment, personality, and lifestyle for each person – often referred to as "precision medicine" [7]. While significant advances in precision medicine have been made for treating select cancers, the practice is not currently in use for most diseases, especially pharmaceutical treatment of chronic diseases for which self-management and monitoring by patients themselves are needed.

Typically, the health care system views pharmaceutical product use in terms of clinical problem-solving (prescribing, monitoring, reconciling) and in terms of medication regimen adherence and persistence (following directions). However, the use of pharmaceutical products by patients is affected by their medication beliefs, personal abilities and motivations, information processing, decision-making, relationships, finances, and the effects of life experiences [8-9]. Patients vary widely in their make-up, their preferences, and their needs. As people use pharmaceutical products, there is a high likelihood that they will involve a personal contact, either lay or professional, to help them [10-12]. Patients have different abilities, motivations, and needs when it comes to pharmaceutical use. The challenge, then, is to meet the needs of each individual within the broader context of populations and to reflect this in value-based assessments. When making drug approval and drug use decisions for populations of patients, these individual differences must be considered in targeting pharmaceutical interventions and management to patient populations.

VALUE-BASED FORMULARY DECISION-MAKING

In the United States, the Food and Drug Administration (FDA) makes decisions about the safety and effectiveness of pharmaceutical products through the use of clinical trials which are tightly controlled studies. Clinical trials, also known

as clinical studies, test potential treatments in human volunteers to see whether they should be approved for wider use in the general population. With tight controls employed in these studies, little attention is given to variation in patient characteristics or to replication under varied conditions.

After a drug is approved for use by the FDA, formulary committees make decisions about the comparative effectiveness and value of pharmaceuticals on behalf of health plans that, in turn, represent populations of patients. Typically, claims for justifying the acceptance and placement of pharmaceutical products on health system formularies, are presented in "potential-value" terms that are either unevaluable or only evaluable in a timeframe or under conditions that are of no practical benefit for making utilization-based value judgments.

To address the gap between current practice and the value-based payment approaches that have emerged, Dr. Langley and colleagues have published a series of commentaries that lay a foundation for taking next steps in validating pharmaceutical product claims [13-17]. The principles are rooted in (1) addressing value-based care, (2) making evaluations practical, (3) using technical standards, (4) developing validation protocols, (5) using explicit formats, (6) conducting formal review, and (7) collaborating on access to data [13-17]. They have proposed that evaluating claims for pharmaceutical products and devices should be seen as a necessary part of any program of continuous quality improvement in health care delivery. The absence of feedback to formulary committees, health care providers, and other decision-makers regarding pharmaceutical product performance is a major and contributing gap in the ability to deliver effective, affordable and high quality healthcare.

To build upon that series of commentaries, Dr. Paul Langley is guiding work at the University of Minnesota, Graduate Program in Social and Administrative Pharmacy to generate discovery, discussion, and debate about the transformation that is needed in ***Guidelines for Formulary Evaluations*** so that value-based assessment of pharmaceutical products and services can be achieved and meet the greater expectations of "better care, smarter spending, and healthier people [18]." INNOVATIONS in pharmacy is pleased to serve as a communication venue for this effort. In addition to Dr. Langley's work, we welcome your contributions to this discourse.

References

1. Rajkumar, R, Conway PH, Tavenner M. CMS – Engaging multiple players in payment reform. JAMA. 2014, May 21; 311(19): 1967-8.
2. Porter, ME. What is value in health care? N Engl J Med. 2010; 363(26): 2477-2481.
3. VanLare, JM, Conway PH. Value-based purchasing – national programs to move from volume to value. N Engl J Med. 2012; 367(4): 292-295.
4. Burwell, SM. Setting value-based payment goals – HHS efforts to improve U.S. health care. N Engl J Med. 2015; 372(10): 897-899.
5. Thomson, S, Sharing L, Charenew ME. Value-based cost sharing from the United States and elsewhere can increase patients' use of high-value goods and services. Health Aff (Millwood), 2013; 32(4): 704-712.
6. Berwick, DM, Nolan, TW, and Whittington, J. The Triple Aim: Care, Health, And Cost, Health Affairs, 27, no.3 (2008): 759-769.
7. Collins, FS, Varmus H. A New Initiative on precision medicine, The New England Journal of Medicine, 2015, 317(9): 793-795.
8. Schommer, JC, Worley MM, Kjos AL, Pakhomov SVS, Schondelmeyer SW. A thematic analysis for how patients, prescribers, experts, and patient advocates view the prescription choice process, Research in Social & Administrative Pharmacy, 2009 (5): 154 – 169.
9. Schommer, JC, Worley MM, Kjos AL, Decision-making during initiation of medication therapy, Research in Social and Administrative Pharmacy, 2014, 10 (2): 313-327.
10. Kjos, AL, Worley MM, Schommer JC, The social network paradigm and applications in pharmacy, Research in Social and Administrative Pharmacy, 2013, Vol. 9, No. 4, 353-369.
11. Kjos, AL, Worley MM, Schommer JC, Medication information seeking behavior in a social context: The role of lay and professional social network contacts, INNOVATIONS in pharmacy, 2011, 2(4): Article 63, 23 pages.
12. Schommer JC, Glinert LH. A Screenful of Sugar? Prescription Drug Websites Investigated, Peter Lang Publishing, Inc., New York, (2014).
13. Langley P. The status of modeled claims. J Med Econ. 2015;18(12):991-992
14. Langley P. Validation of modeled pharmacoeconomic claims in formulary submissions. J Med Econ. 2015;18(12):993-999.
15. Schommer J, Carlson A, Rhee G. Validating pharmaceutical product claims: questions a formulary committee should ask. J Med Econ 2015;18(12):1000-1006
16. Belsey J. Predictive validation of modeled health technology assessment claims: Lessons from NICE. J Med Econ 2015;18(12):1007-1012.
17. Wasser T, Haynes K, Barron J, Cziraky M. Using 'big data' to validate claims made in the pharmaceutical approval process. J Med Econ 2015;18(12):1013-1019.
18. College of Pharmacy. University of Minnesota. Program in Social and Administrative Pharmacy. *Guidelines for Formulary Evaluations* [proposed]. June 2016 (Version 1.0) http://www.pharmacy.umn.edu/sites/pharmacy.umn.edu/files/minnesota_guidelines.pdf