7TH ANNUAL RESEARCH SYMPOSIUM
MEETING REPORT

VALUE-BASED HEALTH CARE
Identifying Benefits for Patients, Providers & Payers

October 16, 2017 – Dallas, Texas

PRESENTATIONS

- Concepts of Health Care Value and Patient Perspectives
- Paying for Value In Health Care
- Best Poster Presentation: Medication Therapy Management Services and the Impact to Health Care Utilization
- Roadmap to Patient Engagement
  - Just Ask the Patient
  - Inspiring Good Patients and Good Shoppers
- Provider Perspectives on Consumer Priorities in Value-Based Care
  - Assessing Value: One Size Does Not Fit All
  - Finding, Counting and Proving Value
- Payer Perspectives on Value
  - Transparency in Health Care: A Roadmap for Consumer Engagement
  - An Employer’s Balance in Managing Clinical Decisions
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WITH APPRECIATION

The AMCP Foundation would like to express its appreciation to the organizations that provided support to the Research Symposium. The live meeting and the summary of its proceedings were made possible in part by those below.
CONCEPTS OF HEALTH CARE VALUE AND PATIENT PERSPECTIVES

Alan Balch

Fully understanding value in health care requires that we develop a standardized process for incorporating the patient perspective into health care decision-making at multiple points in their journey. Currently, many gaps exist in our ability to realize this need. Value frameworks and health economic analyses have yet to fully capture what really matters most to the patients themselves, which prevents those needs and desires from being fully incorporated into the complex equations which inform population-level health care decisions.

Market research conducted by the Patient Advocate Foundation (PAF) confirms the existence of numerous gaps in our understanding of patient preferences and how those translate into perceptions of quality and value. PAF provides direct support to patients with chronic, life-threatening or debilitating diseases experiencing acute affordability and access problems, both through financial assistance and case management. We support approximately 250,000 patients and their families through all of our program service areas. In case management, the patients we served in 2016 had an average income of $23,000 with most coming from a household of two or fewer. They’re also racially and ethnically diverse. Very few of our patients – about 10% – are uninsured; roughly three quarters have coverage either through Medicare or commercial insurance.

About 90% of our patients report having some degree of financial hardship, and about 25 to 30% of these patients say that the financial hardship has some impact on their medical care, such as skipping medication or appointments, or postponing treatment. More commonly, patients in these circumstances are finding a way to pay for treatment by making financial trade-offs – such as not paying utility bills, not buying groceries, missing rent or mortgage payments, or missing care payments. Many of our patients also report consistent challenges with transportation and employment related to their medical care. The latter is particularly problematic because employment is tied not only to the income patients need to pay their expensive medical bills, but also to maintain health insurance without which medical care would likely be financially impossible.

While these factors are top of mind for many patients, they are not commonly considered in value discussions among other stakeholders in the health care system. When we think about out-of-pocket costs in the medical context, we tend to focus on those elements that are part of the insurance benefit design such as deductibles, co-payments and co-insurance. This perspective fails to consider all of the other day-to-day out-of-pocket costs patients experience that are just as much associated with their treatments as their copayments. This disconnect is most evident in the oft repeated notion that only through copays and coinsurance do patients have “skin in the game.”

SURVEY REVEALS PATIENT CHALLENGES

Our survey reveals that transportation and employment – two necessities for many of our patients – are among their greatest concerns, yet are elements often considered indirect or out-of-scope to the consideration of value in health care.

With respect to transportation, several issues arise:

- 10% of our patients report that inability to afford transportation for their treatment as the single most important issue they face.
- About 30% of patients report that travel to and from treatment is somewhat or very difficult. However, of these only 30% attribute the
challenge to distance. Rather, the challenge includes finding someone to go with them, taking time off from work, and finding a way to get to the appointment.

- Roughly 40% of patients report skipping trips to drop off or pick up prescriptions due to transportation challenges.

About half of the patients we help were employed at some point in the past 12 months, and roughly 60% of those report that their treatment has some negative impact on their employment.

### IMPACT ON EMPLOYMENT

<table>
<thead>
<tr>
<th>Impact</th>
<th>Percentage</th>
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<tr>
<td>Lost my job due to illness</td>
<td>12.30%</td>
</tr>
<tr>
<td>Lost income due to the inability to work full time</td>
<td>21.25%</td>
</tr>
<tr>
<td>Unable to perform at normal performance levels</td>
<td>25.14%</td>
</tr>
<tr>
<td>Unemployed for reasons not related to this illness; finding it difficult to find a job now due to this illness</td>
<td>3.74%</td>
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For commercially-insured patients, these challenges to employment can be a major burden as it not only means they would lose income, but also would potentially lose insurance coverage.

In thinking about the value of a treatment regimen to a patient, these findings force us to consider dimensions we might otherwise not. Does a treatment regimen help a patient stay at work longer, or perform better at work? Does it alleviate the transportation burden or make it more manageable?

### TRIPLE AIM: FOR THE PATIENT OR SYSTEM?

The Triple Aim of health care – decreasing cost while improving outcomes and patient experience – has grown in focus over the past decade. But we need to ask whether the achieving the Triple Aim means that the system decides on behalf of patients what is important to them, or that the standard of care should be personalization.

In our surveys, at least 85% of patients across various disease areas prefer some level of shared decision making with their doctors. Another 10% would prefer to be completely in charge the health care decisions related to their diagnosis. These results beg the question of what role should patients have in helping to determine what right care is for them and how success should be measured? Or should other actors in the health care system decide on behalf of patients what is the right care for them and define how success is measured? We suggest a collaborative model of multi-stakeholder engagement that places the patient at the center of these important discussions currently shaping the health care environment as we shift our payment paradigms from “volume to value.”

### THE COST CONTAINMENT CHALLENGE

In the current system, we incur transaction costs when we move away from the standard care pathway. Utilization review costs a considerable amount of time, effort and money, on behalf of payers, providers and patients. This cost containment strategy – realized through efficiencies and economies of scale in how we treat patients – is important when there exists clear evidence that standardization of care improves outcomes and eliminates unnecessary variation in care. Yet the idea of allowing for an appropriate variation in care – by creating
tools and policies that facilitate opportunities for individual characteristics to influence care decisions – is also a cost containment strategy. Here you contain costs by maximizing effectiveness and utility by getting the right care, to the right patient at the right time.

In a recent survey of 1,400 low-income cancer patients, 83% felt that having a treatment that was highly personalized to their unique characteristics was extremely important. By contrast, 57% of patients felt that receiving treatment that was the standard of care was extremely important. Most notably, however, when we asked patients to express a preference between those two approaches, 96% would opt for highly personalized treatment over standardized approaches to care.

The current approach to understanding value and utility in the health care system falls short of capturing many aspects of care that really matter to patients including variation in those preferences based on type of disease, stage of disease, socio-economics, and other characteristics that shape patient preferences. What we’ve done is try to come up with universally applicable means to measure utility – the EQ-5D being an excellent example – which assess general concepts such as pain, stress and anxiety.

PATIENT VIEWS OF QUALITY DRIVERS

While these are important measures, they often don’t represent the true drivers of quality of life across disease areas, treatment regimens, and most importantly at the level of the individual patient. In our survey, for example, we asked cancer patients which side effects they experienced, and to rank them as either moderate or severe. Across multiple indications and treatments, the frequency and severity of pain varied widely, and in some diseases was a secondary concern to other side effects like sexual intimacy or hair loss.

What is lost in the attempt to create a universal definition for utility or value is the variation in side effects – in terms of frequency, severity and importance to the patient. Instead we attempt to universalize and standardize the patient experience rather than taking the time to ask patients what’s important to them and what barriers are they facing to feeling normal and being independent.

Patients want to feel respected, to feel listened to, and to have a personal connection with their providers. It is important that as we build out means to better facilitate this, we do so in a way that is not merely patronizing or token. With a grant from the Robert Wood Johnson Foundation, PAF sought to develop a health care system
model for delivering on the Triple Aim and for creating better clarity in health care decision making. What we developed is based on the idea of co-creation of care and comprised of six key elements:

■ **Shared Decision-Making**: the sources of information shaping the decision should be both the patient and the provider. This requires that patients be prepared for how to be part of the decision-making process and that both patients and providers receive training on how to conduct decision-making in a way that incorporates the patient voice.

■ **Decision Support Tools**: tools which enable providers and patients to make evidence-based treatment decisions that are optimized to the patients goals, priorities and preferences

■ **Care Plan**: a personalized plan that aligns with patient and family-determined goals, including identification of social support, navigation and other care needs.

■ **Care Coordination and Navigation**: focus must be paid to the supportive services needed for a patient to successfully adhere to their treatment regimen and achieve a high quality of life. This should include transportation, financial assistance, counseling and peer-to-peer support based on risk and need assessment.

■ **Quality Measurement**: rapid advancement is needed in the science of quality measurement, reporting and improvement to create the next generation of measures which align to what matters to patients.

■ **Patient Reported Outcomes**: PROs should allow a patient to report and track their progress, side effects and other factors critical to patients and share them with their clinicians.
CONSIDERATIONS ABOUT HOW WE PAY FOR VALUE IN HEALTH CARE

Cliff Goodman

Increased interest in value in health care has been fueled by many factors. Certainly, the great attention to new, high-cost therapies over the past several years has played a key role. Simultaneously, developments in our capabilities for measuring value, through growth in our capacity to generate real-world evidence (RWE) and increasingly sophisticated analytical tools and approaches, better enable stakeholders within the health care system to understand and consider value in our decision-making.

Many payers, including the federal government, are pushing to shift their incentives from volume-based to value-based. This is apparent in the increased interest in alternative payment mechanisms such as outcomes-based or value-based contracting schemes. However, payers are not the only stakeholders leading the charge on value. There is increased interest in ensuring that patient perspective and patient-centered outcomes are captured in regulatory and market access decision-making, and more generally, in moving the discussion of value beyond standardized, population-level metrics such as cost per QALY—which does have a role—towards a more personalized approach that takes into account the drivers of value at the individual patient level.

EMERGENCE OF VALUE FRAMEWORKS

One significant example of the increased focus on value over the past several years, particularly in the US, has been the emergence and greater prominence of a variety of value frameworks. These frameworks offer a means to objectify the elements of value, and in some circumstances, to imply a “fair” price based on that value. However, these frameworks come in many forms, targeting different stakeholder groups, and consequently, no two frameworks are alike. Some of the better-known frameworks in the US include:

The National Comprehensive Cancer Network (NCCN) Evidence Blocks framework is intended as a tool to support decision making for oncologists and their patients. The framework considers value across five categories: efficacy, safety, quality of evidence, consistency of evidence and affordability.

The American Society of Clinical Oncology value framework similarly presents a tool to be used between oncologists and patients, but assesses value differently. In addition to the key factors of overall efficacy, toxicity and net health benefit, this framework awards additional value to therapies that provide a substantial probability of long-term survival, palliation of symptoms, treatment-free interval and improvement in quality of life.

The Institute for Clinical and Economic Review has developed a framework for payers, PBMs and other policymakers. This framework evaluates cost-effectiveness, in terms of cost per quality-adjusted life years gained, as well as potential budget impact, as a means to understand both value for money and affordability of a new treatment or health technology.

Memorial Sloan Kettering’s Drug Abacus represents an experimental tool, designed to help policymakers understand, given their preferences for specific value criteria, what the “right price” for a drug should be. This tool enables users to specify the value of a life year gained, as well as the relative importance of toxicity, novelty, rarity, population burden, cost of development, patient prognosis and unmet need.

As demonstrated by the variation across these frameworks, it is critical to recognize that there is no “one-size fits all” approach to value. They reflect the fact that with the diverse set of stakeholders, markets and disease areas, value must be considered in a diversified, heterogeneous way.
At AMCP, we believe value is in our DNA, and our central mission has always been to deliver the right drug, to the right patient, at the right time, while optimizing health care resources. Today’s shift towards rewarding value over volume is exciting. Managed care professionals have long been committed to improving quality and patient outcomes.

Until recently, however, we’ve lacked the means to effectively assess those outcomes and reward them for value. Now we have the means: the data, the analytical tools, artificial intelligence, and health information technology which can support us in our efforts to implement value-based health care. The following summarizes a number of AMCP’s initiatives in advancing value-based care.

**AMCP ENGAGEMENT IN VALUE**

**Support for Pharmaceutical Information Exchange Act of 2017**

In the last two years, AMCP has been heavily involved in efforts to expand the ability of pharmaceutical manufacturers and payers to communicate with one another. In the world of value, information – solid clinical, scientific and economic – is the coin of the realm. For health care decision makers, access to this information is essential.

AMCP has taken the lead in expanding communications between biopharmaceutical companies and payers and other decision makers. Two previous partnership forums helped put in motion two major policy developments: the issuance of FDA draft guidance and a provision in the 21st Century Cures Act expanding post-market communications under FDAMA Section 114.

But, more ambitiously, the FDA guidelines authorized product communications before FDA approval – which, with safeguards, AMCP supports. To support pre-approval communications, AMCP is exploring ways that we can provide opportunities and venues for the exchange of that type of information. But to solidify pre-approval communication exchange between manufacturers and payers, we believe an act of Congress is needed to create a safe harbor to allow for this type of information exchange. AMCP has been working diligently over the past several months to support the passage of HR 2026, the Pharmaceutical Information Exchange (PIE) Act of 2017.

**Biologics and Biosimilars Collective Intelligence Consortium**

Biosimilars is another area where AMCP is leading. Biosimilars offer the promise of lower-cost therapeutic options for millions of patients and providers. On Capitol Hill and in state capitals, AMCP staff and members are advocating for policies that will facilitate their market entry and acceptance. Our online Biosimilars Resource Center is a policy neutral, objective information-source for providers, policy makers and others.

AMCP believes that biosimilars in particular have the potential of making a major difference in patient treatment options, market competition, and pharmaceutical spend. However, that won’t happen unless patients and providers are confident that biosimilars are safe and efficacious. Seeking to provide those assurances – through post-market surveillance – is the Biologics and Biosimilars Collective Intelligence Consortium, or BBCIC.
AMCP PARTNERSHIP FORUM ON VALUE-BASED CONTRACTING

Earlier this year (June of 2017) we brought together a group of over 30 national and regional leaders representing health plans, integrated delivery networks, PBMs, employers, manufacturers and data and analysis experts.

Goals were straightforward:

- Gain consensus on a definition for value-based contracting,
- Understand strategies for developing and utilizing performance benchmarks,
- Identify best practices for implementation of value-based contracts, and
- Identify action plans to mitigate legal and regulatory barriers.

Prior to discussing these items we sought to assess the current situation: How many value-based contracts are there? What’s the level of interest? At the forum, the results of a 2017 AMCP/Xcenda survey of members were presented. The survey findings indicated that while the pick-up rate is relatively low, interest in value-based contracting is strong and growing. Of the respondents:

- 1 in 5 payers have value-based contracts, as do 1 in 3 manufacturers,
- But two-thirds of payers and half of all manufacturers are interested in implementing value-based contracting.

What are the barriers to value-based contracting? Among payers, the most prevalent barriers were:

- Perceived lack of evidence that they reduced pharmaceutical spending,
- Inability to obtain outcomes data during the contract period, and
- Uncertainty about budgets to manage contracts.

Manufacturers too face barriers, including challenges in obtaining accurate data and outcomes metrics, limits on product communications outside of FDA-approved labeling, and other legal and regulatory barriers.

Defining Value-Based Contracting

Since the emergence of value-based contracting, the lack of a commonly accepted definition has been a challenge. The forum participants’ aim was to craft a definition broad enough to capture an array of agreements and allow for innovation, both in contracting and health care.

After much deliberation, the forum participants settled on a definition, which reads:

“A value-based contract is a written contractual agreement in which the payment terms for medications or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures.”

With this definition, AMCP and others are better able to advocate for process improvements, and also for a regulatory environment that facilitates these new models of payment.

Best Practices for Developing and Implementing Value-Based Contracts

One of the greatest challenges in developing a value-based contract is – simply – how do you measure value? Deciding which outcome to measure can quickly become complex, the participants concluded. They strongly recommended keeping measurements simple, and more specifically, that they be easily measurable, clinically relevant and associated
of manufacturers use outcomes-based contracts, but half are interested.

<table>
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<th>Outcomes-based contract in place</th>
<th>33%</th>
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<tbody>
<tr>
<td>No, but interested</td>
<td>50%</td>
</tr>
<tr>
<td>No, but pending</td>
<td>13%</td>
</tr>
<tr>
<td>No, not interested</td>
<td>0%</td>
</tr>
<tr>
<td>Not sure/ I don’t know</td>
<td>3%</td>
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with financial and/or clinical improvements. These might include health care utilization rates or hard clinical endpoints such as progression-free survival or cure rates, among a multitude of others.

Data – both its availability and quality – is central to value-based contracting. Participants indicated that key questions that should be considered in determining whether available data is appropriate for value-based contracting are:

- What are the sources?
- How will it be collected, validated and analyzed?
- How will the patient populations be defined?
- Is the infrastructure there to perform all the data collection and analytical functions that are needed?

Few things complicate value-based contracting more than time. Namely, patients are typically enrolled for one year and some outcomes take longer to emerge. Participants offered this strategy: Surrogate and escalating endpoints could be used to align outcomes with the allotted time period.

**Mitigating Legal and Regulatory Barriers**

What’s inescapable in any discussion of value-based contracting are the regulatory and legal obstacles. They’re not entirely insurmountable, as the growing number of contracts attests. But they may be limiting value-based contracting’s potential growth.

The federal Anti-Kickback Statute seeks to prevent parties from giving something of value with the intent of influencing a purchase under a federal program like Medicare or Medicaid. Over the years, Congress has created some statutory exceptions, and the Health and Human Services Office of the Inspector General has also created some exemptions and regulatory safe harbors to the Anti-Kickback Statute. Participants at our partnership forum agreed that AMCP should be advocating for a new safe harbor for value-based contracts that includes a wide range of services, such as, for example, wrap-around patient services. In the long term though, AMCP will need to advocate for fundamental legislative and regulatory reforms to the fraud, waste and abuse laws.

The second major regulatory obstacle is Medicaid Best Price. So how does this present a problem? Well, if for example, a value-based contract includes a very large discount or perhaps a refund in cases of treatment failure, the price paid could set a new lowest-best price. One possible solution would be for CMS to create an exception from the Medicaid Best Price rule for value-based contracts.
Over the past several years, value-based contracts have emerged as a means for payers and manufacturers to transact in a way that rewards therapies which are of most value to the health care system. While Dr. Cantrell highlighted many of the challenges which still remain to further adoption of these types of arrangements, our data-driven capability to identify and measure outcomes in real-world populations, and allocate payments against them, is rapidly evolving, making even more possible tomorrow than what is possible today.

Still, as highlighted by the AMCP/Xcenda survey, a major barrier to payers in greater usage of value-based contracts is the perception of a lack of evidence that they actually reduce health care spending. The following case study aims to demonstrate how innovative value-based arrangements are capable not only of reducing health care spending, but of creating value to both manufacturers and buyers of their products. In addition, it aims to show that through collaboration and use of innovative analytical technologies, key challenges not addressed by “traditional” value-based contracts.

**PROCESS**

The following arrangement is between a pharmaceutical manufacturer and a mid-sized integrated delivery network (IDN). The IDN does not have a payer as part of its structure, but does have a number of ACO agreements in place with the health plans with which they engage. In engaging with the IDN, the pharmaceutical manufacturer sought not only to assume risk in return for preferred access, but also to collaborate with the IDN to identify key barriers to meeting the IDN’s population health goals and quality targets.

As a first step in the process, the collaborators established a baseline profile – both nationally and for the IDN’s patient population – within the disease area. This exercise identified specific patients in scope for the agreement, risk drivers, unmet needs and associated costs within the target population with the aim of recognizing key areas for improvement. The exercise also enabled the collaborators to quantify the expected benefit associated with improvements across these criteria.

Using this process, the parties were able to quantify – prior to the implementation of the contract – a “pool” of money that could be saved if the improved outcomes were achieved. In turn, the parties negotiating an agreement by which:

- The IDN would provide the manufacturer exclusive access to at-risk patients; at initiation or switch they would move to one of the manufacturers’ portfolio of products within the disease area in accordance with the IDN’s treatment guidelines and physician’s recommendation,

- Patients would receive the treatment with no copay or coinsurance, and

- The manufacturer would be compensated for at-risk patients not at unit price, but by a percentage of the “pool” generated by improved outcomes; consequently, if no improvements were made, the manufacturer would receive no payment. Consequently, this represented a full risk contract for the manufacturer.

What this arrangement enabled was a far more collaborative and constructive engagement.
During the implementation of the contract, the collaborators worked with Evidation Health, a third party which conducts predictive behavioral analytics. For example, Evidation helped the collaborators identify and implement interventions for non-adherence which enabled a substantial improvement in outcomes among patients who would otherwise likely become non-adherent.

Benefits of Approach

The case study presented here is novel, relative to other forms of value-based contracting, in that it overcomes a number of challenges in the health care system for all stakeholders:

- For patients, there is no-copay. Patients can receive their medication for free at the captive IDN pharmacy. Eliminating a deductible in this chronic disease constitutes the removal of a major financial burden for these patients.

- Similarly, it mitigates the confusion and administrative burden associated with multiple formularies and payers. While physicians maintain choice over the manufacturer’s portfolio – which covers all classes of drugs available to the patient population – there are no access concerns, prior approvals or rejections.

- The IDN has the benefit of greater predictability and lower risk. It is not paying for drugs which do not deliver outcomes. Moreover, its patient population is healthier and downstream resource utilization is dramatically decreased.

- The manufacturer gains from increased access to at-risk patients while maintaining its current share among the well-controlled population. Financially, despite assuming full risk for at-risk patients, by delivering both stronger products and “wrap around” services, its share in the “pool” of value generated through the program substantially exceeds the volume it would have been projected to yield under a standard volume-based or more conservative outcomes-based contract.

Most importantly, however, both the manufacturer and IDN reap the benefits of collaboration by sharing data, analytical capabilities and potential solutions in the clinical setting. Both parties gain a much clearer, real-world understanding of the patient population in question, are able to apply new techniques to identify patients which represent a potential health system burden, and work together to develop the tools necessary to intervene and improve outcomes.
Erin Ferries and Lilian Ndehi

BACKGROUND

This was the most highly rated submission in the Value-based Health Care abstract category at Nexus 2017, jointly organized by the AMCP Foundation and JMCP. Dr. Ferries received an AMCP Foundation Best Poster Award in recognition of her research.

The Medicare Modernization Act, which created the Part D program, requires that every Part D plan sponsor have a Medication Therapy Management Program as a quality improvement feature. Medication Therapy Management, MTM, refers to a variety of activities and resources that are intended to optimize therapeutic outcomes, as well as reducing or preventing adverse drug events. This is done by assessing the patient’s medications, ensuring that they are using them safely and as prescribed, and if issues are identified, bringing them to the attention of the physician for changes to be made.

Current research indicates that there are positive clinical and economic outcomes as a result of the MTM services. However, there is wide variation in study designs and the potential return on investment shown by these studies.

There are two MTM services that Humana offers its patients: Comprehensive Medication Review, CMR, and Targeted Medication Review, TMR.

- During a CMR, the pharmacist will review all of the patient’s allergies, medical history, medications (including prescriptions, over-the-counters, herbas and dietary supplements), as well as their therapeutic goals. The purpose of this consultation is to assess medication usage to determine if medication-related problems exist. This real-time interactive consultation results in a written summary to be given to every patient, which includes three documents: the cover letter, the personal medication list (which provides a list of all the reconciled medications, how each medication is supposed to be used, as well as the purpose of the medication) and the Medication Action Plan, which lists all the actions that a patient should take in order to optimize medication use.

- A TMR is an activity that is specifically focused on identifying and addressing medication-related problems by systematically reviewing the medication profile. A medication-related problem can be identified in a variety of ways, one being system-generated - where information such as pharmacy claims data and medical claims data, is used to identify medication-related problems (MRPs) - or face to face, through a pharmacist consultation. The goal of a TMR is to prevent or resolve medication-related problems, such as adherence gaps, inappropriate use of medications, drug-drug interactions, or the need for additional medication or a medication switch.

The MTM program has one process Star measure: the percentage of members eligible for MTM who receive a CMR.
OBJECTIVE AND METHODS

The objective of the study was to compare patients receiving a MTM service in 2014 to eligible non-participants on acute inpatient admissions and emergency department visits. This was conducted via a retrospective cohort analysis of Humana claims, where participants receiving an MTM service were propensity score matched to non-participants within each MTM service strata: CMR only, TMR only, and patients receiving both CMR and TMR services.

Inpatient admissions and emergency department visits were measured as the change in utilization per 1,000 patients. The propensity score matching yielded just under 65,000 CMR only matched pairs, 5,700 TMR-only matched pairs, and just under 10,000 matched pairs of patients receiving both services in 2014.

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FINDINGS

In the TMR-only cohort, the analysis found a statistically significant reduction of 55.2 fewer inpatient admissions per 1,000 patients, as compared to non-participants. Among participants receiving a CMR and TMR in 2014, the analysis found a statistically significant reduction of 62.1 inpatient admissions per 1,000 patients, as compared to the matched non-participants cohort.

While there were no statistically significant differences in emergency department visits between participants and non-participants within each strata, CMR-only and TMR-only participants had slightly increased emergency department visits post MTM service. And patients receiving both services had slightly less emergency department visits.

Based on the metrics analyzed, receiving any TMR service, either alone or with a CMR service, results in statistically significant reductions in inpatient admissions, which are often inconvenient and very costly, not only to the health care system and the payer, but also to the patient.
DISCUSSION

This analysis highlights the need to understand which MTM services provide the greatest value, in terms of both clinical and economic outcomes.

In order for patients, providers and payers to benefit from the MTM services, it’s important to increase participation of MTM eligible patients, their caregivers and prescribers in both CMR and TMR, with the goal of resolving identified medication-related problems.

With CMR completion rate being captured as a Star measure, there is likely greater emphasis on completing CMRs over TMRs. Based on the findings from this study, TMRs play a critical role in reducing medical utilization - this should be a focus before, during, and after a CMR is completed.

In addition, payers and MTM providers should optimize medication-related problem identification and resolution during a TMR. Medication-related problems can be identified in a variety of ways, including system-generated approaches and consultation. In either case, it is important that information needed to identify the medication-related problems, such as pharmacy claims, cash claims and over-the-counter are collected and utilized.

It is also important to determine which MRP category would have the greatest impact on clinical and economic outcomes and prioritize the identification and resolution of these categories. For patients with several MRPs, this mitigates the possibility of overwhelming the patient with information by allowing the pharmacist to prioritize and address MRPs based on potential severity.

Identifying patients at risk of MRPs can be done through a variety of means – one being to invest in electronic evaluation. Once patients are identified, it is critical that the MTM providers collaborate and follow up with patients and prescribers with the goal of optimizing medication use. Educating stakeholders on the improved clinical benefit associated with MTM is critical to achieving optimal outcomes.

Substantial investment in resources may be necessary to drive MTM program optimization. Examples of investments that could be taken into consideration include:

- **Technological solutions**: tools to obtain information to identify MRPs; ensure that this information is easily accessible to prescribers.
- **Education**: continuous education and/or publications supporting best practice in MTM programs.
- **Resources**: to execute MTMs (particularly TMRs), and to follow up with the patients and prescribers, in order to implement recommendations and resolve TMRs.
Sara van Geertruyden

Patient-centeredness is a concept that continues to gain importance within our health care system. Don Berwick famously stated in 2009 that “leaving choice ultimately up to the patient and family means that evidence-based medicine may sometimes take a back seat.” Since then, patient-centeredness has been included as one of the three key pillars of the Triple Aim, followed by the creation of PCORI (Patient-Centered Outcomes Research Institute), which requires patient engagement in its research and on the Board of Governors, providing a model for the FDA to create a patient engagement advisory committee, and we also see a greater emphasis on the development of patient-reported outcomes (PROs) by the CMS Quality Payment Program.

Nonetheless, the term patient-centered means a lot of things to a lot of different people. A few things that must be considered in a patient-centered perspective are:

■ The range of endpoints, care outcomes and treatment goals that matter to patients;

■ Factors that influence differences in value to patients within populations;

■ Differences in perspectives and priorities between patients, caregivers, people with disabilities, consumers and beneficiaries;

■ How patients want to be engaged in their health care and treatment decisions, and characteristics of meaningful shared decision-making to support this.

A key challenge in patient engagement as it relates to health care decision-making is the use of quality-adjusted life years (QALYs), a metric designed to assess how much value one treatment might have over another. The use of QALYs in decision-making has several substantial limitations and risks:

■ QALYs are often derived from population-based surveys which assess how persons would value their lives in a particular state of health, or what they are willing to trade to treat a hypothetical health condition or symptom. This is a very challenging methodology and its ability to assess patient preferences is questionable. Literature shows that different surveys will often yield wildly different results.

■ The value of perfect health over pre-defined less-than-perfect states of health introduces the potential for discrimination against people with serious conditions or disabilities that may last a lifetime.

■ The “one-size-fits-all” nature of a metric such as QALYs is fundamentally inconsistent with the personalized medicine and patient-centered care movements.

“I think the limitations with a QALY approach is that it’s too blunt of an instrument. It doesn’t really capture the unique variation in value.”
In the US, there has been recognition over the last few decades that QALYs can be problematic in terms of their implications for discrimination. In 1992, HHS rejected Oregon’s prioritized list for their Medicaid waiver, claiming the use of QALYs constituted a violation of the ADA. The Affordable Care Act included provisions that would ban PCORI from using QALYs in their research, but also banned Medicare from using QALYs as the basis for coverage decisions. It is important to recognize that the QALY is a population-based decision-making tool which does not seek to engage individual patients or prioritize individual patient goals and needs.

PCORI has done much to advance the voice of the patient in research. Ten years ago, researchers were reluctant to include engage patients, and yet today, due to PCORI’s requirements for patient engagement, there has been a substantial culture change where scientists and researchers recognize that patient engagement has improved research.

- This culture of patient-centeredness must be incorporated throughout the health care system. Doing so requires a number of key actions:
  - Formalized pathways must be created to incorporate the voice of patients into the creation and testing of alternative payment models (APMs). Measuring and rewarding success must be based on achieving outcomes that matter to patients. Value and quality definitions should be driven by value to patients, and patient-reported outcome measures must be created with patients at the table.

- Shared-decision making is central to the culture of patient-centeredness. This requires enabling patients to make informed choices from the range of clinical care options. Evidence must be accessible and understandable such that patients can identify choices which will best help them achieve their personal treatment goals.

- Stakeholders in the health care system must avoid a singular focus on cost-containment and a “one-size-fits-all” approach. A reasonable balance of standardization and personalization is the best way to save money while maximizing outcomes.

- As new medical advances continue to become available, patient access must be supported to ensure that we can deliver the right drug, to the right patient, at the right time.

“There has been so much investment and so much work to try to make a cost-per-QALY metric work for how we cover, what we cover, for patients. And what patients would really like to see is all that investment go into creating tools that allow patients to fully understand the value of treatments in a more personalized way.”
Paul Hain

Prescription drugs are the most expensive component in commercial health care. We spend more on prescription drugs than we do on doctors, outpatient services, or inpatient services. Spending on specialty drugs is expected to quadruple from $87 billion in 2012 to over $400 billion in 2020. In the US, we pay on average about 50% more than in Europe for the same drug.

Patient engagement, through price transparency tools, can improve our ability to manage health care costs. In Los Angeles, the cost of a hip replacement can vary from $17,000 to $46,000. Across procedures, and across the country, these types of massive differences can be found. However, they are seldom, if ever, readily available to the patient for the purposes of choosing a service. At Blue Cross and Blue Shield of Texas, in an effort to provide patients greater visibility into health care costs, we created a cost estimator tool, which is available online or through our app. The tool enables patients to compare the price of procedures such as MRIs, with an end goal of lowering costs for the patient.

In an effort to understand the impact that price visibility might have in reducing costs, an insurer decided to test a cost estimator in three states and compared it to three states where it was not available. The comparison revealed that over the course of two years, this price transparency had the impact of reducing the expected average cost of an MRI by $220 where the app was available. The analysis showed that there were two factors driving down costs. The first is that members who used the cost estimator were able to save themselves and their employers money by choosing MRI providers who were less costly. More interestingly, however, was that this visibility in turn forced the MRI providers across those three states to start lowering their prices to remain competitive. In fact, non-members in the states where the program was tested observed price reductions for MRIs, suggesting that such a program may have cost-saving benefits beyond the scope of the health plan and its members.

Programs designed to apprise patients of costs, in an effort to help them make an informed choice in their selection of treatments and services, could be broadened to realize greater system-wide cost reduction. Price shopping is most applicable to simple, low-risk services where the patient can feel fairly confident that there is little difference in what to expect across providers. On the other hand, in potentially life-threatening contexts or where products or services are significantly differentiated, price shopping may be less likely to be used. Nonetheless, opportunities may exist to employ similar programs across a broader set of health care offerings, potentially including with prescription drugs.

Bobby Dubois

Many value frameworks have emerged in the past few years. However, the extent to which these frameworks have gained traction is very mixed.

The struggle to articulate cleanly the drivers of value arises from the perceived mismatch across participants in the health care system – that not everyone values something the same.

The National Pharmaceutical Council recently set out to test this assumption. Do patients differ from doctors? Do doctors differ from payers? And how does that all look? The study sought to reach out to patients, payers and providers to assess their preferences in deciding between therapies. In evaluating hypothetical therapies, respondents were asked to consider a variety of factors, including:

- Survival – life extension,
- Quality of life – improved functioning,
- Adverse events – change in number of side effects,
- Treatment requirements – mode and frequency of administration of treatment,
- Patient out-of-pocket costs,
- Total payer costs, and
- Availability of test to determine if drug will work.

The study explores whether perceptions of value differ across health conditions and across subgroups within a patient population. Do preferences differ between doctors and patients? Do they differ between payers and patients? The study explores the notion that value assessment needs to be tailored to those individuals – one size cannot fit all. The results of this study, when available in early 2018, will be submitted for publication.

In advance of the study results, it is likely that:

For payers, when using value frameworks it will be important to recognize that value frameworks consider different factors in different ways; multiple frameworks must be considered to better appreciate these different perspectives. Moreover, deeper incorporation of the patient perspective into benefit design presents a substantial challenge and opportunity. Patients clearly differ from one another. Yet benefit designs seldom do. Even for value-based insurance designs, which provide high-value therapies at lower cost, decisions about value are made by plan administrators, not patients. The opportunity exists to invent a new value benefit design taking into account those elements important to the patient.

For providers, it is important to appreciate that what the patient considers important may very well differ from what you do. The best way to understand this is to ask the patient! Eliciting preferences and tradeoffs – such as the importance of survival versus quality of life – is instrumental in ensuring the patient perspective is included in treatment decisions.

For the pharmaceutical industry, there exists similar opportunity to improve. In developing new therapies, the industry should strive to understand patient preferences and how they differ across patient groups.

“Stakeholder priorities for factors that contribute to value vary. Value assessment needs to be tailored.”
Payers and manufacturers are extremely interested in value. Both want a value-based future. Both see the opportunity that exists through innovative approaches.

At the same time, they share similar challenges. They often operate with a great deal of complexity of regulations, complexity of business relationships and constraints. These elements are very difficult to navigate, especially in the course of having a dialogue with a counterparty in a negotiation. Fear and concern about having an information disadvantage, or a technical expertise disadvantage, represent another hurdle. So while in concept value-based care is of interest to both parties, often times payers and manufacturers don’t make much progress towards implementing it in the form of a value-based contract.

Collective effort and ingenuity on behalf of both parties is vital to success in these negotiations.

Still, what is currently lacking is a simple, repeatable, generalizable framework to enable a dialogue around a value-based agreement. To that end, the most basic questions that need to be addressed revolve around three key domains:

- **Population**: On whom would the agreement be focused? What disease states? What people? What conditions? What value proposition?
- **Proof**: Where are statistics? Where is the success measurement? What are the metrics? What are the key levels of confidence? Who are you going to compare yourself against?
- **Economics**: How much value can be created? How much risk should be taken? How much reward? How are we going to share it and over what timeframe?

Broadly, the health care industry knows well how to identify populations clearly, and how to identify opportunities and unmet needs among them. However, where the industry needs to continue to progress is learning how to do this...
in a collaborative, retrospective fashion with the counterparty as a partner. This should not be viewed as research, but rather research directed towards a potential business arrangement.

Answering questions around proof can be more complicated. A variety of statistical and technical considerations must be taken into account when deciding how to measure success of a value-based arrangement. The measurement period is a major consideration here; if an arrangement is only in effect for one or two years, is it possible for a treatment to realize measurable value in that timeframe? Moreover, consideration of whether to measure against clinical or cost metrics, how to isolate the potential effect from confounding real-world factors, and technical statistical considerations can have a substantial impact on its success. Nonetheless, coming to conclusions about proof is both art and science – the science of statistics and health economics, but also the art of negotiation – and as such, it is a sophisticated dialogue.

Finally, answering the economic question is almost purely art, leaving science behind. The fundamental design decision for the manufacturer is whether the arrangement should focus on assuming risk or seeking new value. A risk-assuming arrangement provides a manufacturer the opportunity to prove that a treatment can create value while protecting the counterparty from risk. A value-seeking arrangement is more ambitious, possesses more long-term potential and creates more excitement among payers in the medical community. Under this type of arrangement, a manufacturer takes on even greater risk but is in position to reap greater economic benefit.

Nonetheless, even in answering these three fundamental questions, the process of finalizing and enacting a value-based arrangement can be painstakingly slow. Accelerating the process is key to seeing greater use of value-based arrangements.

At Healthagen, our contribution comes in the form of value prototyping. The iterative process involves designing an arrangement and applying it against a year’s worth of retrospective data – “real world evidence in silico” – to assess the outcome. In turn, changes can be made and reapplied. This process enables much faster value-based arrangement design and optimization. Moreover, in circumstances where a value-based design proves economically unviable for one or both parties, it enables the parties to fail quickly and during negotiations. It also helps gain trust between parties and increases the chance of a deal that is economically viable, creative, and timely.

A SYSTEMATIC APPROACH: THE “VALUE PROTOTYPING” PROCESS

Objective: “Pretend” that you are entering into a VBC in the PAST, and see how you did…

Evaluation of Each Candidate Value-Based Arrangement Design or “Scenario”

Conclusion: Prototyping Can Be a Valuable Contribution to “Closing the Value Uncertainty Gap”
Caroline Steinberg

Often, we consider the major choices that a consumer may make – such as choosing a plan, choosing a provider and choosing a treatment option – as being independent from one another. But in fact, each of these decisions governs the choices that consumer will have in the future. The health plan chosen governs what providers a patient can go to, and in turn, the provider they go to will often determine their treatment options.

In order to get consumers engaged in making value-based care decisions, they need to have good tools and resources that, in most circumstances, are lacking today. The Network for Excellence in Health Innovation sought to explore these tools, with the main objective of answering the following questions:

■ What are the most critical information needs for consumers?

■ How well do our current tools and resources meet these needs?

■ What can be done to improve consumer decision-making?

CONSUMER INFORMATION NEEDS

At a high level, our analysis found that what consumers need is information that is simplified and specific, but which affords them the opportunity to learn more if they want or need to. In choosing a plan, they benefit from having an estimate of their total cost, including premiums and cost sharing, and similarly in choosing a provider, their highest priority is understanding their cost, taking into account their own specific deductibles and the price negotiated between their plan and the provider. When making treatment decisions, however, they need to be able to delve into details – potential risks and benefits, out-of-pocket costs, and potential burden on patient and family members, for example - and weigh them against their preferences and values.

A key finding here is that many consumers don’t even realize or understand that they have choices, and that these choices can make a significant difference in terms of cost, quality and outcomes. Given this, perhaps it is not surprising that very few consumers are using even the better tools that are available. If you don’t realize you have a choice, you’re not likely to be looking for tools to support your decision.

CURRENT CONSUMER TOOLS AND RESOURCES

Some very good tools exist for consumer decision-making. The State of New Hampshire has a highly-rated decision support tool, as does Aetna. Yet only 1% of the population and 2% of enrollees, respectively, use these tools. More needs to be done to build awareness and usage of such resources.

When faced with inaccurate or incomplete data, consumers can make decisions that are extremely hazardous. For example, a recent study found that while 99% of consumers went to preferred hospitals for emergency care, 27% of them received bills from physicians that were out of network. In this case, without complete information regarding network status of physicians, consumers faced a major cost burden. Another recent study found that 27% of plans in health care exchanges had different pharmaceutical coverage listed in the web tool compared to the plan documentation, and in some circumstances, there was no information at all.
Physicians and caregivers are the most trusted source of information for patients. However, in many circumstances these individuals are not currently trained, rewarded, or equipped with the necessary information to help their patients make key decisions.

**AREAS FOR IMPROVEMENT IN CONSUMER DECISION-MAKING**

Value-based payment arrangements are one way by which consumer engagement may find growth. By providing physicians greater visibility into the costs of imperfect consumer decision-making – for example through a more complete understanding of the costs of downstream referrals or outcomes – providers will be better equipped to help patients understand the implications of the choices they have. Moreover, there have been proposals to have measures of shared decision-making included directly in these arrangements.

Finally, tools must be actively promoted at the time of decision-making. Simply informing a consumer at the time of open enrollment that a cost or quality tool exists, for example, is unlikely to yield substantial usage at the time a decision needs to be made. A best practice here would be to trigger the delivery of information to the consumer at the time a claim occurs. For example, if a claim occurs for a prenatal visit, it would trigger the sending of information on choices of hospitals for delivery, the dangers of elective C-sections, and other timely information most germane to decisions surrounding pregnancy and childbirth.

This AMCP Foundation report is provided for the sole purpose of broadening public understanding of varied perspectives of “value considerations” in the delivery of health care services. Views expressed herein are those of the individual speakers and/or the organizations they represent.

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Readers are encouraged to view the archived version of our Research Symposium Highlights webinar at: [http://www.amcp.org/foundationwebinars/](http://www.amcp.org/foundationwebinars/). The archived webinar may be accessed for personal use.
At Southwest Airlines, we have over 57,000 employees and over 130,000 members in our health plan. We operate in over 100 cities, and with 13 unions. Most of our employees don’t understand many of the factors that go into picking the best plan for them – things like deductibles, co-pays, co-insurance, maximum out-of-pocket, in and out of network. To expect our employees to make decisions on their own would be unrealistic, and so a major focus for our organization is to help our employees navigate these challenges on a daily basis.

Employers face a number of challenges in managing employee wellness today:

- Drug costs are soaring, and we have limited visibility into these. Understanding the real cost of drugs to our organization, and in turn making decisions between competitive products is extremely challenging.
- We have limited resources and expertise in-house to make value decisions. Often, we need to rely on consultants and individuals with appropriate clinical backgrounds to support us.
- We have limited visibility into drug spend overall.
- Finally, preserving our member experience is a major challenge. At Southwest, we pride ourselves on expecting our employees to be fun-loving, have a warrior spirit and a servant’s heart, and we must ensure that we are offering a benefit that meets the needs of these employees and their families.

Overall, in the decisions we make on a daily basis, we are challenged to find a balance between a variety of factors which are critical but often in contradiction with one another. What is clinically appropriate? What is best for our plan? What drugs are most costly, and should they be covered? Should we have exclusive formularies or not? Should we have specialty guideline management?

As an employer, we can look at our overall specialty spend and where it’s coming from. Yet it’s very confusing for us to really understand what decisions we can make that would most benefit our employees. Consultants help us make better sense of the data, integrating across pharmacy and medical systems to identify trends, drivers, outlier claims and savings opportunities.

At Southwest, we’ve implemented a number of successful solutions for management of specialty drugs. These have included:

- Analyses which have resulted in changes to PBM guidelines,
- An oncology split-fill program which limited financial risk to patients and drug wastage,
- A prior authorization program for chemotherapy which reduced PA time from 21 days to 3 days and ensured patients receive most appropriate treatment upfront, and
- A site-of-care redirection program which ensured administration of specialty drugs at most cost-appropriate sites.

In summary, while the landscape surrounding specialty drugs continues to pose a challenge, active management is key to achieving optimal outcomes while containing costs and preserving the member experience.
About AMCP Foundation

The AMCP Foundation advances collective knowledge on major issues associated with the practice of pharmacy in managed health care, including its impact on patient outcomes. Other Foundation programs that facilitate the application of medication-related research include the *Emerging Trends in Health Care* series and Best Poster competitions.

The Foundation cultivates future leaders in the field through immersive experiences for student pharmacists, like our National P&T Competition. The Foundation was established in 1990 as a 501(c)3 nonprofit organization, and is the philanthropic arm of the Academy of Managed Care Pharmacy (AMCP).

About AMCP

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

This report was prepared by IQVIA and the AMCP Foundation.

For copies of symposium presentations, please visit [www.amcp.org/amcp-foundation/Resources/Proceedings/](http://www.amcp.org/amcp-foundation/Resources/Proceedings/).

Paula J. Eichenbrenner, CAE, Executive Director
Ebony S. Clay, Program Manager
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Research about health care trends that place new demands on the practice of pharmacy continues to be an integral element of the Foundation’s mission. Our research initiatives are facilitated to advance the collective knowledge about how managed care pharmacy impacts patient outcomes. Below is a brief summary of past symposia, with greater details available under Reports & Research at www.amcpfoundation.org.

**Balancing Access and Use of Opioid Therapy — 2016**

Opioid pain therapies and related challenges confronting health plans, prescribers, payers and others were the focus. Symposium presenters examined the role managed care pharmacy and health plans can – and should – play in addressing this national health care emergency in terms of access to appropriate therapy and prescriber perspectives; as well as opioid use monitoring measures, managed care and health plan initiatives, and research gaps and the future of pain treatment. This program was made possible through support from Alkermes, Inc., Optum, Inc., Purdue Pharma L.P., and Teva Pharmaceuticals Industries Ltd.

**Opportunities & Challenges in Patient Care, Prevention, & Adherence — 2015**

Experts addressed innovative ways to take on the chronic disease challenge through prevention; while assessing the growing impact of chronic disease treatment on our economy and the health care delivery system. Presenters also examined the historical perspective of treatment management; reviewed what has worked, what has not, and what is needed; and investigated barriers such as plan design, care coordination, and the patient’s role in chronic disease care. This symposium was supported by Amgen, Inc., Eisai, Merck & Co., and Novo Nordisk, Inc.

**Specialty Pharmacy and Patient Care: Are We at a Tipping Point? — 2014**

Key issues included a focus on the specialty drug conundrum: why is something so great so expensive? Under pressure to improve outcomes, but also control costs, many payers are employing cost containment tools - such as high copays - that some say have gone too far. Others, including providers and patients, are beginning to question the ROI. The following sponsors provided unrestricted grants to support the symposium - Amgen, Biogen Idec, the National Pharmaceutical Council, and Pfizer Inc.

**Transplanting European Health Technology Assessment (HTA) to America: What’s Wrong with Our Version? — 2013**

The thrust of this research symposium was to review current drug evaluation policies and processes in the U.S. and compare to those in Europe. Presenters defined key changes in CER, HTA and risk-adjusted contracting and the challenges they create for more robust specialty decision making. Identifying barriers to widespread adoption of CER, HTA and risk-adjusted pricing were also explored. Symposium supporters included Amgen, Alkermes, AstraZeneca and National Pharmaceutical Council.

**Contemporary Applications for Specialty Pharmacy — 2012**

Presenters focused on two key emerging questions: What exactly is specialty pharmacy? and What differentiates it from traditional pharmacy? Presentations highlighted the innovative research initiatives undertaken by AMCP members in specialty pharmaceuticals, particularly with regard to clinical and outcomes management for specialty pharmaceuticals. Unrestricted grant support was received from Amgen, Daiichi-Sankyo, Gilead, Teva Pharmaceuticals and Xcenda.

**Dialogues in Managed Care Leadership — 2011**

The initial symposium focused on thought leaders exploring new dynamics of managed care pharmacy within the changing health care system. Stakeholder leaders from all aspects of pharmacy addressed the proposition that pharmacists, through a dialogue format, can lead the policy discussion by leveraging their pharmacy knowledge in a business environment. Presentations centered on strategic concepts of change for the managed care industry and identifying ways in which leadership can prepare pharmacists to lead managed care policy decisions. This program was supported by The Birchfield Group, Alkermes, Eisai, Merck and Humana Pharmacy Solutions.