

White Paper

From Big Data to Measurable Outcomes: Aligning Stakeholder Needs for Value Based Contracts

Richard Gliklich, MD
CEO, OM1



Background

A heightened focus on value is driving efforts across health care to improve outcomes and reduce costs. For pharmaceutical companies, this focus translates into a shift away from traditional payment models to more outcomes-based, risk sharing agreements. In many ways, these agreements present the opportunity to better align interests across health care's stakeholders. However, they also introduce significant challenges, such as defining measurable and standardized outcomes, developing and implementing effective programs to measure those outcomes, and determining new ways to improve outcomes to better succeed under these programs.

In the context of value-based care, value is defined as outcomes divided by cost. Outcomes, therefore, are a fundamental component of value-based care, and, as such, are the subject of renewed attention from payers, providers, regulators, and researchers. While previous efforts to emphasize outcomes have failed to fundamentally change medicine, three distinct trends are coalescing in a manner that will make the current focus on outcomes lasting and transformative across all levels of health care. First, massive digitization of health care records and the development of sophisticated analytic tools have made it possible to measure and compare outcomes across large patient populations efficiently and continuously. Second, the demand for information on patient outcomes has increased across stakeholder groups, creating an incentive to collect more outcomes data. Third, both public and private payers are shifting from fee-for-service to value-based reimbursement models that use patient outcomes and quality measures to determine reimbursement rates.

While value-based care is relatively new, it has significant momentum. Its potential to improve outcomes while reducing costs is attractive to nearly all health care stakeholders. It has already been adopted at multiple levels of health care, and the concept is backed by the Medicare Access and CHIP Reauthorization Act (MACRA), which was passed with bipartisan support by the U.S. Congress and signed into law in 2015. Initiatives that focus on value, such as outcomes-based contracts, are likely to become more common as value-based care advances. To succeed in these arrangements, stakeholders must learn to leverage big data sources and new analytic tools to understand their patient populations, identify areas of risk, and find strategies to mitigate those risks.

TABLE 1. TYPES OF OUTCOMES-BASED CONTRACTS

Type of Contract	Example
Payment based on desired outcome	Agreement between Cigna and Novartis for Entresto, indicated for heart failure and costing, in which payment is tied to hospitalization rates ¹
Larger rebates in absence of desired outcome	Agreement between Harvard-Pilgrim and Amgen for Repatha® (evolocumab), indicated for high cholesterol, in which missed cholesterol goals result in larger rebate amounts ²
Payment based on how well drug performs against competitor drug(s)	Agreement between Harvard-Pilgrim and Eli-Lilly for Trulicity, indicated for Type 2 diabetes, in which rebate amount is based on comparison of patients on Trulicity who reach A1c target (<8%) compared with patients using other GLP-1 drugs ³
Indication specific pricing	Agreement between Express Scripts and Genentech for Tarceva, indicated for lung and pancreatic cancer, in which pricing differs by tumor type based on expected survival rates ⁴

Outcomes-Based Contracting

Outcomes-based contracting refers to several types of arrangements that tie payment to the performance of a drug and the resulting patient outcomes. Over the past several years, four basic types of outcomes-based contracts have emerged. Table 1 describes each type and provides an example. Many other outcomes-based contracts exist in different therapeutic areas. For example, in addition to the agreement with Novartis cited below, Cigna has outcomes-based contracts with pharmaceutical companies covering medications for high cholesterol, diabetes, multiple sclerosis, and hepatitis C.

Pharmaceutical companies and payers typically have several goals when considering an outcomes-based contract. For pharmaceutical companies, goals may include improving a drug's position on the preferred drug list of a health plan, accelerating the availability of new treatments on a formulary, reaching an agreement on a reimbursement framework when some longer-term benefits are still unproven, and getting drugs to the market more quickly. For payers, costs are a primary concern, particularly for high-cost new therapies that are unproven in the real world. Payers are also interested in improving allocation of resources towards their members most likely to receive benefit.

Health plans in the United States are increasingly interested in entering into outcomes-based contracts, particularly in therapeutic classes with expensive new treatments. In 2015, Avalere conducted a survey of 42 U.S. health plans representing 161 million covered lives; survey respondents included integrated health systems, national health plans, and regional/state health plans. Among respondents, 63 percent expressed high interest or very high interest in outcomes-based contracts for hepatitis C drugs. Plans also expressed high or very high interest in outcomes-based contracts for oncology (53 percent), rheumatoid arthritis (41 percent), and multiple sclerosis (35 percent). In addition to specialty treatments, health plans showed interest in more widely used drugs, such as the cholesterol lowering PCSK9 inhibitors.

Standardization of Outcomes to Support Value-Based Care

Most outcomes-based contracts currently tie payment to events of interest that will occur in a relatively short time frame, such as hospitalizations, blood glucose reductions or cholesterol reductions. However, some are including longer-term outcomes, such as rates of myocardial infarctions or non-spinal fractures. Outcomes-based contracts rely on measurement of outcomes and, more specifically, measurement of standardized outcomes.

Standardized outcomes are necessary to compare data across patient populations and subgroups. As payment models increasingly link outcomes to payment, there will be a need for alignment of outcomes among providers, payers, and pharmaceutical companies and device manufacturers. In fact, there is already growing support for the definition of and use of standardized outcome measures across condition areas, and many efforts are underway to harmonize existing outcome measures or to produce new standardized sets of outcome measures across the more expensive health care conditions. The Centers for Medicare & Medicaid Services (CMS), the U.S. Food and Drug Administration (FDA), the National Library of Medicine (NLM), the Agency for Healthcare Research and Quality (AHRQ), and others are actively working in this area. For example, AHRQ recently funded a two-year project to assess the feasibility of using the Outcome Measures Framework (OMF)⁷ to harmonize outcome measures in five condition areas.

Efforts to standardize outcomes measurement are likely to increase as these measures are used in more value-based care initiatives. As evident in the OMF, measurement of the outcomes of interest will require multiple data types – not only administrative data, but clinical data and in some cases patient-reported data. For example, the Comprehensive Care for Joint Replacement (CJR) bundled payment program from CMS uses data from clinical, administrative, and patient-reported sources. Data elements include body mass index, pre-operative use of narcotics, date of birth, Medicare Health Insurance Claim (HIC) number, patient-reported pain in non-operative lower extremity joint(s), and either the patient-reported Veterans RAND 12 Item Health Survey (VR-12) or PROMIS-Global. Use of multiple data sources introduces complexity, but also provides a more complete picture of patient outcomes.

Understanding Risk and Tracking Performance under an Outcomes Based Contract

To succeed under outcomes-based contracts, pharmaceutical companies must consider what is being measured in the contract and how the necessary information will be collected and analyzed. These considerations can be grouped into three categories: planning, proving, and partnering. Figure 1 highlights the major considerations in each category.

Before discussing these considerations, it is helpful to define big data in the context of health care. Data in health care comes from many sources, including administrative claims, clinical records or electronic health records, pharmacies, laboratories, and patient reports. These data are complex, with a mix of structured and unstructured data and significant heterogeneity. They are also incredibly valuable when linked at the individual patient level across multiple sources and at scale, which results in data that are representative of care and outcomes on the national and regional levels – even to the level of 3-digit zip codes. When linked in this manner, big data can provide valuable insights to help stakeholders appropriately plan for and succeed under outcomes-based contracts.

FIGURE 1. PLANNING, PROVING, PARTNERING

Planning

- Understanding the potential risks
 - Modeling and benchmarking
 - Selecting the right endpoints
- Prediction

Proving

- Do data sources make a difference?
- Are secondary measures important?

Partnering

- Improving overall success by aligning incentives and 'going beyond the pill'

Before discussing these considerations, it is helpful to define big data in the context of health care. Data in health care comes from many sources, including administrative claims, clinical records or electronic health records, pharmacies, laboratories, and patient reports. These data are complex, with a mix of structured and unstructured data and significant heterogeneity. They are also incredibly valuable when linked at the individual patient level across multiple sources and at scale, which results in data that are representative of care and outcomes on the national and regional levels – even to the level of 3-digit zip codes. When linked in this manner, big data can provide valuable insights to help stakeholders appropriately plan for and succeed under outcomes-based contracts.

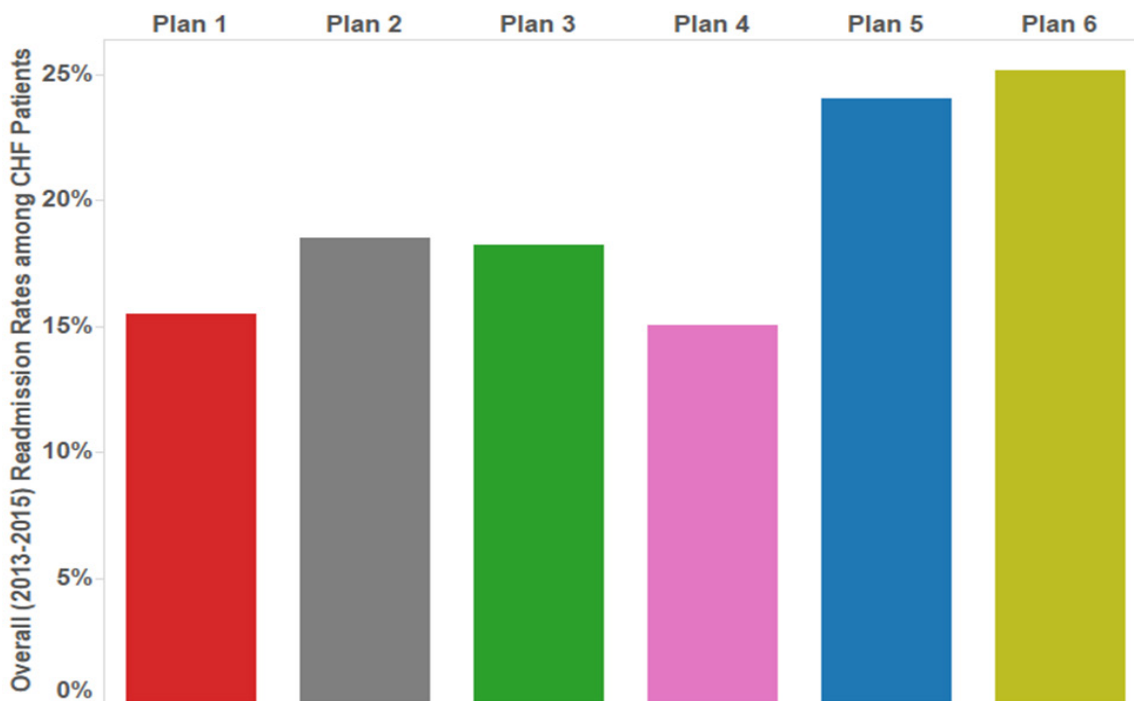
Planning

Adequate planning, including a thorough analysis of the eligible patient population, is essential to mitigate risks under an outcomes-based contract. Planning questions include:

- What are the baseline rates of the condition of interest in existing data?
- How are the rates trending? Are there variations by plan, geography, or other factors?
- Is it possible to identify patients with high risk profiles in advance and exclude them from the measurement?

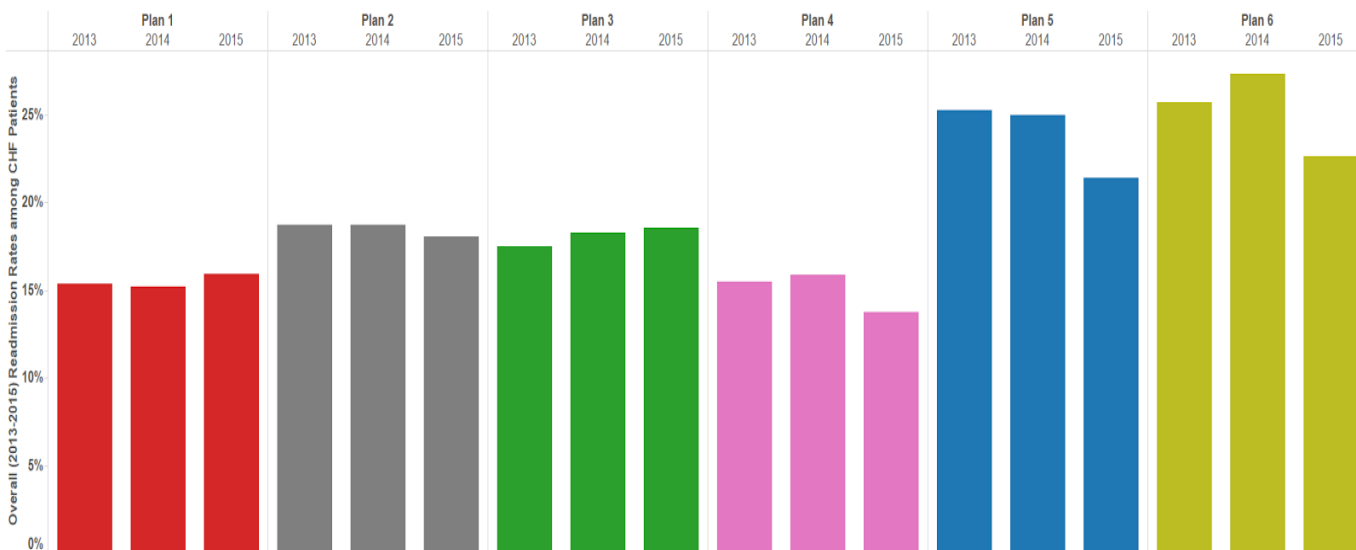
Consider readmission rates among congestive heart failure (CHF) patients. As shown in Figure 2 below, readmission rates differ markedly across six national health plans.

FIGURE 2. CHF READMISSION RATES BY PLAN, 2013-2015⁹



Trends in the data are also important. Again using CHF as an example, Figure 3 shows the proportion of patients within each plan, for each calendar year, that went on to have a readmission. In some plans, such as Plan 5, readmissions are dropping, while they appear stable in other plans. Understanding the reason for this difference would be important before entering into an outcomes-based contract with these plans.

FIGURE 3. PERCENT OF CHF PATIENTS WITH READMISSION BY PAYER AND BY YEAR⁹



Lastly, the concentration of patients with specific conditions varies geographically by plan and is not necessarily representative of variations in the overall population. For example, CHF patients covered by one plan may be concentrated in Texas, while CHF patients in another plan are concentrated in New York. Payment policies also vary by plan and can drive changes in the patient population.

Differences in patient populations are important because patient outcomes may vary significantly in different geographies and different health care markets, thereby affecting risk under an outcomes-based contract. Figure 4 shows the overall relapse rate by plan for multiple sclerosis patients. In addition to variation across plans, the relapse rate varies widely within the same plan by geographic region. For example, Plan 2 and Plan 5 have similar overall relapse rates (19 percent and 18 percent, respectively), but the relapse rate in Texas is 6 percent for Plan 2 and 20 percent for Plan 5.

FIGURE 4. RELAPSE RATES FOR MULTIPLE SCLEROSIS IN SIX HEALTH PLANS, OVERALL AND BY STATE⁹

Multiple Sclerosis	Plan 1	Plan 2	Plan 3	Plan 4	Plan 5	Plan 6
Overall Relapse* Rate	11%	19%	13%	11%	18%	10%
Florida Relapse Rate	14%	19%	6%	8%	5%	10%
Texas Relapse Rate	10%	6%	No Cov	3%	20%	5%

*Defined as a significant relapse requiring hospitalization

Understanding the possible reasons for these types of variations is essential for addressing risk in an outcomes-based contract. In the CHF example (Figures 3 and 4), further analyses show that low socioeconomic status predicts readmission rates in one plan, whereas socioeconomic status does not seem linked to readmission in another plan.

This type of predictive information can be used to inform exclusion criteria and shape appropriate contracts. Prediction, in this context, refers to projecting what the next year will look like within a plan and then specifically identifying patients most likely to have a negative outcome and determining if there may be a reason to exclude those patients from the outcomes measurement.

The selection of the outcome that will be measured is equally critical. Typically, agreements focus on the outcome that is included in the product label. However, there is some interest in other endpoints, such as economic outcomes. For example, demonstrating a significant improvement in total medical costs would present a strong case for contract renewal or renegotiation. Secondary endpoints can also be important to avoid having one measure as a pass/fail test.

Proving

Proving, in the context of outcomes-based contract, refers to the measurement of the outcomes included in the contract. Beyond the technological issues of setting up appropriate infrastructure and data feeds, it is essential to consider what data sources are used for the measurement and how complete the data are for the outcomes of interest. Payers have access to claims data, but, for some outcome measures, necessary data elements may be missing from claims and may need to be extracted from clinical data for an accurate measurement. Questions about the accuracy of claims data also need to be considered. For example, a 2014 analysis found significant disagreement between electronic medical record data and claims data for rheumatoid arthritis patients.

In some areas, patient-reported data may be important. Patient-reported outcomes (PROs) are increasingly included in clinical trials and product labels and valued in clinical practice. The technology to collect PROs has also advanced and is now readily available, reliable, and inexpensive. A PRO endpoint may therefore be appropriate for some products.

Partnering

Lastly, partnering is an important component of outcomes-based contracts. Ideally, these contracts should go beyond simply achieving specified metrics to helping stakeholders develop partnerships that meet the joint goals of improving patient outcomes while managing costs. Predictive analytics are one way to partner in outcomes-based contracts. For example, Aetna and Merck recently announced a partnership that combines an outcomes-based contract for Januvia® (sitagliptin) and Janumet® (sitagliptin plus metformin) with a joint effort to use predictive analytics to identify patients at higher risk. The program targets higher-risk patients for health and wellness services, including programs designed to support treatment adherence and reinforce healthy lifestyle behaviors.

When used in support of an outcomes-based contract, predictive analytics help stakeholders understand what is likely to happen next within a specified patient population. For example, predictive analytics can be used to answer questions about which patients are most likely to have a specific complication, to be readmitted, or to go to the emergency room. Importantly, predictive analytics can also help identify factors that can be modified to reduce risks. Some examples of questions that can be addressed by predictive analytics are:

- What is the probability that this CHF patient will be readmitted in the next 30 days and why?
- Which of my diabetes patients will be most costly in the next year and why?
- Which of my CAD patients are likely to have a cardiovascular event in the next 180 days?
- What is the probability that this patient will do well with this therapy?
- What is the probability of a complication following a treatment and why?
- Which patients are likely to be non-compliant with medications and why?

These types of predictions can result in cost savings and improved patient outcomes. In hip procedures, for example, three avoidable events – non-routine discharges, complications, and readmissions – account for \$3 billion in excess costs each year. Identifying the patients most at risk for these events in advance and taking proactive steps to reduce the risks – for example, by providing pre-surgery education – can result in significant cost savings.

Under outcomes-based contracts, stakeholders can leverage predictive analytics in the planning phase to include appropriate populations and outcomes. Once a contract is in place, predictive analytics offer a way to identify high-risk patients in advance so action can be taken, resulting in improved performance under the contract.

Conclusions

Health care is rapidly moving to value-based care, and outcomes-based contracts are likely to become more common as a tool to improve outcomes while managing costs. Success under these agreements begins with careful planning using representative and sophisticated data and analytics to inform negotiations. Accurate and auditable outcomes measurement, leveraging the most informative data sources, is also essential. Lastly, partnerships that make use of innovative tools and data can provide value to all parties.

REFERENCES

- ¹ Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), (H.R. 2, Pub.L. 114–10). <https://www.congress.gov/bill/114th-congress/house-bill/2>.
- ² Cigna. Cigna’s Two New Value-Based Contracts with Pharma for PCSK9 Inhibitor Cholesterol Drugs Tie Financial Terms to Improved Customer Health. May 11, 2016. <https://www.cigna.com/newsroom/news-releases/2016/cignas-two-new-value-based-contracts-with-pharma-for-pcsk9-inhibitor-cholesterol-drugs-tie-financial-terms-to-improved-customer-health>.
- ³ Herman, Bob. Harvard Pilgrim cements risk-based contract for pricey cholesterol drug Repatha. Modern Healthcare. November 9, 2015. <http://www.modernhealthcare.com/article/20151109/NEWS/151109899>.
- ⁴ Teichert, Erica. Harvard Pilgrim scores discounts on Novartis, Lilly drugs. Modern Healthcare. June 28, 2016. <http://www.modernhealthcare.com/article/20160628/NEWS/160629889>.
- ⁵ Loftus, Peter. New Push Ties Cost of Drugs to How Well They Work. The Wall Street Journal. May 26, 2015. <http://www.wsj.com/articles/new-push-ties-cost-of-drugs-to-how-well-they-work-1432684755>.
- ⁶ Avalere. Health Plans Are Interested in Tying Drug Payments to Patient Outcomes. June 16, 2016. <http://avalere.com/expertise/life-sciences/insights/health-plans-are-interested-in-tying-drug-payments-to-patient-outcomes>.
- ⁷ Gliklich RE, Leavy MB, Karl J, Campion DM, Levy D, Berliner E. A framework for creating standardized outcome measures for patient registries. *J. Comp. Eff. Res.* 3(5), 473–480 (2014).
- ⁸ Centers for Medicare & Medicaid Services. Comprehensive Care for Joint Replacement (CJR) Model. Provider and Technical Fact Sheet. <https://innovation.cms.gov/Files/fact-sheet/cjr-providerfs-finalrule.pdf>
- ⁹ Rates calculated from OM1 Data, a representative sample of U.S. claims and electronic health records data.
- ¹⁰ Maeng D, Boscarino J, Stewart W, Yan X, Steigerwalt N. PS1–11: A Comparison of Electronic Medical Records vs. Claims Data for Rheumatoid Arthritis Patients in a Large Healthcare System: An Exploratory Analysis. *Clinical Medicine & Research.* 2014;12(1–2):108. doi:10.3121/cmr.2014.1250.ps1–11.
- ¹¹ Aetna. Aetna and Merck Sign a Unique Value-Based Contract for Januvia® and Janumet®. October 11, 2016. <https://news.aetna.com/news-releases/aetna-and-merck-sign-a-unique-value-based-contract-for-januvia-and-janumet/>.
- ¹² Menendez ME, Schumacher CS, Ring D, et al. Does “6-Clicks” Day 1 Postoperative Mobility Score Predict Discharge Disposition After Total Hip and Knee Arthroplasties? *J Arthroplasty.* 2016 Sep;31(9):1916–20.

About OM1

OM1, Inc. is a digital health company focused on solving the problem of determining and understanding the true results of healthcare and offering a more complete view of patient outcomes than has been available until now. Bringing together multiple data sources at the individual patient level to construct patient journeys and to measure and forecast patient outcomes, OM1 combines expertise in clinical research and informatics with big data technology and advanced data science to reinvent how real world evidence is generated and used.

OM1, Inc.
(888) 324-3899
www.OM1.com

