# When we talk about value-based agreements, why don't we talk about diagnostics?

*by* Hannah Mamuszka

Over the past decade, as the US healthcare system has attempted to begin migration from fee-for-service payments to outcomes based incentive contracts, payers have entered into many 'value-based' care agreements, designed to incentivize improved patient outcomes (and reduce total cost of care). There have been two broad type of agreements- value based contracts with providers (physicians and physician groups) whereby the physicians are compensated based on improved outcomes metrics, and with biopharmaceutical companies, whereby payers and the company usually agree on terms for a rebate or refund for therapy determined to be ineffective.

There is little question that the fee for service payment structures misalign incentives. In fee for service systems, (which is still the traditional and most prevalent payment model of the US healthcare system), providers and physicians are reimbursed on the basis of the number of services they provide, procedures they conduct, drugs they prescribe and diagnostic tests they run. The payers (insurance companies, government agencies, or patients themselves) are billed for every test, procedure, and treatment rendered whenever a patient visits the doctor, has a consultation, or is hospitalized. The fee for service model rewards physicians and hospitals for the volume and quantity of services provided, regardless of the outcome of the patients. Within Medicare, the current reimbursement methodology for Part B drugs administered in physician offices and hospital outpatient departments is Average Sales Price (ASP)+6 percent, which effectively means that Medicare pays physicians 6% on top of the price of a drug prescribed- so the higher the price of the drug, the greater that 6% is, effectively incentivizing use of expensive drugs. (Some physicians may argue this doesn't change how and what they prescribe, but unfortunately statistics prove otherwise, and the American Medical Association (AMA) has lobbied to allow this practice to continue).

Outcomes based agreements, whereby the provider is rewarded when patients have a better outcome, generally defined as less frequent and shorter hospitalizations, fewer adverse events, more symptom-free days, should align the interest of most parties. Outcomes based agreements can also allow health systems to focus on standardizing how they treat a wide variety of diseases and conditions, and align processes to improve treatment algorithms and patient outcomes. Ideally, these structures can overcome inefficiencies and provide high quality care to more patients, for both disease prevention as well as management and treatment. The payment structures can vary from being fully capitated, where the providers agree to manage the patients for a set budget annually, and if they are able to do so are able to retain whatever is remaining at the end of the year, or bonus structures, where providers may achieve bonuses for certain metrics agreed to manage certain patients.

In 2017, Harvard Pilgrim Healthcare and Amgen announced the first outcomes based agreement in cardiovascular disease for Repatha, a PCSK9 inhibitor approved as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) with homozygous familial hypercholesterolemia (HoFH), who require additional lowering of LDL-C. The contract provided Harvard Pilgrim with a rebate for the cost of Repatha for an eligible patient who has a heart attack or stroke while on Repatha. At the time of the agreement, the cost of Repatha was $14,600; perhaps not a high price compared to some drugs in oncology, but given the potential market size for PCSK9 inhibitors (there are more than 10 million American who could theoretically benefit from reduction in bad cholesterol),[1] payers had understandable concerns about the $140B a year cost (in theory) to treat all patients.

As the data developed, two things were proven. First, in terms of patient impact, major heart problems or strokes occurred in 11.3% of patients without Repatha, and 9.8% of patients taking Repatha, meaning 1.5% of patients avoided a serious event. That puts the Number Needed to Treat (NNT) at 1 in 67 patients. Patients treated with a Repatha-statin combo within one year after a heart attack showed a 25% risk reduction in follow-up CV events, including heart attack, death or stroke, over statins alone. In patients treated with the combo, there was a reported 15% risk reduction after the one-year mark. Importantly, there was no change seen in overall mortality. Second, while those numbers suggest some impact, a study by Sabatini et al[2] demonstrated that the cost effectiveness price would be somewhere between $6780-$9669. Interestingly, in October of 2018 Amgen announced it was lowering its price for Repatha to $5850, as a way to encourage broader use in the market.

In January of 2019, Blue Cross Blue Shield of North Carolina (BCBSNC) announced the rollout of their Blue Premier program, and their intention to have all primary care physicians in value based agreements within five years. Under Blue Premier, health care providers collaborate to take a closer look at a patient's overall health, led by primary care physicians. BCBSNC believes this will enable them to spend more time with patients who need it the most, identify patients who need more services before they become expensive, and streamline both care and cost. It also makes doctors more responsible for improving patients' health, tasking them with reducing waste that some estimates say are between 20 and 40 percent of total costs. Physicians and hospitals earn more payments for services when they deliver high-quality care and share in cost savings if they meet patient health benchmarks – and share in the losses if they fall short. BCBSNC outlines that they are providing easy-to-use technology and data analytics tools that help make 'positive changes to a patient's care experience'.

Many health care analysts advocate these arrangements. Accountable Care Organizations (ACOs) in Medicare have successfully implemented these reforms in tying physician and hospital renumeration to patient outcomes, and advocating for strategies including increased disease screenings and better management of chronic conditions. In November of 2019, Humana announced that the value based care incentives within their Medicare Advantage program had reduced overall healthcare costs by $3.5 Billion.% Physicians in value-based care arrangements represent 67% of Humana's total individual plan beneficiaries in 2018. In a report issued by Humana describing how they achieved those savings along with improved outcomes, they describe a focus on social determinants of health, including food insecurity and social isolation, as well as how physicians are engaging and supporting patients to promote healthier lifestyles and behaviors including medication adherence. These measures resulted in 27% fewer hospital admissions and 14.6% fewer emergency room visits, compared with standard Medicare.

At this year's Personalized Medicine Coalition Annual Meeting, the last session of the meeting was a robust discussion entitled, "Toward a Shared Value Proposition in Health Care: Pursuing Value-Based Solutions in Research, Reimbursement, and Clinical Adoption", led by William Dalton, PhD, MD, of M2Gen. The panel itself featured Michael Sherman, MD, CMO of Harvard Pilgrim Health Care and the pioneer of the Repatha agreement with Amgen; Sarah K. Emond, COO of Institute for Clinical and Economic Review (ICER), a group that calculates the actual value in clinical and economic impact terms; Anne-Marie Martine, PhD, of Novartis; and Bonnie Addario, Co-Founder and Chair of the GO2 Foundation. The group discussed and debated how to pay for high cost medicines, why certain drugs can be worth very high price tags, and how drug reimbursement reform, clinical adoption, and broader patient access to better therapy choices can be achieved simultaneously..

Absent from this panel, and the Blue Premier

strategy, and the Humana press release, and the Repatha agreement, was any mention of any diagnostic strategy to optimize care and broaden access. Nowhere is any of these value-based care agreements is there any indication of any diagnostic strategy, either for use of currently available, but often under-utilized diagnostics, or for the initiation of development of novel diagnostic tools. Not even the MIT NEWDIGS excellent report[4] on the financing of value based care takes diagnostics into account. A 2017 study in Plos One[5] demonstrated a 52% reduction in hospital readmission rates by using pharmacogenetic (PGx) testing and a decision support tool to prevent drug-drug and drug-gene interactions in patients on multiple medications. Reduction of hospital readmission rates is on virtually every checklist for value-based care. This represents an opportune time for the diagnostics industry to show how it can contribute to the value based care discussion, and participate in the economics and improved outcomes

In thinking about these opportunities in chronic disease, consider below a comparison of a few models of value.

## Scenario 1: Multiple Sclerosis with no-value based care arrangement

A pharmaceutical company develops a therapy that can treat MS, a disease with a prevalence of ~100 patients per 100,000 covered lives. The drug is priced at $50k a year and works in 35% of patients for which it's prescribed; 5% of patients have a moderate to severe adverse events which add additional costs of $55k per patient, and 60% of patients see no benefit to their disease, but no harm (other than chronic disease progression).

Let's do some math.

1M member plan = 1000 patients with this disease

35% respond (1000*.35= 350 responding patients)

Cost to treat responders (350x $50k) = $17,500,000

65% don't respond (1000*.65= 650 non-responding patients)

Cost to treat non-responders (650x $50k) = $32,500,000

Cost of adverse events in non-responders (650x .05)= 32.5 events x $55k/event =$1.79M

**Total cost to treat population: $17.5M + $32.5M + $1.79M = $67.9M** of which only $17.5M improved patient care

## Scenario 2: Rebate for inefficacy, but no diagnostic strategy

A pharmaceutical company develops a therapy that can treat MS, a disease with a prevalence of ~100 patients per 100,000 covered lives. The drug is priced at $50k a year and works in 35% of patients for which it's prescribed; 5% of patients have a moderate to severe adverse events which add additional costs of $55k per patient, and 60% of patients see no benefit to their disease, but no harm (other than chronic disease progression).

A payer realizes the overall cost of this therapy and strikes a 'value-based agreement' with the pharmaceutical company, whereby the payer will pay up front for all patients treated, but will receive 85% back for the patients for patients who had a moderate to severe adverse event, and 60% back for the patients that saw no benefit but no harm, because symptoms in autoimmune diseases are often seen as 'subjective'.

Now let's do some math.

1M member plan = 1000 patients with this disease

35% respond (1000*.35= 350 responding patients)

Cost to treat responders (350x $50k) = $17,500,000

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Cost to treat non-responders (650x $50k) = $32,500,000

Cost of adverse events in non-responders (650x .05)= 32.5 events x $55k/event =$1.79M

Total cost to treat population upfront: $17.5M + $32.5M + $1.79M = $67.9M

Rebates for non-response and adverse events:

Non-responders: .55 x $32.5M = $17.875M

Non-responders with adverse events: (.85x 50,000) x 32.5= $1.38M

Total upfront cost $67.9M – (17.875M+1.38M)= **$48.645M Total Cost**

## Scenario 3: Upfront diagnostic strategy to only prescribe drug to patients who benefit

A diagnostic test is used to determine who is prescribed the drug in this scenario. Instead of subjecting all patients to trial and error, only the patients indicated by the diagnostic to be likely responders

And now let's do some math.

1M member plan = 1000 patients with this disease

Cost of diagnostic test: $1500 ($1500 x 1000 = $1.5M)

Test identifies the 35% respond (1000*.35= 350 responding patients)

Cost to treat responders (350x $50k) = $17,500,000

Total upfront cost ($1.5M for diagnostic for all patients + $17,500,000 drug)= **$19M Total Cost**

Of course, this example is imperfect and has many caveats. Payers would say that those numbers don't represent their true savings, because if a test tells them a patient isn't going to respond to a drug, that just means they will have to find another drug to treat them, and that drug will have costs too. On the other hand, a patient may *not* respond to any available therapy, in which case a significant amount could be spent with no benefit. No diagnostic test is perfect of course, and some patients (although likely to be very few) could miss out on a therapy that they would benefit from.

But if we want to talk about value, and include patient experience and total cost of care in that value, there is no value is prescribing patients a drug they won't respond to, because of their genetics or disease biology. There is no value in performing procedures or utilizing devices if the patient doesn't have a better quality of life afterwards. The diagnostics industry needs to find a way to insert ourselves into the value-based care discussion if we really want value-based healthcare. JoPM

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